



## FINAL REPORT

# BUILDING A COMPETITIVE AND SOCIALLY INCLUSIVE LOCAL PHARMACEUTICAL MANUFACTURING IN WEST AFRICA THROUGH ENHANCING RESEARCH, INNOVATION & INTELLECTUAL PROPERTY



Compiled by Prof Tom Ogada, Team Leader, December 7<sup>th</sup>, 2019

## Acronyms

<b>ACTS</b>	African Centre for Technology Studies
<b>ARV</b>	Antiretroviral
<b>ARIPO</b>	African Regional Intellectual Property Organization
<b>API</b>	Active Pharmaceutical Ingredient
<b>A/U-I</b>	Academia/ University – Industry
<b>AMA</b>	African Medicine Agency
<b>ANRP</b>	Advanced Networking Research Price
<b>AUC</b>	African Union Commission
<b>ASET</b>	Applied Science, Engineering and Technology
<b>ATMs</b>	Africa Traditional Medicines
<b>BE</b>	Bioequivalent
<b>BPP</b>	Bureau of Public Procurement
<b>CAC</b>	Corporate Affairs Commission
<b>CAME</b>	Central Purchasing Office for Essential Drugs and Medical Consumables
<b>CAPAs</b>	Corrective and Preventive Actions
<b>CSIR</b>	Council for Scientific and Industrial Research
<b>CET</b>	Common External Tariffs
<b>CBBR</b>	Centre for Bioequivalence and Biopharmaceutical Research
<b>CEMAC</b>	Central African Economic and Monetary Community
<b>CFA</b>	Financial Community of Africa
<b>CCTAS</b>	Community Centre for Appropriate Technologies for Health
<b>CNNCI</b>	National Committee for International Trade Negotiations
<b>CDC</b>	Deposit and Consignment Fund
<b>CT</b>	Clinical Trials
<b>CPR</b>	Cardiopulmonary Resuscitation
<b>DASP</b>	Directorate of Private Sector Support
<b>DFID</b>	Department for International Development
<b>DPs</b>	Department of Public Safety
<b>DPM</b>	Directorate of Pharmacy and Medicines
<b>DPMED</b>	Department of Pharmacy and Medicines
<b>DGID</b>	General Directorate of Taxes and Domains
<b>EU /ACP / WHO</b>	European Union and the countries of the African, Caribbean and Pacific Group of States
<b>ECOWAS</b>	Economic Community of West Africa States
<b>EGPAF</b>	Elizabeth Glaser Pediatric AIDS Foundation

<b>ERPP</b>	ECOWAS Regional Pharmaceutical Plan
<b>EU</b>	European Union
<b>ENIAB</b>	Benin National School of Nurses and Nursing Assistant
<b>ENIEB</b>	Benin National School of Nurses and State Registered Nurses
<b>ENAS</b>	National School of Social Welfare Assistant
<b>ETLAM</b>	National School of Clinical Laboratory Technicians
<b>ENTS</b>	National School of Sanitary Technicians
<b>ERCG</b>	Ebola Research Commission in Guinea
<b>EOI</b>	Expression of Interest
<b>FDA</b>	Food and Drug Administration
<b>FPP</b>	Finished Pharmaceutical Products
<b>FMST</b>	Federal Ministry of Science and Technology
<b>FMUC</b>	Faculty of Medicine of Coimbra
<b>FMoH</b>	Federal Ministry of Health
<b>GATT</b>	General Agreement on Tariffs and Trade
<b>GIZ</b>	German Corporation for International Cooperation
<b>GCP</b>	Good Clinical Practices
<b>GCpharm</b>	Ghana College of Pharmacists
<b>GFDA</b>	Ghana Food and Drug Authority
<b>GDP</b>	Gross Domestic Products
<b>GoG</b>	Government of Ghana
<b>GMP</b>	Good Manufacturing Practices
<b>GSK</b>	GlaxoSmithKline
<b>GHS</b>	Ghana Health Services
<b>GIRC</b>	Ghana Innovation and Research Commercialization Centre
<b>KNUST</b>	Kwame Nkrumah University of Science and Technology
<b>HIV/AIDS</b>	Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome
<b>HMO</b>	Health Maintenance Organizations
<b>ICER</b>	International Centre for Excellence in Research
<b>ICT</b>	Information Communication and Technology
<b>IMF</b>	International Monetary Funds
<b>IFAN</b>	Fundamental Institute of Black Africa
<b>IRD</b>	Institute of Research and Development
<b>IPTTO</b>	Intellectual Property Technology Transfer Office
<b>IP</b>	Intellectual Property
<b>IPR</b>	Intellectual Property Rights

<b>IPR&amp;TT</b>	Intellectual Property Rights and Technology Transfer
<b>ITM</b>	Improved Traditional Medicines
<b>INN</b>	International Non propriety Names
<b>INMES</b>	National Health Institute
<b>INMES</b>	National Medico-Social Institute
<b>ISO</b>	International Organization for Standardization
<b>LDCs</b>	Least Developed Countries
<b>LICs</b>	Low Income Countries
<b>LPP</b>	Local Pharmaceutical Production
<b>LMIS</b>	Logistic Management Information Systems
<b>MAHs</b>	Marketing Authorization Holders
<b>MPP</b>	Medicine Patent Pool
<b>MoH</b>	Ministry of Health
<b>MTAs</b>	Improved Traditional Medicines
<b>MSMEs</b>	Micro, Small & Medium Size Enterprises
<b>MOUs</b>	Memorandum of Understanding
<b>NAB</b>	National Accreditation Board
<b>NAFDAC</b>	National Agency for Food and Drug Administration and Control
<b>NCPP</b>	National Council on Public Procurement
<b>NCC</b>	Nigeria Copy right Commission
<b>NEEDS</b>	New Economic Empowerment Development Strategy of Nigeria
<b>NEPAD</b>	New Partnership for African Development
<b>NEPC</b>	Nigeria Export Promotion Council
<b>NHIS</b>	National Health Insurance Scheme
<b>NPSP</b>	New Public Health Pharmacy
<b>NHIL</b>	National Health Insurance Levy
<b>NMP</b>	National Medicine Policy
<b>NMPC</b>	National Medicine Price Control
<b>NHIF</b>	National Health Insurance Fund
<b>NIPER</b>	National Institute for Pharmaceutical Education and Research
<b>NIPRD</b>	National Institute for Pharmaceutical Research and Development
<b>NIMR</b>	Nigeria Institute of Medicine Research
<b>NUC</b>	National University Commission
<b>NNMDA</b>	Nigeria National Medicine Development Agency
<b>NMRAs</b>	National Medicines Regulatory Authority
<b>NOTAP</b>	National Office for Technology Acquisition and Protection

<b>NIPO</b>	Nigerian Intellectual Property Organization
<b>NPP</b>	National Pharmacy Policy
<b>NPR</b>	National Patent Registry
<b>OAPI</b>	African Intellectual Property Organization
<b>OTC</b>	Over The Counter
<b>OAU</b>	Obafemi Awolowo University
<b>ORS</b>	Oral Rehydration Salts
<b>PASET</b>	Partnership for the Development of Applied Science, Engineering & Technology Skills
<b>PPA</b>	Public Procurement Act
<b>PATHS</b>	Partnership for Transforming Health Systems
<b>PEPFAR</b>	President's Emergency Plan for AIDS Relief
<b>PENPI</b>	National Intellectual Property Policy and Strategy
<b>PSGH</b>	Pharmaceutical Society of Ghana
<b>PhD</b>	Postgraduate Doctoral Degree
<b>PNA</b>	National Pharmacy Supply
<b>PMG-MAN</b>	Pharmaceutical Manufacturing Group of Manufacturers Association of Nigeria
<b>PPP</b>	Public Private Partnership
<b>PHC</b>	Pharmacy Health Care
<b>PV</b>	Pharmacovigilance
<b>QMS</b>	Quality Management Systems
<b>RMRDC</b>	Raw Materials Research and Development Councils
<b>SEZs</b>	Special Economic Zones
<b>SSNIT</b>	Social Security and National Insurance Trust
<b>SCMP</b>	Supply Chain Master Plan
<b>STI</b>	Science Technology and Innovation
<b>STEPRI</b>	Science and Technology Policy Research Institute
<b>SMEs</b>	Small and Medium Sized Enterprises
<b>STG</b>	Standard Treatment Guidelines
<b>SIDA</b>	Swedish International Development Cooperation Agency
<b>SSFFC</b>	Substandard Spurious Falsify labelled Falsified and Counterfeit
<b>TETFUND</b>	Tertiary Education Trust Fund
<b>TB</b>	Tuberculosis
<b>TBT</b>	Technical Barrier to Trade
<b>TRIPs</b>	Trade Related Aspects of Intellectual Property Rights
<b>TEC</b>	Technology Executive Committee

<b>TT</b>	Technology Transfer
<b>UCAD</b>	Cheikh Anta Diop University
<b>UNAIDS</b>	United Nations Programmes on HIV/AIDS
<b>UNESCO</b>	United Nations Education Scientific and Cultural Organization
<b>U-I</b>	University - Industry
<b>U-IC</b>	University – Industry Collaboration
<b>UHC</b>	Universal Health Coverage
<b>UG</b>	University of Ghana
<b>UNDP</b>	United Nations Development Program
<b>UDS</b>	University for Development Studies
<b>UNIDO</b>	United Nations Industrial Development Organization
<b>UNICEF</b>	United Nations Children’s Emergency Fund
<b>UNCTAD</b>	United Nations Conference on Trade and Development
<b>USA</b>	United States of America
<b>USAID</b>	United States Agency for International Development
<b>USD</b>	United States Dollars
<b>USP</b>	Unique Selling Proposition
<b>USSR</b>	Union of Soviet Socialist Republic
<b>Uni-CV</b>	University of Cape Verde
<b>USTTB</b>	University of Sciences Techniques and Technologies of Barmako
<b>VAT</b>	Value Added Tax
<b>VCU</b>	Virginia Commonwealth University
<b>WAEMU</b>	West African Economic and Monetary Union
<b>WAHO</b>	West African Health Organization
<b>WAPCP</b>	West African Postgraduate College of Pharmacists
<b>WAPMA</b>	West African Pharmaceutical Manufacturers Association
<b>WB</b>	World Bank
<b>WHO</b>	World Health Organization
<b>WIPO</b>	World Intellectual Property Organization
<b>WTO</b>	World Trade Organization

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## CHAPTER ONE

### 1.0. INTRODUCTION

#### 1.1. Overview of the local pharmaceutical Industries in West Africa.

Many African countries, through their development plans, have prioritized provision of and access to affordable healthcare services. However, the realization of these aspirations has been constrained due to the high costs of imported medicines, which not only increase the health burden but also have negative implications for access and affordability. Affordability is important since up to 90 % of the populations buy medicines through out-of-pocket payments. As a result, many African countries have started initiatives to promote local pharmaceutical industries, to address the issue of high costs of imported medicines and to tap on additional benefits that local pharmaceutical industries can bring, such as creation of employment opportunities, technology and skills transfer and enhancing intra-Africa trade. Today, there are over 172 local pharmaceutical industries in the region (Table 1.1)

**Table 1.1.: Distribution of Pharmaceutical Manufacturers in ECOWAS**

Country	No. of Manufacturers	Remarks
Benin	1	Francophone
Burkina Faso	1+	Francophone
Cape Verde	1	Lusophone
Côte d'Ivoire	5+	Francophone
Gambia	-	Anglophone
Ghana	37	Anglophone
Guinée Conakry	1	Francophone
Guinea Bissau	-	Lusophone
Liberia	-	Anglophone
Mali	1	Francophone
Niger	-	Francophone
Nigeria	120+	Anglophone
Senegal	5	Francophone
Sierra Leone	-	Anglophone
Togo	4	Francophone
<b>Total</b>	<b>172+</b>	

*Source: Assane Coulibaly\_UNIDO\_West Africa\_Inside the African Pharma Market, 2018*

Most production consists of non-complex, high volume essential products, such as basic analgesics, simple antibiotics, anti-fungal against, anti-helminthics, anti-diabetics, anxiolytics, anti-malarial drugs, antacids and vitamins. Despite huge potentials for local pharmaceutical production in ECOWAS, the above-mentioned challenges facing African countries in the sector militate against the policies of governments of the ECOWAS, which largely seek to promote local production of pharmaceuticals.

##### 1.1.1. Côte d'Ivoire

Cote d'Ivoire currently has five pharmaceutical industries, which contributes to only 6 % of the medicines consumed in the country. The bulk (94 %) is imported. Massive imports lead to

problems of traceability and drug quality. The multiple intermediaries also entail an additional cost. To overcome these problems, Côte d'Ivoire has decided to undertake reforms through the 2016-2020 National Development Plan to promote the development of a local pharmaceutical industry. Most of the Ivorian market is supplied by the wholesaler of imported products DPCI/Tedis/Laborex and Eurapharma.

Several specialized distributors are competing in the medical accessories segment. In the generics segment, 52% of the products come from India, China or the Maghreb. There are 8 local manufacturers, mainly small laboratories, with only 3 units exceeding one billion euros in annual turnover, including Cipharm, which accounts for about 60% of local production. The top 5 local producers employ about 300 people. It should be noted that there are 2 specialized manufacturers in the drug niche for external use, a conditioner and a manufacturer of plant medicines. In view of the development objectives of the pharmaceutical industry in Côte d'Ivoire, partnerships between public and private actors are essential. Private actors are increasingly being solicited by public authorities as an alternative to the sometimes-failing systems of production, supply and distribution of medicines.

### **1.1.2. Nigeria**

Nigeria has the most promising and rapidly growing pharmaceutical market in West Africa with over two hundred registered (200) pharmaceutical firms, out of which 120 are manufacturing companies employing about 500,000 people. Nine of these firms are listed on the Nigerian Stock Exchange including five (5) indigenous companies. The listed firms control 58 percent of the manufacturing of pharmaceutical products in Nigeria (AUC/UNDO, 2012; Gumel 2014; Ugbam and Okoro, 2017). While most pharmaceutical firms are affiliated with multinational companies others are either privately or publicly owned (FMoH/WHO, 2002). The Nigerian pharmaceutical industry is a major player among the Economic Community of West African States (ECOWAS) with the potential to be a leader in the production and distribution of pharmaceuticals to Sub-Saharan Africa. Health products produced in Nigeria accounts for about 60% of all drug consumption in ECOWAS (PMG-MAN, 2010). Nine pharmaceutical firms in Nigeria export their products to various ECOWAS countries. The estimated value of the Nigerian pharmaceutical industry in 2016 was \$9.4bn and is expected to rise to \$13.2bn by 2020. Given this impressive potential, the Nigerian pharmaceutical industry is yet to fully maximize its capability. Local drug capacity utilization is about 40 per cent, with only about 25 per cent of the local demand for drugs satisfied while imports mainly from Indian and China account for the remaining 75 per cent. Nigeria does not feature among the 17 notable growth markets in the sector (Ugbam and Okoro, 2017). 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.

### **1.1.3. Senegal**

The local pharmaceutical industry is still underdeveloped despite some attempts to create generics production units. In the past, Senegal has had four drug manufacturing units (three large scale manufacturing factories and a unit for the production of the yellow fever vaccine (the Pasteur Institute of Dakar). The local pharmaceutical industry only meets 10 to 15% of the country's drug needs. The low level of satisfaction of drug needs by the local pharmaceutical

industry is due, according to manufactures, to high production costs and raw material taxes; the narrowness of the Senegalese market, the weakness of investment in this area, tough international competition and the current regulations specifying that 51 shares must belong to pharmacists. In 2017, local production experienced a huge change with the exit of the Pfizer production site covering all of West Africa and the acquisition of the Sanofi aventis site by Medis, a Tunisian industry. However, in January 2019 had the inauguration of Parenterus. As a result, Senegal currently has five pharmaceutical production units.

There are also 4 pharmaceutical projects ongoing as the creation of Teranga Pharma, West Pharm, Socaphi and extension of the yellow fever vaccine production plant by the Pasteur Institute.

In Senegal, we have a National Pharmaceutical Policy (NPP), whose last revision was in 2014. This NPP is developed by various pharmaceutical industry stakeholders with the support of the World Health Organization (WHO) under the renewed partnership EU /ACP / WHO (European Union and the countries of the African, Caribbean and Pacific Group of States) on strengthening pharmaceutical policies.

Medis Senegal: oral drugs, injectables
West Afric Pharma: only secondary packaging
Parenterus: Parenteral drugs
Valdafrique: mainly topical forms and disinfectants
Institut Pasteur: yellow fever vaccines

The NPP remains essential to ensure the availability of drugs following health financing reforms with the free policies on certain essential drugs.

The promotion of local industries is Objective Number 6 of the NPP and the following strategies have been established to develop them:

1. Creating an institutional and legal environment favorable to investment in the pharmaceutical industry;
2. Incentive arrangements for the emergence of local production;
3. Promotion of medicines manufactured in Senegal.

The Ministry of Health and Social Action will be responsible for the implementation of this NPP in collaboration with all stakeholders in the pharmaceutical sector.

A national pharmacy master plan for a five-year period and a two-year priority action plan will be developed for the implementation of the policy (NPP 2014).

The Ministry of Health will designate a multidisciplinary and multisectoral national group to monitor and evaluate his implementation. (NPP 2014)

#### **1.1.4. Benin**

Benin has only one pharmaceutical industry. According to the United Nations COMTRADE database on international trade, Benin Imports of Pharmaceutical products was US\$110.38 Million in 2018, comprising over 90% of total demand. About 66% was imported from France, followed by India 13%, Denmark 4.4%, Belgium 3.8%, Germany 3.1% and China 2.3%. Due to the cost recovery policy in Benin, drug prices in government health facilities are usually high. Funding from the Ministry of Health (MoH) is limited, hence there is overreliance on user fee charges as a major revenue source for health facilities. Under the universal health coverage policy, children under five years, pregnant women and people aged 70 years and above are

provided with free medicines in public hospitals. However, the availability of medicines in public facilities is limited due to poor warehousing and inventory management practices; acute shortage of qualified health workers and; inadequate pharmaceutical system governance, pharmacovigilance, and regulatory capabilities.

#### **1.1.5. Mali**

Mali also has only one factory and therefore imports numerous pharmaceutical products. Imports of international non-proprietary name generics constitute 80 percent of drug supply in Mali. Since U.S. companies, the main exporters, enjoy a competitive advantage in the pharmaceuticals sector, Mali will continue to import large quantities of all kinds of pharmaceuticals in the next several years. However, imports of illegal and counterfeit pharmaceutical products represent about 55% to 60% of the market and pose significant problems, according to the Order of Pharmacists of Mali (Ordre des Pharmaciens du Mali). In addition to traditional wholesalers and retailers, Mali's large informal sector imports and sells pharmaceuticals without authorization. Although imported drug prices are controlled through a gentleman's agreement between the government, wholesalers and retailers, they are still relatively high.

The Bamako Initiative promulgated jointly by UNICEF and WHO in 1989 advocated for cost-recovery model based on user fees to supplement the low public spending. The cost recovery policy however, resulted in exclusion of most vulnerable people, over time, who could not pay the user fees. The policy was reversed in the early 2000s and user fees abolished. However, the user fee charges continued since it had become a major revenue to cover operating budgets of the health facilities. By 2015, user fees represented 50% of the revenues in primary health care facilities despite the universal health coverage policy. The charges became a major financial barrier to healthcare access. According to the 2017 EMOP survey, 46 percent of the population in need of health care stopped using health services because it was too expensive. The government recently introduced universal health coverage (UHC), which advocates for free healthcare at the point of use for pregnant women and children under five. Through the UHC policy, tax legislation and price control, the Government has managed to reduce prices of some international nonproprietary name essential medicines. However, their availability in public facilities is limited due to frequent stock outs.

#### **1.1.6. Cape Verde**

Cape Verde also has only one pharmaceutical industry. In Cape Verde, high price of medicines in the legal markets and distance to the pharmacy stores has led to emergence of a parallel illegal market. A market which is highly permeable to the distribution of counterfeit, falsified, spurious and substandard medicines. Approximately one in four people purchase medicines outside the legal circuit and, the Praia municipality is the most problematic, reaching one in three people. The problem is compounded by lack of awareness of the risks involved in counterfeits. However, Cape Verde is among the countries which have implemented universal health care in the recent past. All Cape Verdeans are entitled to a basic package of health services, which covers antenatal care; emergency treatment; and treatment and prevention of HIV/AIDS, tuberculosis and malaria. Some other medicines and consultations involve a US\$ 1 surcharge, a fee that is substantially less than the actual cost of the treatment provided. For patients requiring treatment beyond the capacity of Cabo Verde's health care system, such as tertiary care for some

types of cancer, the Government provides flights to Portugal and covers the treatment costs there. Between 600 and 700 people receive this sort of health care each year.

### **1.1.7. Guinea**

Guinea Imports of Pharmaceutical products were US\$109.21 Million in 2017 according to the United Nations COMTRADE database on international trade. About 50% was from India, followed by China 22%, France 20% and Belgium 1.7%. In Guinea, health service is paid for through out-of-pocket payments, making it unaffordable, particularly for indigent households, most of whom are in remote parts of the country. The government finances only one-third of health expenditures, the rest is paid by the private sector, 92 percent of which comes from the out-of-pocket payments of user fees. Insurance programs to provide financial protection for poor households are largely nonfunctioning or nonexistent. In theory, indigent people are entitled to an exemption from user fees, but in reality, the limited public financing and the tendency of health workers to augment their incomes from charge fees, lack of transparency, accountability, and the challenge of identifying who is indigent, limit the effectiveness of this policy.

### **1.1.8. Ghana**

The Ghana pharmaceutical manufacturing industry has been active since the nineteen sixties (1960) with the state owned GIHOC Pharmaceuticals as the biggest company. The other pharmaceutical companies were mostly private expatriate pharmaceutical distribution companies with a small manufacturing unit attached. The capacity of GIHOC Pharmaceuticals was developed through a bilateral arrangement between GoG and the Hungarian Government. Through this arrangement GIHOC was able to produce a wide range of dosage forms including syrups, suspensions, tablets, capsules and injectable to serve both the public and private health facilities. In the nineteen eighties (1980), the then military government introduced a restricted list of twenty (20) medicines<sup>1</sup> which were barred from imports and reserved only for local manufacture. This policy gave a surge to the establishment of several pharmaceutical manufacturing companies like Ernest Chemists and Letap Pharmaceuticals. The restricted list has been expanded to forty-nine (49)<sup>2</sup> in 2018 as found in EI 181<sup>3</sup>.

Currently, all the pharmaceutical manufacturing companies have majority equities owned by the private sector. There is one company who has majority equity owned by a MNC and that is Kama Health Industries owned by Aspen. There are 37 pharmaceutical manufacturers. Only about 30% of the medicines are manufactured locally with the rest imported from India and China. The public sector is the highest purchaser of medicines which is funded through the National Health Insurance Scheme.

The pharmaceutical sector is estimated to have a size of about 600million USD with a CAGR<sup>4</sup> of about 13.9%. The drivers of the growth are the NHIS which has improved access and enrolment in healthcare, urbanization as more of the population are moving into the cities and can access

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<sup>1</sup> Annex 7.1

<sup>2</sup> Annex 7.2

<sup>3</sup> <https://fdaghana.gov.gh/wp-content/uploads/2017/06/EXECUTIVE-INSTRUMENT-FOR-LIST-OF-MEDICINES.pdf>

<sup>4</sup> IMC Worldwide, 2018, Preparatory Analysis and Investment Packaging for Ghana Pharmaceutical Production Sector



healthcare. The others are the growth of the middle class of the population and the rapid expansion of healthcare infrastructure.

### **1.1.9. Togo**

Togo has 4 pharmaceutical manufacturers out of which 3 are in free zone. There is no official statistics of the consumption of local manufacturers' drugs. The latest version of the national pharmaceutical strategic plan put the accent more on drug access and their rational use, rather than on local manufacturers. Indeed, as part of West African Economic and Monetary Union (WAEMU), imported drugs in Togo are VAT free, making imported drugs more competitive than local products. Most of the imported products are assumed to be brought by the private sector (95 % of the market) even if there's no official statistics sustaining those data.

The ongoing (2017 - 2022), National Health Development Plan put in its fifth strategic axis, the increase of quality drugs' access, while none of the priority actions planned focused on local manufacturing.

Last but not least, there is an ongoing (2017 - 2022) National Development Plan carried by the Head of States, which plans in its second strategic axis to foster on local manufacturers. The said manufacturers on the plan are extractives and food ones.

All this said, local manufacturers seem to have no specific policy helping them in improving their quality and their competitiveness. The existing incentives are general such as good logistics facilities for both air and sea products shipment to Togo.

## **1.2. Justification for Promoting the development of pharmaceutical industry in the Economic Community of West Africa States**

The Economic Community of West African States (ECOWAS), which was established by the Lagos Treaty of 1975, brings together 15 countries; 5 Anglophones; 8 Francophones and 2 Lusophones. The need to promote local pharmaceutical industries in the region is motivated by the following, among other factors:

1. **High disease burden:** Although the language differences significantly influence policies, practices and business activities, as well as systems of medicines regulation, the region has similar disease burden – namely huge burden of malaria, HIV-AIDS, tuberculosis as well as neglected tropical diseases, amongst others. Like most other regions; ECOWAS region also have high incidences of poverty and malnutrition, which also impact on the types of medicine required.
2. **High cost of imported medicines:** West Africa countries, like the rest of African, through their development plans, have prioritized provision of and access to affordable health. However, the realisation of these aspirations has been constrained due to the high costs of imported medicines, which not only increase the health burden (medicines account for 20-60% of health spending) but also have negative implications for access and affordability. Affordability is important since up to 90 % of the population buy medicines through out-of-pocket payments.
3. **Growing regional market for medicines:** With a population of about 365 million, and an estimated market size of \$4b, the pharmaceutical industry in West Africa has enormous potential and opportunities for the production and supply of essential medicines. Less than 30 % of this demand is satisfied through local production. The main

source of medicines for the region in SouthEast Asia, mainly India and China. Furthermore, this demand is likely to grow due to high rates of economic growth and a fast-growing middle class and youthful population.

4. **Expected increase in access to anti-retroviral drugs:** The anti-retroviral drugs market in West Africa is expected to grow significantly as the region strives to reach the African Union's target of 80 % coverage up from the current treatment coverage of only 40 %. Due to limited production capacity, almost all of the region's antiretroviral medicines are imported from India. Furthermore, there is concern in some quarters that the low margins in antiretroviral medicine manufacturing for Africa may cause Indian manufacturers to shift their capacity away from African antiretroviral medicine volumes towards higher-margin products and markets, creating a real urgency for the region to develop its own supply.
5. **Pressure from non-governmental organizations:** Civic society and the private sector are also mounting pressure on African countries to provide concrete support to local pharmaceutical manufacturing. For example, the Pan African Civil Society Platform on Access to Medicines has a mandate to promote the development and implementation of policies and strategies aimed at increasing access to quality and affordable medicines for all underprivileged citizens of Africa especially in the sub-Saharan region of the continent.

### **1.3. Challenges facing the development of pharmaceutical industry in the Economic Community of West Africa States**

Currently, there are 166 local pharmaceutical industries, based in 10 out of 15 West African countries. Out these, 120 are in Nigeria; 36 in Ghana; 2 each in Senegal and Cote d'Ivoire and one in Cape Verde. These initiatives have been aimed to promote local pharmaceutical industries, not only to address the issue of high costs of imported medicines but also to tap on additional benefits that local pharmaceutical industries can bring, such as creation of employment opportunities and enhancing intra-Africa trade. However, there are several bottlenecks experienced by the sector, along its value chain (access to inputs, manufacturing, and marketing). These include the following:

1. **Access to raw material:** Over 90 % of the inputs for local pharmaceutical manufacturing is imported. These are mainly: Active Pharmaceutical Ingredients (APIs); packaging materials, as well as other inputs that are not manufactured in the region. Furthermore, raw materials prices fluctuate at will depend demand from other countries. Due to long delivery period of the imported raw materials, most manufacturers are forced to maintain very high raw materials inventories to keep their production lines running and this depletes their working capital.
2. **Shortage of skilled labour:** The human resource challenge is not only on the number of pharmacists and other professionals (in areas such as regulatory affairs, pharmaceutical technology, drug formulation and development and clinical studies) but also on their limited or on-exist industrial pharmaceutical knowledge and skills. This shortcoming is attributed to curricula at the universities and the limited collaboration between the pharmaceutical industry and the training institutions. Training curriculum in the region's universities has not been tailored to suit both traditional and modern trends of

pharmaceutical developments. Most manufacturers, therefore, rely on expatriates for highly skilled operations, training and supervision of the local staff.

3. **Expensive pharmaceutical manufacturing equipment and technology:** There are three issues related to access to pharmaceutical equipment and drug technology:
  - a. The bulk of the pharmaceutical manufacturing equipment are imported, and therefore expensive. Even where local manufacturers have maintenance workshops, maintenance activities for critical machinery are dependent on sourcing of replacement and parts, and, on some occasions, specialized technical personnel from abroad.
  - b. There is also low investment in pharmaceutical R&D in the region. ECOWAS states governments have recognized the critical role of research and development in the promotion of quality health care. As a result, there have been some modest efforts in the establishment and maintenance of research institutions through allocation of resources, with the support of partners. The Centre for Scientific Research into Plant Medicine in Ghana, the National Institute for Pharmaceutical Research and Development in Nigeria and the Louis Pasteur Research Institute in Senegal are but a few examples. A common feature shared by all these institutions in the ECOWAS Member States is their poor funding by the state, and in most cases the governments only support staff emoluments. As a result, most of their research activities are donor-funded and therefore do not necessarily address regional health priorities.
  - c. Limited utilization of TRIPS Flexibilities. While international agreements such as TRIPS provide opportunities for technology transfer and has inbuilt flexibilities that could be exploited for national interest, only a few Africa countries have taken advantage of the opportunities under TRIPs. Intellectual property is viewed largely as a hindrance rather than a facilitator of medicines, even though WHO reports that up to 95 % of drugs in its essential medicines list are off-patents. ECOWAS has not yet followed the examples of other regions that have made great advances towards harmonization of regulations towards access to TRIPS flexibilities
4. **Medicines Regulations:** In the ECOWAS region, member states have in place basic legal framework for the regulation and control of the manufacture, distribution and utilization of medicines for human use. There are two different systems – In Anglophone countries, the regulatory functions are centralized in a semi-autonomous/autonomous body; where in French and Portuguese-speaking system has regulatory functions shared between several bodies under the authority of the Ministry of Health. A review of these systems showed that medicine regulation is still problematic, due to weak infrastructure, weak enforcement power, and inadequate human resource capacity, amongst others. The medicines regulatory sector is also faced with the problems of poor motivation and low retention of staff; high levels of counterfeit and illicit medicines and lack of harmonization of medicines regulation. There are also differences in the requirements for medicines registration in member countries
5. **Accessing market:** Medicines are supplied through the public and the private sector, as well as, non-governmental organizations, faith-based organizations, and international aid agencies involved in the procurement and distribution of medicines and health supplies. The national medical stores are responsible for the procurement, storage and distribution of medicines and health supplies for the public sector, while the private sector is served

through a chain of wholesale and/or retail pharmacies, chemist shops, and private clinics. The local manufacturers have the following two problems:

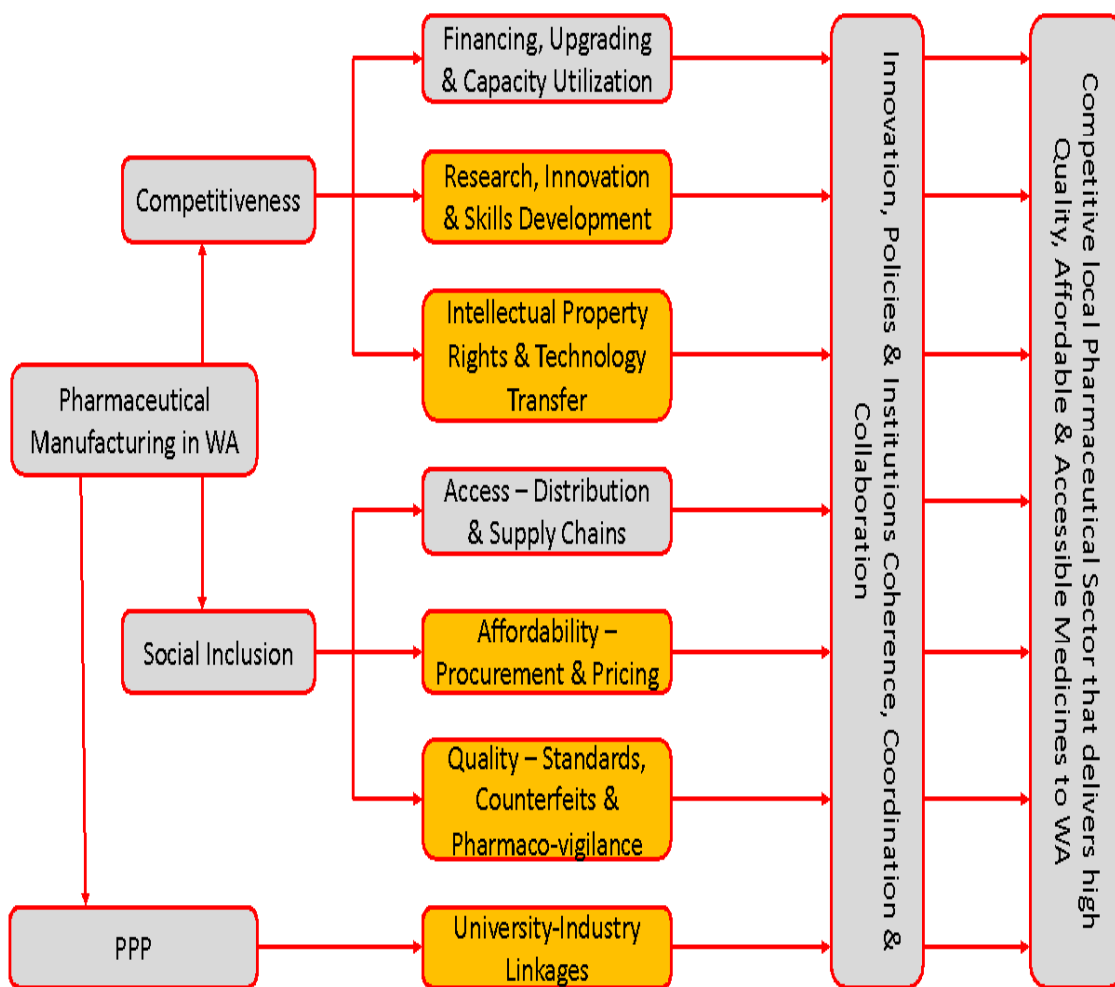
- a. Procurement of pharmaceutical products by public agencies is usually based on the quoted price, with a tendency to select the lowest bidder. This normally favours international pharmaceutical agencies over local industries due to the low production costs of the former.
  - b. All donor and development partners funded procurement of essential medicines requires that supplier should have World Health organization's product prequalification. This is therefore out of reach of most local manufacturing due to lack of prequalification
6. **Stiff competition in the generic drug sector:** Given the low health budgets of African governments and the dire need for antiretroviral medicines, African countries pay far lower prices for their antiretroviral medicines than do developed markets. The implication is that generic antiretroviral medicine manufacturing for West Africa is a tough business with very small margins. In fact, the same is true of most products in Africa, given the high share of generics. In such a low-margin business, African manufacturers must become cost competitive against international peers to survive and thrive.

However, not much progress has been realized due to several bottlenecks experienced by the sector including importation of almost 90 % of the inputs, shortage of skilled labour, lack of technology, low level of R&D, and weak policy, legal and regulatory systems, amongst others.

#### 1.4. Purpose of the Study

The purpose of the study is to review the sector and propose interventions that can help build a competitive and socially inclusive local pharmaceutical manufacturing industry in West Africa. The study focuses on selected dimensions of industry competitiveness, social inclusion and public-private partnerships. These are affordability; human resources; research and development; intellectual property; and technology transfer (Figure 1.1).

It covered nine countries in West Africa - Ghana, Nigeria, Senegal, Côte d'Ivoire, Togo, Benin, Mali, Cape Verde and Guinea Conakry, all of which have at least 1 industry each. In a sub region with a population of about 365 million, and an estimated market size of \$4b, the pharmaceutical industry in West Africa has enormous potential and opportunities for the production and supply of essential medicines.



### 1.5. The Overall and Specific Objectives of the Study

The overall and specific objectives of the project are shown here below

1. **Affordability:** The overall objective of the study is to enhance the use of public health procurement, by West African Countries, as a tool for enhancing local pharmaceutical production (LPP). The specific objectives are: to document the existence of policy incentives that promote local pharmaceutical industries and their impact on production and consumption patterns; growth and capabilities of the local pharmaceutical manufacturing; and ability of the local manufacturing to serve the poor; to document the existence of similar policy incentives at the regional level; to document experiences, best practices and success stories from those countries that have implemented such policies; and to make appropriate policy recommendations and interventions.
2. **Human Resource:** The overall objective of the study is to strengthen the human resource capacity to support the growth of LPP in West Africa. The specific objectives are to: document the current human resource situation in the pharmaceutical industries and what coping strategies the industries have adopted; document the role played by the national universities and other training institutions to address the human resource challenge; explore

what role the diaspora can play to provide the required human resource expertise in the pharmaceutical industries; explore to what extent collaboration with countries from Asian countries can help to support the sector, by documenting success stories and lessons learned from other countries; explore to what extent developed pharmaceutical sector, can help other West African countries to develop their local pharmaceutical industries; and to make appropriate recommendations.

- 3. Research and Development:** The purpose of the study is to strengthen the use of R&D to support the local pharmaceutical industries in West Africa. The specific objectives are to: document status of R&D in the pharmaceutical sector and the bottlenecks LPPs are facing in starting local production of Active Pharmaceutical Ingredient (API) and what needs to be done to jumpstart local production; to document the activities of universities, research organizations and centres of excellence<sup>5</sup> that are striving to develop local pharmaceutical raw materials to support local industries and understand what needs to be done to enhance their efforts; document existing activities around drug development targeting treatment of malaria and HIV-AIDS based on indigenous knowledge and biodiversity; and to make appropriate recommendations
- 4. Intellectual Property Rights and Technology Transfer:** This covers the following objectives: undertake a case study on some of the companies that are currently producing ARVs and other generic medicines based on TRIPs Flexibility and document: the nature of the agreement entered into; the domestic circumstances that led to the negotiations of these agreements; how they have handled the requirement for WHO certification as a condition for technology collaboration and licensing; experiences and lessons learned; and the extent to which voluntary licensing have contributed to improving access to medicines; and to document success stories and best practices from elsewhere in Africa and outside Africa.
- 5. Academia-University Linkages:** This study will involve two parts. First is to document the current successes and challenges relating to university industry partnership in focusing on policy incentives at national level; institutional policy and support structures; success stories on academia-industry linkages and technology transfer in the pharmaceutical area. Secondly is to document the best practices and lessons learned from successful developing countries that have excelled in academia-pharmaceutical linkages (India, China, Brazil, and Indonesia) as well as developed countries such as Germany and the USA.
- 6.** Make appropriate recommendations based on the findings from above

## **1.6. Study Design and Methodology**

### **1.6.1. Study Design**

The following study design was adopted

- 1. Regional comparative studies:** West Africa region, through ECOWAS, has promoted a regional approach to addressing issues related to enhancing access to medicines and promoting the competitiveness of the local industries. These include ECOWAS Regional

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Pharmaceutical Plan (ERPP) developed by the West African Health Organization (WAHO) in 2014; programs to strengthen the manufacturing capacity of selected pharmaceutical firms and the supply of anti-malarial and anti-retroviral drugs within the region; “ECOWAS Charter on Public Private Partnership Initiative for Local Pharmaceutical Production of Priority Essential Medicines” in Praia, Cape Verde in April 2013; and TRIPS flexibilities policy and guidelines for the ECOWAS, which was validated and adopted in October 2012 in Accra by Intellectual Property Officers from all the 15 Member States, ARIPO, OAPI, UNDP and WHO. These initiatives were reviewed, and relevant achievement documented.

2. **Comparative country case studies:** Focusing on the dimensions selected above, the comparative country studies documented differences and similarities in approaches between anglophone and francophone, in addressing the challenges of promoting local manufacturing and what lessons derived. This was based on the in-depth national/in-country studies.
3. **National/in country assessment:** A comprehensive national/in-country study was undertaken covering all the issues and questions listed under overall and specific objectives as well as some country specific issues identified during the inception report. The country assessments were done by nationals from these countries
4. **Firm level studies:** Selected existing pharmaceutical manufacturing companies were interviewed on a wide range of issues covering questions listed under specific objectives.
5. **Single/multiple case studies:** Case studies focused on cases where specific programmes have been implemented and the studies geared towards drawing lessons and experiences on the outcomes, impacts or challenges. These included experience on procurement policy incentives; university industry Linkages; application of TRIPS flexibilities; and training and skills development.
6. **Benchmarking studies:** Benchmarking studies were undertaken with India, China, Brazil and Indonesia drawing lessons and experiences on the outcomes, impacts or challenges on. These included experience on: procurement policy incentives; university industry Linkages; application of TRIPS flexibilities; and training and skills development.

### **1.6.2. Methodology**

The consultant used a seven-step approach to address the terms of reference

1. Data Collection through review of existing documents
2. Data Collection through field work
3. Data Collection through case studies
4. Analysis of the data collected
5. Preparation of the draft report
6. Validation of the report by stakeholders’ workshop
7. Preparation of the final report based on comments and suggestions from the workshop participants

### 1.6.3. Brief Profile of the Consultants

The project is being undertaken by six national consultants as summarized below:

Country	Consultant Name/Photo	Brief Profile
ACTS - Kenya	 <p><b>Prof. Tom P. Ogada</b></p>	<p>Prof. Ogada has enormous experience at senior management levels in research, university, public and private sector. He is the Lead Consultant &amp; currently the Executive Director of ACTS and also the Chairman of the Board of NACOSTI. He has been a consultant of the WIPO since 2000. Previously he was the MD of KIRDI, a UNDP funded research fellow at the National Economic and Social Council, (a Kenya government policy advisory body), and Advisor to the British Council on a DFID funded project - African Knowledge Transfer Partnership. Prof. Ogada holds an MSc in Mechanical Engineering from, Minsk, USSR (1987), PhD in Chemical Engineering from Germany (1995) and MBA in Strategic Management from Moi University, Kenya (2005).</p>
Nigeria	 <p><b>Prof Wilson O. Erhun</b></p>	<p>Prof. Wilson Erhun is a Professor of Pharmacy Administration and current Dean of the Faculty of Pharmacy, Obafemi Awolowo University, Ile Ife with about 40 years of university teaching and research experiences. Currently Chairman of Faculty of Social and Administrative Pharmacy of WAPCP. He has over 60 research publications to his credit. He is a pharmaceutical consultant to many organisations and served as key Consultant to Nigeria Essential Medicines programmes for many years. He has been Chairman of different Accreditation panels for the Pharmacists Council of Nigeria accreditation of Faculties of Pharmacy in Nigeria Universities and member of many other panels of the National University Commission for institutional accreditation. Prof Erhun is a Foundation Fellow, Nigerian Academy of Pharmacy; Fellow, West African Postgraduate College of Pharmacists and Fellow, Pharmaceutical Society of Nigeria</p>
Ghana	 <p><b>Mr. Louis Nortey</b></p>	<p>Nortey has vast experience in the pharmaceutical industries spanning over 36 years in Ghana, Togo, Benin, Nigeria, Cameroun, Gabon, Burkina Faso, Guinea Bissau, Liberia, Sierra Leone, Guinea, Mali, Senegal, and Chad. Nortey currently is the Chief Pharmaceutical Policy Analyst at PHEBS Consult and previously served as the National Pharmaceutical Expert for over 20 years at United Nations Industrial Development Organization; Director, International Marketing at Kinapharma Limited; Deputy Sales &amp; Marketing Manager at Phyto-Riker Pharmaceuticals; Senior Medical Representative at Pharmacia &amp; Upjohn; and Senior Research Assistant at Centre for Tropical Pharmacology &amp; Therapeutics.</p> <p>He holds Bachelor of Pharmacy, Fellow West African Postgraduate College of Pharmacists, Executive Masters Business Administration, Certificate in Health Technologies Assessment and Fellow Ghana College of Pharmacists.</p>
Senegal	 <p><b>Dr. Aida Sall Toure</b></p>	<p>Aida is Pharmacist working currently as Pharma GMP Consultant for local companies based in West Africa. Previously worked for Pfizer West Africa as the Site Leader; Aida holds first cycle of Pharmaceutical studies in, Senegal and second cycle of Pharmaceutical studies in Bordeaux; She held also a Master 2 Management Project for Development of Pharmaceutical and Nutritional Products.</p>



<p><b>Côte d'Ivoire</b></p>	 <p>Dr. Jules-Olivier Gbolo</p>	<p>Gbolo is currently the QHSE Manager at Pharmacist (Pharma D). Previously, he served as the Regional Manager for the Western area of CIV (Pharmaceutical Wholesaler Company – DPCI; Regional Manager for central and Northern area of CIV (Pharmaceutical Wholesaler Company – DPCI); Pharmacist at Pharmacy Owner of Pharmacie D'Agou; Quality Manager for ESTHER Ltd(Local Pharmaceutical Company Phytotherapy); and Nutrition Adviser for Nestle Nutrition.</p> <p>Gbolo holds a Pharmacy degree, Master degree in Health Systems Engineering option QHSE Management, University degree in Management option Pharmacy Management and MBA ALTIS/ CERAP in progress.</p>
<p><b>Togo</b></p>	 <p>Dr. Mouhoudine Yerima</p>	<p>Mouhoudine is currently the Pharmacology Assistant Professor at Health Sciences Faculty of the University of Lomé, and also Pharmacovigilance Country Head at the Ministry of Health of Togo. He is currently involved in four projects which are on-going. Previously, he worked as the DREPATEST Country Project Manager, an international multicentric study of Rapid Diagnostic Test Validation of Sickle Cell Disease, conducted in Togo, Mali and Democratic Republic of Congo; and also Clinical Research Associate in Pharmacology Department of Institut de Recherche Pierre Fabre (IRPF), Toulouse-France.</p> <p>Mouhoudine holds a Bachelor degree in Pharmacy, Master degree in Pharmacology (Clinical trials option), and a PhD in Pharmacology.</p>
<p>Benin Mali Cape Verde/ Guinea Conakry</p>	 <p>Mr. Pharesh Ratego</p>	<p>Ratego has vast experience in research and consultancy spanning for over 40 years. Currently he works at Development Shift Consulting Ltd as an Associate Consultant. Previously Ratego worked at Homa Bay County Government as the County Executive Member in charge of Energy and Natural Resources; USAID –Kenya for 20 years in various positions (Project Management Specialist; Monitoring &amp; Evaluation Specialist; &amp; Financial Analyst); Development Finance Company of Kenya as Project Manager; Kenya School of Professional Studies as Director of Studies; Kenya Polytechnic as Senior Lecturer; Ministry of Cooperative Development as Auditor. Ratego holds a Bachelor Degree in Commerce – Accounting, Diploma in Development Finance and Master Degree in Development Finance.</p>
<p>ACTS-Kenya</p>	 <p>Mr. Patrick Obunga</p>	<p>Patrick is currently a Resource Mobilization Officer/ Research Fellow at ACTS and Incharge of coordinating the consultancy. Previously worked for Well-drill &amp; Geotechnics Engineers/ Consultants (Projects Engineer), BAC (Projects Monitoring &amp; Evaluation Officer cum Project Engineer), Equity Bank Limited (Relationship Officer), NESAC (Research Associate) &amp; KIRDI (Research Assistant).</p> <p>He has accumulative of twelve years of experience &amp; holds a BSc. Engineering from Egerton University, Postgraduate Diploma in Project Management from Kenya Institute of Management, MA in Project Planning and Management from University of Nairobi and MSc. Civil Engineering from the University of Nairobi. Also has done professional courses in Project Monitoring &amp; Evaluation Skills Development; Value Chain Development; Community Managed Disaster Risk Reduction; &amp; Curriculum &amp; Instructor Guide Development.</p>

## CHAPTER TWO

### USE OF PUBLIC PROCUREMENT TO SUPPORT LOCAL PHARMACEUTICAL INDUSTRIES AND ENHANCE ACCESS AND AFFORDABILITY

#### 2.1. Procurement policies and legislations

The study established that most of the West African countries have strived to put in place policy incentives to support the local pharmaceutical industries. Ghana, Nigeria, Senegal, Cote D'Ivoire and Togo have policy incentives and provides between 5-15 % preferential treatments of local industries for public procurement of medicines.

##### 2.1.1. Ghana

The Government of Ghana uses legislation to support public procurement of pharmaceuticals as espoused in the Public Procurement Act (Act 914) <sup>6</sup>as Amended in 2016. In section 60 of the Act, local manufacturers are entitled to a margin of preference over foreign industries. A margin of preference of 15% is allowed for locally produced medicines under National Competitive Tendering as well as International Competitive Tendering according to the procurement law regulations. However, in public procurement of medicines, there are three procurement levels, National, Regional and Facility (Hospital, Clinic, etc.). Since the law does not capture the margin of preference in relation to regional and facility levels, they are not applied there. Investigations in 2015 showed that the value of medicines procured at the national level is similar in quantum or value to that at the regional and facility levels combined. Since procurement at all levels are done through competitive bidding or restricted tendering process which comprises both foreign and locally produced pharmaceuticals, the local manufacturers loose out at the regional and facility procurement levels where the margin of preference is not considered.

#### The Act states

A procurement entity may grant a margin of preference for the benefit of tenders for work by domestic contractors or for the benefit of tenders for domestically produced goods or for the benefit of domestic suppliers of services or any other preference authorized by the Board or required by Regulations or any other enactment.

The margin of preference shall be calculated in accordance with the procurement regulations and reflected in the record of the procurement proceedings;

The margin of preference shall be authorized by the Board and be subject to approval by the Board

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<sup>6</sup> PPA (Act 914) as Amended 2016

### Regional Facility

A regional facility is a procurement entity with a cap, so they can initiate procurement of medicines from local manufacturers to alleviate stock-outs and facilitate payments as well. Payments at the lower tiers (below national) often take shorter times than at the national levels due to bureaucracy. A non-availability certificate may be issued from the regional level for an out of stock item to qualify for procurement by a facility from the private sector. For an out-of-stock item, each procurement cycle requires the issuance of a non-availability certificate. A non-availability certificate can only be used once. If there is the need to buy that same stock again, a new non-availability certificate will have to be issued.

The application of the margin of preference at the national level clearly offers some price advantage for the local manufacturers but the PM are often not very competitive at the regional and facility levels where the margin of preference is not applied.

#### 2.1.2. Côte d'Ivoire

The Ivorian pharmaceutical industries benefit from various advantages granted by the Ivorian State in order to facilitate their development.

The first is the "*national preference agreement*"

Prohibiting the import of medicines with the same active ingredient, pharmaceutical formula and dosage as those manufactured locally.

However, following the devaluation of the FCFA, this agreement is only applicable in a situation where the price of the drug does not exceed the imported one by more than 16%.

The second is called: "*priority approval for investment*"

Procurement in the public sector is ensured by the New Public Health Pharmacy (PSP) on the basis of a National List of Essential Medicines and Medical Consumables. The NPSP is a central government purchasing office of the NPE type (National Public Establishment of an Industrial and Commercial Nature) organized according to the terms of Decree No. 2002-334 of June 13, 2002..Regulatory measures have made it possible to carry out the reform of the Public Health Pharmacy (PSP) which has changed status from an Industrial and Commercial EPN (EPIC) to a Non-Profit Association (NPO) called "New PSP-CI" by Decree N° 2013-792 of 20 November 2013 .NPSP is the main supplier to public health institutions in Côte d'Ivoire .They are required to obtain 85% (university hospitals) and 100% (other health facilities) of their needs from the NPSP. NPSP therefore has a virtual monopoly on the distribution of pharmaceutical products in these health Institutions, which constitute the totality of its. NPSP also receives support for medicines from organizations such as PEPFAR, the Global Fund, United Nations agencies, USAID etc. PSP, which does not have departmental distribution branches, has strengthened its logistics to ensure deliveries. Despite this, stock shortages are still to be deplored in some sanitary facilities. This is why these public health facilities are authorized by the NPSP under a procedure known as the Non-PSP Procedure, to source from private companies. However, it is important to note that this derogation is not always carried out in compliance with the above-mentioned procedure.

PSP's procurement procedures include tendering international and limited consultation. A limited part of the products is however, acquired by mutual agreement. The drugs are ordered under INN in the National List of Essential Medicines. Local manufacturers participate in tenders on the same basis as external suppliers. As stated in the national pharmaceutical plan, they must benefit from the advantages of national preference or sub-regional as recommended by the Ministers of Health of the CFA franc zone since December 1999(As stated in the national Pharmaceutical policy).However, we noticed that they do not really benefit from the advantages of national preference regarding tender business because of their lack of competitiveness compared to imported drugs and their inability to honor volumes of medicines ordered by NPSP

The support of the State is essential to enable the development of local industry. It must take the form of a public procurement orientation and incentive public policies, like what has been done in other countries (Morocco, Tunisia and Egypt) with conclusive results. For example, Morocco, which is the continent's second largest pharmaceutical producer after South Africa, has introduced and reinforced the principle of national preference into public tenders. Now, the country has about 40 industrial pharmaceutical units, which supply more than 70% of domestic demand and export part of it to neighboring countries.

With regard to public procurement in Cote d'Ivoire, it is necessary to reinforce and to make applicable mechanisms by which public and private purchasing centers obtain their supplies primarily from local producers, and use imports only to fill volumes that cannot be served locally. Expectations are high in the management of public purchasing bodies, both for the reliability of their orders and for the timely payment of receivables, which, when late, can have a significant impact on the cash flow of producing companies.

Incentive policies must take into account the specific characteristics and constraints of the pharmaceutical industry. The installation and maintenance of production equipment requires significant investments. To regulate the sector and promote the pharmaceutical industry, the decision-making bodies have set up the key instrument for guiding drug policy, which is the National Pharmaceutical Policy of 2015, updated and the Strategic Plan for the Implementation of the National Pharmaceutical Policy (October 2016).

The Strategic Plan for the Development of the Local Pharmaceutical Industry (July 2017) aims to promote the development of the pharmaceutical sector with the promotion and development of local industry as one of its focal points.

This Vision is translated into strategic objectives divided into 3 steps:

**1<sup>st</sup> Step:**

1. Achieve within 5 years 30% coverage of national drug needs through local manufacturing
2. Mobilize investments in the pharmaceutical industrial sector amounting to US\$100 million over these 5 years

**2<sup>nd</sup> Step:**

3. Reach 45% coverage in 10 years

4. Conquering the Ivorian IPL image = quality IPL improving the accessibility and availability of medicines

### **3<sup>rd</sup> Step:**

5. Become a major drug supplier in the region

To achieve these assigned strategic objectives, a strategic action plan to promote local industries has been drawn up in 22 actions to undertake:

1. Government Commitment
2. Organization of an international symposium on the promotion of local pharmaceutical industries
3. Tax measures including VAT
4. Advantages of emerging industry and protective measures
5. Organization of partnership days ( country / country)
6. Awareness note for the banking system
7. Granting of sector-specific credit lines
8. Discussion with international organizations for the implementation of support funds for study
9. Creation of an industrial zone dedicated to non-polluting industries
10. Advantages of public procurement
11. Coordination with health insurance
12. Implementation of an Anti-Dumping Monitoring Cell
13. Development of a specific investment code
14. Strengthening of the pharmaceutical regulatory authority
15. Implement WAEMU regulations
16. Increase drug registration fees and remits them to the Agency (NLSP in the meantime)
17. Review the list of imported medicines taking into account the quality/efficiency/cost ratios with local products.
18. Review the Deadline for Granting Operating Licenses
19. Increase in profit margins for local products.
20. Continue the upgrading programs
21. Evaluation of implementation of this strategic plan and assessment of sectoral developments (every three months and at each time as necessary)
22. Implement a strategy for the training of senior managers and technicians attending to work in local Pharmaceutical industries.

Despite the implementation of the strategic action plan, it must be noted that, not much success has been realized mainly due to the lack of real commitment of the actors in charge of its roll-out.

### 2.1.3. Nigeria

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 (NCP), 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 Bureau of Public Procurement oversees the implementation of the Public Procurement Act 2007, which has 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 the time the time set the limits and compute the margins of preference and determine the contents of goods manufactured locally.

### 2.1.4. Senegal

In Senegal, the National Pharmacy Supply (PNA) has a monopoly on supply, storage and distribution of essential drugs and products to the country's public health establishments, such as hospitals, districts, non-governmental organizations, special programs, para-public structures, and even private wholesale distributors (on some molecules). Currently, there are two tenders' programs established to support local industries:

1. **National Preference during international tender:** The PNA proceeds mainly by international tender for the procurement of medicines by following the public procurement code (2014). There is a policy governed by the public procurement code applicable to the local pharmaceutical industry. According to this code, WAEMU local industries benefit from a national preference of 5-15% during international tenders organized by the PNA (*source DPM, article 50 public procurement code*). The national preference does not apply only to Senegalese' industries but concerns all WAEMU member countries due to the fact that all WAEMU member countries must respect the economic and free movement of medicines agreements.

- 2. National tender:** To promote the local pharmaceutical industry, PNA in collaboration with the industries has developed a national tender program (all WAEMU countries) in 2017. For that purpose, a list of 60 products has been established and only the local industries had the right to bid with a contract over 3 years to the winner. However, this operation was not successful as expected due to the fact that the industries could not have in their portfolio the 60 requested products. (Source PNA).

#### **2.1.5. Togo**

There is a policy (2014). In Togo, there is a national committee composed of members from academia, public and private sector, dedicated to the help of local manufacturers. Their missions include helping the local industries in launching their activities through technical support about procedures; preparing their Market Authorization according to CTD template; and holding extraordinary session to assess their Market Authorization dossiers in order to help them gain time in new drugs release. The committee was appointed by a note of the Ministry of Health for one manufacturer. Its mission is assumed to be extended to all the manufacturers. There are also customs and economic facilities in raw material procurement, since they are considered pharmaceutical products.

### **2.2. Other Incentives provided to local pharmaceutical industries**

Apart from procurement policies, some countries provide additional incentives in terms of tax exemptions and local content policies.

#### **2.2.1. Tax incentives and local content policy to promote investment in Cote d'Ivoire**

In 1986, the strategic status of the pharmaceutical industry was already recognized by the Côte d'Ivoire authorities and the first local pharmaceutical manufacturing units were already given priority approval. This approval granted local Pharmaceutical manufacturing (LPM) full exemption from customs duties and VAT on investments (industrial equipment, spare parts, materials and construction costs for industrial buildings). A 10-year exemption from income tax on industrial and commercial profits had also been granted. Other benefits that investors in the pharmaceutical industries can benefit from include:

1. Tax exemptions ranging from 50% to 75% over a period of five (5) to fifteen (15) years depending on the investment areas.
2. Tax exemptions relate to income tax, including the flat-rate minimum tax, the contribution of patents and licenses, the contribution payable by employers, the tax on income from securities for dividends paid to national shareholders and the tax on property assets.
3. Tax credits determined as a percentage of the amounts invested. At the end of the implementation of their investment programs, the rates set by the new code vary between 25% and 50%.

In addition to tax incentives, international investors are urged to rely on local companies in the conduct of their operations in order to benefit from the facilities offered by the new legal framework. The objective is of course to open up spaces of opportunity for SMEs and to give a

more inclusive character to Ivorian economic growth. Thus, large foreign companies eligible for the tax benefits, particularly those entitled to tax credits provided that they apply a local content policy relating to job creation, the opening of share capital to nationals and subcontracting.

For local employment, an additional tax credit of 2% is granted to foreign investors whose number of Ivorian executives and supervisory staff represents 90% of the total number of these two categories of employees. The same rate is applied to companies that subcontract to national companies, the realization of goods intended to be incorporated into a final product in Côte d'Ivoire and abroad as well as for companies that open their share capital to nationals. The implementing decree of 18 December 2018 identifies the conditions for access to the tax credit. Companies in agriculture, agro-industry, health and hotel sectors as well as companies in other sectors of activity excluding companies in the trade and liberal professions, the banking and financial sectors and the non-industrial construction sector. These companies must also open at least 15% of their share capital to Ivorian nationals.

### **2.2.2. Government initiatives that support local pharmaceutical industries in Senegal.**

There are several policy incentives that the Government of Senegal has put in place. These include the special economic zones, export free company, and industry labelling.

**Special economic zone (ZES):** The Senegal Emergent Plan (PSE) has planned the realization of two or three large-scale industrial platforms designed as an ecosystem of high-performance services and incentives, with the aim to promote industrial development. (*Source Ministry of Investment Promotion of partnerships and development of teleservices of the Government Decret 2017 2189*). In this perspective, Senegal currently has 3 special economic zones (Diass, Diamniadio, Sandiara) in Senegal which are spaces for the reception of economic activities. The purpose is to offer to companies a set of infrastructures and services which ensure them better conditions for carrying out their activities. The ZES constitute investment opportunities for new industries.

Companies and promoters can benefit from an incentive package that entitles them to tax and customs exemptions. (*National Agency for the Promotion of Investments and Major Works APIX*). As provided in Law No. 2017-07 of 06 January 2017 on the incentive scheme applicable in ZES and the decree n ° 2017-1174 implementing the law n ° 2017-07 of January 06, 2017, the exempt companies will benefit Over a period of 25 years' renewable:

1. the right of admission free of all duties and taxes levied, excluding Community levies on raw materials, equipment and other goods, and the duty free of export outside the national territory;
2. an exemption from payment of any income tax;
3. a tax rate of 15% on corporation tax;
4. the possibility of concluding fixed-term contracts for a period of five years;
5. an exemption from the lump sum contribution from the employer or any other tax based on salaries
6. an exemption from the flat rate minimum tax on companies.

**Export Free Company:** We also have export free companies that are individually licensed companies. These companies have the following advantages: Exemption VAT import and exemption duties and taxes of customs. *Decree approving the status of free enterprise of*



*exploitation February 2018.* The creation of these areas is a real advantage for local industries. Currently, several pharmaceutical industries take benefit of privileges granted to these areas, like Medis, Parenterus, West Africa Pharma (WHAPHA). (Source APIX) The new company Teranga Pharma has acquired the former Pfizer site in the Export Free Zone

**Industry Labelling « PSE »:** PES is a new model of development that Senegal has put in place to accelerate its progress towards emergence. This strategy is the guidance for economic and social policy in the medium and long term. (*Senegal Emergent Plan*). This labeling concerns more the creation of new industries. It helps to reduce administrative delays, and helps companies to have the right administrative information or support for business start-ups.

**Support for investment:** In Senegal we do not have a direct subsidy from the Government to local industries. However, the following initiatives support the local pharmaceutical industries in one way or the other.

**Sovereign Strategic Investment Fund (FONSIS):** FONSIS is a sovereign investment fund that governs the operation of the largest international sovereign wealth funds of the member countries of the International Monetary Fund (IMF). The mission of FONSIS is to promote the role of the Government of Senegal, as an investor, partner and complement of the private sector, with the aim of supporting direct investments in order to accelerate the economic and social development of the country by creating wealth and jobs for present and future generations. In a globalized world where investors are looking for new emerging markets and niches with strong potential for growth and profitability, FONSIS will contribute its capital in well-structured projects alongside domestic and foreign investors. Several pharmaceutical industries have benefited from the support of FONSIS. Moreover, Investments in the pharmaceutical industry represents 25%. (Source FONSIS).

**Deposit and Consignment Fund (CDC):** Senegal's CDC, a special-status public institution created in 2006, is expected to play a major role in the Senegalese economic environment. This instrument, which positions itself as a public institutional investor, constitutes a kind of financial arm of the Government, capable of responding to economic and social issues. (Source CDC). The new manufacturing site Parenterus was supported by CDC during his creation.

**Priority Investment Guarantee Fund (FONGIP):** FONGIP has been set up to act in complementarity with other public entities in the financial ecosystem in order to mobilize public and private financial resources for MSMEs by providing greater comfort to financial institutions. It is therefore an innovative response adapted to the social demand by allowing to mitigate the risks associated with granting credit to SMEs by generally reluctant financial institutions; complement the intervention mechanism of financial institutions for MSMEs; and improve interest rates currently applied by financial institutions. (Source FONGIP)

### **2.2.3. Impact of the public procurement policies and legislations**

The public procurement policies which provide 5-15 percent preferential treatment have had little impact to promote local industrial. This is mainly due to the high cost of production locally; high cost of importation of inputs and VAT on medicines.

local production of medicines is only appropriate if the costs of raw materials and factors of production make it possible to obtain a lower cost price than comparable and imported products. For example, Ivorian manufacturers, just like most other West African countries, depend mainly on imports for their local pharmaceutical production. Almost all machinery and equipment, laboratory equipment and reagents, and raw production materials, including APIs, aluminum foil for blister packaging, other labelling materials, and excipients are imported. The local contribution to production inputs in the pharmaceutical sector is limited to certain starches and sugars. It is estimated that nearly 95% of API needs are covered by imports. The use of imports for inputs has real and significant financial implications. The time required for them to arrive from Asia means that credit terms offered by suppliers can be used before inputs even reach manufacturers' warehouses and well before they are processed into end products and distributed in the market. This has a significant consequence on working capital given the high cost of financing in the country. The government's intervention is required to address this cash flow problem in order to significantly contribute to the sustainability of local pharmaceutical companies. In addition the cost of energy and water makes increases significantly the cost of local production, making the local industries less competitive.

Although incentive policies and legislation in place for the development of the pharmaceutical industry exist and constitute important levers to promote industry in the sector, the problem of the competitiveness of these industries remains a major challenge that should be addressed to have an impact at the level of the objectives set.

According to the World Economic Forum's Global Competitiveness Index and according to its level of GDP per capita (US\$1,291 in 2013), Côte d'Ivoire is one of the countries where the cost of production factors remains crucial for competitiveness. Four key factors constitute the major obstacles to the competitiveness of local industries:

1. transport logistics
2. availability and cost of industrial land,
3. electricity,
4. and inadequate labour costs and vocational training.

#### **2.2.4. Success stories from elsewhere**

There are several success stories and lessons learned. Countries with a thriving pharmaceutical industry, such as India, China and Brazil, provide significant government support to their producers in the form of incentives and protectionist policies. Policy instruments that have been used to protect the pharmaceutical sectors in these regions include.

- 1. High customs duties on imported products:** For example, India applies customs duties on formulas up to 56% on import tariffs. Brazil 15% on formulas and China has recently imposed import tariffs of up to 37% on sulfamethoxazole (SMZ) imported from India.
- 2. Purchasing preferences:** For example, Brazil enjoys preferential prices of 25%, whereas Russia has introduced measures to ensure that 70% of the products purchased by the state are manufactured locally and this has apparently led many Indian companies to consider building manufacturing plants in Russia. South Africa benefits from preference points for local production in tenders and is currently replacing this system with another in which a percentage of designated products will be purchased only from domestic producers. Legislation on purchasing preferences is in place in a number of other countries in Africa, but it is not always implemented.

Moroccan production covers nearly 60% of the country's needs. Morocco has been able to lay the foundations of a pharmaceutical industry since the sixties. The Government has instilled a regulatory dynamic; it has introduced a very strong regulation and developed a political will to ensure therapeutic sovereignty. These are the first steps to put in place for a local industry which is a strategic sector. However, it was only the private sector that has invested in this sector. After the sixties, the Government prohibits the importation of medicines that could be manufactured in Morocco. Tablets, suppositories, syrups, drinkable ampoules, were banned on import to promote local manufacturing. This allowed the multinationals that were established in Morocco to move to the production stage. This implantation contributed to provide expertise and technology transfer. Subsequently, training was put in place with pharmacy studies in 1986-1987. (*The drug in Africa: how to better respond to the issues of accessibility and quality? April 3, 2018 French Development Agency*)

### **Comparative table of the pharmaceutical manufacturing units sector by (Africa)**

	Ghana	Macro	Tunisie	Côte d'Ivoire
Manufacturing Units	37	32	56	8
Coverage rate of needs (%)	30	70	49	6
Import taxation	Y	N	N	N
VAT for FPP	Y/N	Y	Y	Y
Tax exemption on raw materials and packaging articles	Y	N	Y	Y

These examples highlight that some emerging countries have taken active measures to protect and support their pharmaceutical industries. Manufacturers often also benefit from other types of support. In India, producers of drug formulations receive substantial government support to promote exports, including Duty-free imports of equipment and raw materials for the products to be exported. Others include ten years of tax relief if located in Special Economic Zones (SEZs); and export credits; low utility rates; working capital loans and valued depreciation allowances.

Other countries to learn from Ethiopia and Bangladesh. Ethiopia is said to be doing very well in the pharmaceutical industry as they have put in place good and working policies, which support local industries and create a conducive environment for investment. For example, if a local pharmaceutical industry wins a tender, the government provides for 30 % mobilization and a letter which can be used to get credit facility

#### **2.2.5. Other government initiatives on access and affordability for social inclusion**

All the five countries have put in place programs that support access and affordability of medicine for social inclusion. Ghana for example, has in place three programs that address the

access and affordability. These are Supply chain master plan; national medicines policy of 2018 and National Health Insurance Scheme.

1. **Supply Chain Master Plan:** In 2007, supply chain reforms were initiated in the public procurement of pharmaceuticals which resulted in the development of the Supply Chain Master Plan (SCMP)<sup>7</sup>. The SCMP amongst others recommended the implementation of a Framework Contract at the regional and facility levels for the supply of about fifty-four (54) products. The outcome of the supply chain reforms in the public health sector is to improve pharmaceutical services to the poor and vulnerable and all who patronize the public health facilities. The impact of these reforms are expected to eliminate stock-outs, reduce inventory warehousing cost, improve warehouse management and generally to improve pharmaceutical services. As part of these reforms, a Logistics Management Information System (LMIS)<sup>8</sup> has been put in place which came on live in June 2019. The expectations of this LMIS on pharmaceutical services will be transformational including cost reduction. It is expected that the supply chain reforms in the public health sector will provide a surge in the growth of LPP because the public health sector is the largest consumer of pharmaceuticals. The major local manufacturers have distribution centres in most of the regions, which therefore helps to bring their products to the doorsteps of the consumers at reasonable prices.
2. **National Medicines Policy 2018 and Gazette Notice LI 2255:** In 2018, GoG launched the third edition of the National Medicines Policy (NMP). Under the NMP<sup>9</sup>, it is the intention of GoG to provide UHC for all residents in Ghana and ensure financial access to all, especially at the point of use. The NMP identified too many taxes and tariffs on medicines and recommended the setting up of the National Medicine Price Committee (NMPC), framework contracting, competitive procurements, VAT exemptions on Finished Pharmaceutical Products (FPP) and Active Pharmaceutical Ingredients (APIs). These policies it is hoped will make medicines more financially accessible. In August 2017, through a Gazette Notice Volume. 2017 No 74 (LI 2255<sup>10</sup>), the GoG removed VAT from some FPP and APIs and also ring-fenced some forty-nine (49) products per EI 181 to restrict them to only local manufacturing with the hope that this policy intervention will bring down the prices of those products.
3. **Ghana National Health Insurance Scheme:** Ghana has in place a National Health Insurance Schemes NHIS<sup>11</sup> to ensure social inclusion of all residents who patronise public health services. The National Health Insurance Scheme (NHIS) is a social intervention program introduced by government to provide financial access to quality health care for residents in Ghana. The NHIS is largely funded by the National Health Insurance Levy (NHIL), which is 2.5% levy on goods and services collected under the Value Added Tax (VAT); 2.5 percentage points of Social Security and National Insurance Trust (SSNIT) contributions per month; return on National Health Insurance Fund (NHIF) investments; and premium paid by informal sector subscribers. The NHIS is a health insurance scheme for which all residents are mandated to subscribe to pay an annual premium. Enrolment into the NHIS has been increasing year on year. Analysis of NHIS subscribers by category shows that the major beneficiaries are the disadvantaged members of the society, namely the informal sector (34 %) and children below 18 years (47 %). NHIS is a major player in the Pharmaceutical sector and a determinant on the

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<sup>7</sup> <http://iaphl.org/wp-content/uploads/2016/05/GhanaSCM-2013.pdf>

<sup>8</sup> [www.moh.gov.gh/wp-content/uploads/2018](http://www.moh.gov.gh/wp-content/uploads/2018)

<sup>9</sup> <http://www.moh.gov.gh/moh-launches-revised-national-medicines-policy/>

<sup>10</sup> <https://ghalii.org/gh/gazette/GHGaz/2017/2017/74/01-august-2017>

<sup>11</sup> <http://www.nhis.gov.gh/files/ACT852.pdf>

promotion of LPP. It is estimated that more than 50% of pharmaceuticals to consumers are financed by NHIS. LI 2255, which exempts APIs from VAT payments for manufacturers, is a way to reduce the cost of production inputs to make pharmaceuticals more affordable. Due to the introduction of this policy, the NHIS is in discussion with the stakeholders to reduce their published prices by 30%.

In Nigeria, the public sector contribution to healthcare still remains low though it has been on the rise since the introduction of the subsidized National Health Insurance Scheme (NHIS) in 2007. The intervention of Public Bureau for Public Procurement has facilitated bulk purchase of medicines and other products, lowering the cost of medicines for NHIS. However, many Nigerians are yet to be enrolled into NHIS, only the Federal public servants and their families making up a large share of subscribers to the scheme. The scheme was officially launched in 2005, with a presidential directive that there should be universal coverage by 2015. The scheme was to oblige all public and private sector employees to contribute 15 percent of their salary towards the Health Maintenance Organization (HMO), which will arrange for the necessary healthcare. NHIS is yet to be extended to the informal sector in Nigeria. The Federal Government is expected to procure drugs for the Federal University Teaching Hospitals and Federal Medical Centres; who are at the tertiary levels whereas the state and local governments cater for the healthcare in their subunits respectively. This fragmentation of drug procurement also affects the affordability, quality and quantity of drugs dispensed at each level of healthcare in Nigeria. State and cooperative organizations health insurance schemes are being established in different locations in Nigeria to bridge the coverage gaps left by the NHIS. Nineteen states are at various stages of their implementation of health insurance schemes (PwC, 2019). The sub-national schemes just like NHIS establish a government agency for the implementation and management of the scheme. The State Governments commit funds to the scheme to offer premiums for the poor and vulnerable in their various states.

In WAEMU (Côte d'Ivoire, Togo, Senegal, Mali, Benin, Burkina Faso, Niger and Guinea Bissau) imported medicines are classified at zero rate, granting them exemption from customs duties and VAT on imports. In return for this privilege, the final consumer of the medicinal product does not pay VAT. No exceptional measures are applied to protect local production and no VAT credit can be granted to manufacturers. This measure has enhanced affordability of medicines by the final consumers.

### **Common external tariff ECOWAS/Evolution of the taxation system (Within the framework of the common external tariff TEC- ECOWAS and from January 2015)**

The ECOWAS Customs Union Agreement with free movement of goods and persons and the Common External Tariff (CET) entered into force in January 2015. Two trends are emerging, with on the one hand, countries that have a pharmaceutical industry to protect and produce more than 30% of their medicines, namely Nigeria and Ghana. On the other hand, the WAEMU countries, which import more than 90% of their medicines, with Côte d'Ivoire as the lead country.

The table below illustrates the importance of these positions and clearly shows that the two countries have protected themselves with customs duties and taxes.

Table: Customs tariff applicable before the CET (ECOWAS)

Local industries	customs duty on inputs	customs duty on FPP	Pharmaceutical market* (million \$us)	Number of Local Industry	Market Share	Existence of deferral lists
Ghana	10%	10%	300	37+	35%	Y
Nigeria	5%	20%	2500	158+	45%	Y
Côte d'Ivoire	0%	0%	200	8	6%	N
WAEMU	0%	0%	-		-	N

The CET Monitoring Committee adopted the WAEMU position by applying the zero tariff band to the chapters on inputs and medicines (HS Chapters 28-29 and 30 /Harmonized Commodity Description and Coding System of the World Customs Organization (WCO) adopted by the Community/).In addition, the TEC Monitoring Committee authorizes Ghana and Nigeria to apply import taxes on medicines in order to protect their pharmaceutical industries during five (5) year transition period: these taxes are:

1. The Degressive Protection Tax (DPT)
2. The Conjunctural Import Tax (CIT)
3. The ECOWAS Compensatory Customs Tax (ECCT)
4. These measures have been applicable since 1 January 2015

### 2.2.6. Impact of donor subsidies on local industries

Donor subsidies negatively impact local manufacturing:

1. To participate in donor funded procurement requires that the product must be WHO prequalified. Out of the 172+ manufacturing companies, only 6 have products that are prequalified.

2. Where the supply a product which is manufactured locally, this distorts the market.

This AMFm policy brought a crushing blow to some of the local PMs because they had invested heavily to produce the antimalaria ACT when this subsidised ACT came in and they could not compete. The case of Amponsah Efah Pharmaceuticals (AEP) can illustrate the issue. In 2010, GoG implemented the AMFm policy to improve the access of antimalarias at affordable prices. The policy involved the introduction of ACTs at predetermined prices to be distributed by selected companies for a commission. At the time, AEP has embarked upon upgrades of equipment and machinery to transition from chloroquine production to ACTs. The policy made AEP products uncompetitive and created huge cash flow challenges for the company. The policy has elapsed and AEP is back producing the ACTs eg. Luzatil (artemether 20/Lumefantrine 120).

3. Another case (Danadams)

On the orthodox side, Danadams Pharmaceuticals is the only company making ARVs for distribution in Ghana and elsewhere. The products are not WHO PQ so they do not get

patronage from the MOH to be procured because MOH funding comes from the DPs. The MOH is the major purchaser of ARVs. Table 6 below gives an indication of how much is spent by the DPs to provide subsidised medicines and it is huge, in hundreds of millions of USD.

Somewhere along the line, Danadams Pharmaceuticals applied for the WHO Expression Of Interest (EOI) for their ARVs to be inspected. The WHO officials visited Danadams Pharmaceuticals as follow-up and made some recommendations to the latter to be addressed but the latter did not follow them through. So Danadams Pharmaceuticals' ARVs are not WHO PQ and therefore cannot take part in the donor-funded procurement processes.

Some of the ARVs produced at Danadams are Bivek-E Combipack (Lamivudine, Zidovudine, Efavirenz), Lamdek-100 tablets (Lamivudine). They have Danoxine (Pyrimethamine/Sulphadoxine) tablets and Danmethar (Artemether/Lumefantrine) tablets as antimalaria products.

WAHO tried to show support for Danadams by buying their ARVs in 2012 for distribution in some ECOWAS countries. But after that initial order, nothing has been bought again. The Global Fund (GF) usually funds the purchase of ARVs. At the time of purchase from Danadams, GF was in default at the time but once they got their act together all companies not PQ were removed including Danadams.

4. The interviews conducted allowed to conclude that the major part of the subsidy programs' medications is either not locally produced or if they are locally manufactured does not fully comply with all the criteria required to take advantage of these programs. Indeed, the drugs that benefit from the various subsidy programs (Roll back Malaria, IMF, WHO ...) must most often meet the WHO Prequalification. Today the only known prequalified drug in Senegal is the yellow fever vaccine manufactured by the Pasteur Institute for UNICEF.
5. Positive aspects please input (UNICEF and UNFPA)

There are other advance institutions which offer postgraduate training and therefore are involved in TT e.g. USP Ghana. In 2019, USAID which was so concerned about umbilical cord disinfection to reduce child mortality organized the PM and FDA to transfer the formulation and production of chlorhexidine hydrochloride used to disinfect the umbilical cord after childbirth. In that same vein, United Nations International Children's Emergency Fund (UNICEF), through south-south cooperation brought some officials from Thailand to transfer the production of zinc tablets to the local PM to be used as a co-therapy with ORS to manage diarrhoea in children.

### **2.2.7. Recommendations**

This study has made the following recommendations:

To effectively support the poor and vulnerable to access medicines, public policy must be used to do that because over 50% of medicines in Ghana are financed through the NHIS; the government is the biggest purchaser of medicines in the country. It is inconceivable to think that the private sector will do things to lower medicine prices.

The pharmaceutical supply chain must be secured at each step of the way as a first step to make medicines affordable. The supply chain should be such that one cannot just enter the chain at any point to make supplies as pertains now especially in the public sector. The weakness of the supply chain contributes to high medicine prices because if the chain is robust and strong all entries will conform to the standards including prices; information technology can be used to do that.

The PPA Law allows procurements at three levels (national, regional, facility) and the devolution of this important function weakens the supply chain for some miscreants to infiltrate with spurious and poor-quality products with questionable prices. The procurement process must be centralised to a large extent to protect prices and quality of medicines. The proposed SCMP envisages the setup of a supply chain unit which will be solely responsible for some basket of products within the chain. The proposed unit is going to ride on the back of IT to give transparency, visibility and traceability tools for monitoring. In Turkey<sup>12</sup>, the total supply chain in both the public and private sector are linked and controlled from a central point for proper monitoring to address any significant deviations and adherence to policies. Any sales, whether public or private are all recorded.

The supply chain must ride on the back of a LMIS to provide transparency, visibility, accountability and monitoring tools to ensure adherence to policies. Ineffective implementation of public policy must be strengthened to protect prices of medicines.

In Ethiopia<sup>13</sup>, successful bidders of public medicine tenders are paid 30% upfront to facilitate their performance. The contractors are also able to use the successful bids as bankable instruments for banks assistance to be able to deliver on time in order not to disrupt the supply chain and cause stock outs. GoG, through the NHIS, should consider reimbursing medicines supplied on time because their delays to pay leads to price gouging by medicine suppliers and co-payments by consumers.

The migration of companies along the GMP Roadmap must be aligned to public procurement of medicines. That is a company's current GMP classification should determine which products they can bid for in a public procurement process of medicines. This is because the more a company deviates from the WHO GMP standards, the more risky the products it produces. Therefore only companies classified as "acceptable" should be allowed to bid for risky products like parenteral. It is believed this can be the motivational factor needed to spur the industry to upgrade to the WHO GMP standards.

It has been noted that local manufacturers have not sufficient capacity to outperform during international tenders despite the 15% national preference and even during national tender. To succeed, local industries should regroup to submit together. Manufacturers will be able to divide the products portfolio so that each manufacturer has its own list of products for submission.

They could be able to make partnerships with Indian industries to receive bulk products and make secondary packaging. This will help to have at least the finish goods packaged in Senegal and to increase their portfolio during the bidding and to meet PNA needs.

To face products importation, It would also be preferable for African countries to create regional markets and avoid having units that manufacture the same thing. It is important to have centralizations, poles of excellence. This would limit costs for economies of scale and compete with the Indian model.

African countries lack the industrial capacity to face Indian competition should think of targeting the ECOWAS market which is the 17<sup>th</sup> largest economy in the world and have 385 potential consumers with the recent adhesion of Morocco (Moroccan Media 360).

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<sup>12</sup> PWC, 2014, Review of the Pharmaceutical System of Turkey.

<sup>13</sup> IMC Worldwide, 2018, Preparatory Analysis and Investment Packaging for Ghana Pharmaceutical Production Sector



To facilitate this, there is a need for regulatory harmonization and therefore a reduction in the number of regulatory registrations.

The ongoing ECOWAS program «Regulatory Capacity Building Program and Regional Harmonization Process in the ECOWAS region », will be very helpful to succeed to this ECOWAS market.

The subsidy programs could have been a great way for industries to grow because of the large amounts allocated. So, it is important that medicines that fall under health subsidies, including essential drugs, to be manufactured locally and pre-qualified WHO to benefit from international subsidy programs. Once manufacturers have the capacity to produce essential medicines, the authorities could implement a patient reimbursement policy that can only concern locally manufactured products.

## **2.3. World Health Organization Certification**

### **2.3.1. Ghana**

Although there are various GMP certification schemes, the Ghana regulator (GFDA) uses the WHO GMP standards so that was what was adopted.

#### **1. Why the need for WHO GMP Certification.**

- a. the local companies cannot participate in the donor segments of the pharmaceutical market where the big ticket tenders are offered
- b. the pharmaceutical companies are producing risky products
- c. the quality of products keeps investors away from investing in the sector

#### **2. What was done?**

- a. A WHO GMP consultant was recruited by UNIDO in conjunction with the GFDA.
- b. A WHO GMP assessment was carried out on representative companies in the sector by the WHO GMP consultant. The report recommended that all the companies should build new premises because their current premises will be too expensive for a brownfield investment to make the standard and that a Greenfield investment will be better. A new premise was estimated at the time to cost 10 million USD.
- c. The industry was briefed on the WHO GMP standards to demystify the WHO GMP standards
- d. The industry wide assessment report was used to draw a stepwise WHO GMP Roadmap for the sector
- e. The pharmaceutical companies were assessed individually to identify their gaps from the standards.
- f. The gaps identified for each company was used to draw a CAPA plan for that company and signed off by the company's top management
- g. The CAPA plans were lodged with the regulator to be used to assess the companies annually.
- h. The program ends in 2020 by which time all the companies should be WHO GMP compliant. But there has been complains about inadequate funds by companies to implement their CAPAs. GoG made 20million USD available to two companies in 2015 to build new premises which went to two companies (Ernest Chemist and Entrance Pharmaceuticals). Currently the 5 companies are building new premises. They are: Ernest, Pharmanova, Letap, Eskay and Entrance Pharmaceuticals.

- i. GoG is collaborating with GIZ to build a BE&BP Centre to support drug evaluation studies
- j. WAHO is also pursuing a regional WHO GMP Roadmap for the region which may be a basis for a WAHO Certification

### **Ghana GMP Roadmap**

WHO certification is critical to enable LPP to access the donor sponsored medical supply. There are many GMP standards supervised by different organizations like WHO GMP Scheme, PICS and USP but Ghana subscribes to the WHO GMP standard which is enforced by the GFDA, the pharmaceutical manufacturing regulator. Before now, the GFDA used to categorize the companies based on their WHO GMP compliance as A, B, C, D, E and sub. But that system has been abandoned because the GFDA believe it is not very rigid enough. Now the companies are categorized<sup>14</sup> after inspection as acceptable, improve or inadequate.

Where: Acceptable:” if no (i.e. “minor”) deficiencies were observed in areas related to a specific key quality element. Improve: “requires improvement” (short: “improve”) if only few (< 5) “major” deficiencies were observed in areas related to a specific key quality element. Inadequate:” if at least one “critical” and/ or a considerable number (> 5) of “major” deficiencies were observed in areas related to a specific key quality element, or if the entire quality element was not available at a company.

There is a program being pursued by the GFDA with the companies to ensure that the latter are all WHO GMP compliant by 2020: that is the Ghana GMP Roadmap, 2015-20. To complement the roadmap, WHO has been providing training and arranges for attachment for GFDA officials in reputable institutions, to bring them up to speed with the WHO GMP regulations to assist the roadmap implementation.

Ghana benefits greatly from DPs, for the procurement of medicines for malaria, TB, HIV/AIDS, and reproductive health. However the procurement processes for these medicines are always beyond the reach of the local pharmaceutical companies because their products are not WHO GMP Prequalified. Thus the donor supported segment of the Ghana pharmaceutical market has never included the local pharmaceutical companies. It was based on this observation that UNIDO stepped in to help local pharmaceutical companies demystify WHO GMP standards<sup>15</sup> due to the vast array of requirements needed to comply so that they can upgrade their products to WHO GMP Prequalified status to meet the procurement criteria.

In 2015, UNIDO recruited a GMP consultant to assist the companies to be WHO GMP compliant. An initial assessment was done using representative companies from categories A, B, C, D, and sub. The assessment results were used to draw a Stepwise Ghana GMP Roadmap 2015-20.

As a follow up to the GMP Roadmap, the companies were individually assessed to find their gaps from the WHO GMP standards. The report from each company was used by the companies with the guidance of the GMP Consultants to draw CAPAs for each company. The CAPAs show when each gap will be addressed and were signed off by top management.

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<sup>14</sup> Ghana GMP Roadmap 2015

<sup>15</sup> Quality assurance of pharmaceuticals. A compendium of guidelines and related materials. Volume 2, 2nd updated edition. Good manufacturing practices and inspection. World Health Organization, Geneva, 2007”, as subsequently updated through the WHO Technical Report Series (TRS), especially TRS 961, Annex 3 and TRS 986, Annex 2.

The CAPAs have been deposited at the GFDA which the latter is using to inspect the companies annually to see their conformance to their own plans to address the WHO GMP gaps. Should the program go as planned most of the companies are expected to be WHO GMP compliant within five years by 2020.

Simultaneously, WAHO also launch a regional ECOWAS GMP Roadmap in February 2017 in Accra. The plan was to assist the companies in each ECOWAS country to be WHO GMP compliant within five years.

The PM are very slow to follow the WHO GMP Roadmap and hence their own CAPAs to bridge the gaps identified because they complain of unavailability of a long term or development financing needed for the upgrades.

### **Recommendations and way forward**

This study has made the following recommendations:

1. To effectively support the poor and vulnerable to access medicines, public policy must be used to do that because over 50% of medicines in Ghana are financed through the NHIS; the government is the biggest purchaser of medicines in the country. It is inconceivable to think that the private sector will do things to lower medicine prices.
2. The pharmaceutical supply chain must be secured at each step of the way as a first step to make medicines affordable. The supply chain should be such that one cannot just enter the chain at any point to make supplies as pertains now especially in the public sector. The weakness of the supply chain contributes to high medicine prices because if the chain is robust and strong all entries will conform to the standards including prices; information technology can be used to do that.
3. The PPA Law allows procurements at three levels (national, regional, facility) and the devolution of this important function weakens the supply chain for some miscreants to infiltrate with spurious and poor-quality products with questionable prices. The procurement process must be centralised to a large extent to protect prices and quality of medicines. The proposed SCMP envisages the setup of a supply chain unit which will be solely responsible for some basket of products within the chain. The proposed unit is going to ride on the back of IT to give transparency, visibility and traceability tools for monitoring. In Turkey<sup>16</sup>, the total supply chain in both the public and private sector are linked and controlled from a central point for proper monitoring to address any significant deviations and adherence to policies. Any sales, whether public or private are all recorded.
4. The supply chain must ride on the back of a LMIS to provide transparency, visibility, accountability and monitoring tools to ensure adherence to policies. Ineffective implementation of public policy must be strengthened to protect prices of medicines.
5. In Ethiopia<sup>17</sup>, successful bidders of public medicine tenders are paid 30% upfront to facilitate their performance. The contractors are also able to use the successful bids as bankable instruments for banks assistance to be able to deliver on time in order not to

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<sup>16</sup> PWC, 2014, Review of the Pharmaceutical System of Turkey.

<sup>17</sup> IMC Worldwide, 2018, Preparatory Analysis and Investment Packaging for Ghana Pharmaceutical Production Sector

disrupt the supply chain and cause stock outs. GoG, through the NHIS, should consider reimbursing medicines supplied on time because their delays to pay leads to price gouging by medicine suppliers and co-payments by consumers.

6. The migration of companies along the GMP Roadmap must be aligned to public procurement of medicines. That is a company's current GMP classification should determine which products they can bid for in a public procurement process of medicines. This is because the more a company deviates from the WHO GMP standards, the more risky the products it produces. Therefore only companies classified as "acceptable" should be allowed to bid for risky products like parenteral. It is believed this can be the motivational factor needed to spur the industry to upgrade to the WHO GMP standards.

### **2.3.2. Côte d'Ivoire**

Status of Pharmaceutical Companies in Cote D'Ivoire on WHO certifications:

Support provided by government and other organizations

Although pharmaceutical production has existed in some ECOWAS member countries for several years, none of the pharmaceutical manufacturing companies has so far been able to obtain WHO prequalification or Good Manufacturing Practices (GMP) certification for a given product. This is an essential condition for success, as antiretroviral drugs, antimalarial drugs and anti-tuberculosis drugs are mainly purchased by donors who require that the companies that produce the products they purchase have international certification. However, local pharmaceutical industries from Cote d'Ivoire apply the Good Manufacturing Practice Guidelines for Pharmaceuticals for Human Use in force in the WAEMU region. This WAEMU GMP was drafted in 2008 and has been in force since 2010 in Côte d'Ivoire. These GMPs are almost identical to the 2009 WHO GMP

The specificity of WAEMU GMP concerns the packaging of pharmaceutical products (chapter 5) In Côte d'Ivoire, the implementation of the WAEMU GMP was carried out in successive stages:

1. Training of IPL pharmaceutical personnel in GMP: 2013
2. GMP training and GMP inspection of DPML pharmacists: 2010(Dakar), 2013
3. Development of a UEMOA and/or WHO GMP inspection grid
4. Application of the inspection grid to Local Manufacturing and external Pharmaceutical Industries
5. 1 Scheduled and 1 unannounced inspection of IPLs per year
6. Audit of any new local manufacturing wishing to obtain Cote d'Ivoire's Market Authorization (decree 94)
7. Drafting of inspection reports with recommendations and corrective measures
8. Establishment of a CBPF-CI that allows IPLs to export their products.
9. Qualification type inspection + validation before any opening of IPL or extension of activity

### **Recommendations**

To strengthen the implementation of WAEMU GMP in Cote d'Ivoire, it would be necessary to:

1. Transpose WAEMU GMPs into Ivorian law
2. Develop a pharmaceutical inspection manual
3. Create a body of sworn pharmaceutical inspectors

4. Strengthen the human, institutional and operational capacities of the DPML-AIRP
5. Carry out an external audit of IPLs with a view to developing a roadmap for their upgrading

### **The GMP Roadmap**

In Accra, Ghana, March 1st, 2017 ' Under the leadership of the Economic Community of West Africa States (ECOWAS), the West African Health Organization (WAHO) in collaboration with United Nation Industrial Development Organization (UNIDO), was organized the regional kick-off workshop on the ECOWAS Pharmaceutical Good Manufacturing Practice (GMP) Roadmap initiative.

The workshop was held in Accra from February 28th to March 1st 2017 and in attendance were representatives from the National Medicines Regulatory Authorities (NMRAs) from 14 ECOWAS Member States, (Benin, Togo, Niger, Mali, Ghana, Nigeria, Cape Verde, Guinea, Guinea Bissau, Côte d'Ivoire, Sierra Leone, Burkina Faso, Senegal and The Gambia), key stakeholders and partners such as WHO, USAID, Africa Union/NEPAD, IFPMA, USP-CePAT, West African Pharmaceutical Manufacturers Association (WAPMA) and pharmaceutical experts.

The objective of the initiative is to establish a strong pharmaceutical manufacturing industry in the ECOWAS region by bringing pharmaceutical manufacturers up to WHO GMP and other international standards in a step-by-step individualized improvement program to meet the goals of access to quality safe and affordable medicines. To effectively achieve this objective a fruitful agreement between ECOWAS/WAHO and UNIDO has been established to develop the GMP roadmap. The span of the project would last for 18 months.

The vision of the project is to ensure that all pharmaceutical manufacturing in ECOWAS meets international GMP standard to improve sustainable and affordable access to safe and effective essential medicines and contribute to economic growth. The ECOWAS region with a population of more than 300 million inhabitants is currently reliant on imports for roughly 80% of essential medicines.

The workshop provided the opportunity to introduce the project to stakeholders from across the region and partners to discuss and comment on the proposed approach. The participants recognized the importance of Pharmaceutical Good Manufacturing Practice (GMP) Roadmap initiative for the West Africa region due to the challenges faced by the countries to access to quality medicines. They called for support and ownership of the project by all stakeholders and recommended:

The objectives of the ECOWAS pharmaceutical Good Manufacturing Practices roadmap initiative are to:

1. support the West African Pharmaceutical Manufacturers Association to achieve international standards;
2. develop structures for the establishment of national level Good Manufacturing Practices (GMP) roadmap initiatives;
3. develop a regional framework of reference for the pursuit of associated approaches at country level;

4. address the unequal distribution of the manufacturing facilities in ECOWAS which implies that different policy measures are required from country to country;
5. serve as standards for monitoring; the road map then becomes a stringent strategic tool by which the national regulators would apply to ensure that the industries meet stipulated standards;
6. make available improved quality medicines from local manufacturers in close proximity to reduce the incidence of Substandard, Spurious, Falsely labelled, Falsified and Counterfeit (SSFFC) medical products in the region;
7. strengthen regulatory capacity in all countries for inspection of manufacturing facilities;
8. guide the set-up of new facilities that are GMP compliant in countries that wish to establish or expand their pharmaceutical manufacturing sector;
9. promote intra-regional trade and improve the supply chain management for a competitive and efficient regional pharmaceutical manufacturing to ensure the supply of essential medicines produced in the region expands from 30% to 60% by the year 2020

### **2.3.3. Nigeria**

In 2006, in collaboration with the 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).

As a result of policy, legal and regulatory initiatives, the capacity utilization of installed facilities in Nigeria 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.

The harmonization of medicine registration within ECOWAS and WHO certification and prequalification of some Nigerian pharmaceutical manufacturers are some of the major milestones, when reached, will have a very positive impact on the pharmaceutical business in Nigeria over the next 10 years.

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.

The WHO Certification Scheme for finished pharmaceutical products is an international voluntary agreement to provide assurance to countries participating in the Scheme, about the quality of pharmaceutical products moving in international commerce (World Health Assembly resolution WHA22.50(1969), World Health Assembly resolution WHA28.65 (1975), World

Health Assembly resolution WHA41.18 (1988), World Health Assembly resolution - WHA45.29 (1992), World Health Assembly resolution WHA50.3 (1997).

#### **What has been done?**

1. Upgrade of labs with support of DFID in 2006, which led to reduction of counterfeits from 40% to 17%
2. In Nigeria WHO has worked with eleven pharmaceutical firms to achieve international good manufacturing practices (GMP) standards and to have products prequalified by WHO (AUC-UNIDO, 2012). Available records show that only four drug manufacturing companies have been prequalified by WHO. The companies are: Swiss Pharma Nigeria Limited, Evans Pharmaceutical Ltd, May & Baker Pharmaceutical Ltd and Chi Pharmaceutical Ltd. (Chukwu, 2014).

#### **2.3.4. Togo**

Status of WHO certification and effort provided by the government

None of the 4 local manufacturers has obtained the WHO certification. Government effort consists of 2 parts: 1) the appointment of an expert committee to assist the companies, 2) the conformance to UNIDO and ECOWAS GMP Roadmap initiative.

The roles of WAHO, UNIDO and ECOWAS were described previously. The GMP initiative consists of 3 phases, and the first 2 are already completed. The phases are the following:

- Phase 1: introduction of key actors to the project and national technical groups' creation;
- Phase 2: technical assessment of local manufacturers leading to the development roadmap;
- Phase 3: (upcoming): manufacturers and regulators trainings.

#### **2.3.5. Senegal**

In Senegal, the only known prequalified drugs in Senegal are the yellow fever vaccine manufactured by the Pasteur Institute for UNICEF.

However The DPM grants GMP certificate to local manufacturers by using WHO standards.

The GMP roadmap which had already started in Senegal is a good initiative for local pharmaceutical manufacturing industry to comply with internationally recognized GMP standards.

It is also important to note that upgrading manufacturing standards is very complex because that requires not only knowledge and technical expertise, but also the combination of many other factors such as environment that encourages investments, technologies and human resources. Manufacturers need support and advice to develop their business and time to implement the resulting upgrade plans. This work has been already started in some countries like in Senegal where 2 pharmaceutical companies Medis and ValdAfrique have been evaluated as drug manufacturing. (*Source DPM*)

### **2.4. Human Resource Development and LPP**

#### **2.4.1. Human resources situation**

The potentials of the pharmaceutical manufacturing sector can only be realised with a strong human capital base. The current HR situation of the LPPs in west Africa is very precarious.

There is a mixture of small proportion of local and plenty Indian technologists manning the

sector. The industrial pharmacists in the pharmaceutical manufacturing sector are mostly sourced from India under individual efforts by the companies and their Indian partners. It happens that the young pharmacists who enter the sector do not stay long enough because they do not find it attractive enough. In Ghana for example, there are about fifty (50)<sup>18</sup> local pharmacists in the industries which makes about 1.9% of total pharmacists registered with the PSGH of about two thousand six hundred and eighty-two (2682)<sup>19</sup>.

Another great challenge facing the availability of skilled personnel in the pharmaceutical industry is the problem of brain-drain. A recent survey on the financial cost of medical personnel, pharmacists inclusive, emigrating from sub-Saharan Africa revealed that a large number of medical personnel in sub-Saharan countries were, in fact, working in the United Kingdom, Australia, Canada and the United States. The actual numbers are estimated by various parties to be in the thousands and account for an estimated loss of return on investment for these West African countries of almost US\$2.17bn while the net gain for the developed countries to which they emigrated was estimated at US\$4.55bn (Mills *et al.*, 2011).

In Senegal, however Pharmacists do not have a strong representation in pharmaceutical industries; we can note a maximum ratio of 22% of the total number of senior staff. (Source Local industries).

In Togo, all the technical positions are held by Indians or Chinese while Togolese hold the position of superintendent.

Table 1 shows the situation of human resources in manufacturers in Togo.

**Table:** Human resource situation

<b>Manufacturer</b>	<b>Shareholder</b>	<b>Strategic Technical Positions</b>	<b>Strategy</b>
GGIA	Togolese	Togolese	Local production
DO PHARMA	Togolese	Indians	Local production
SPRUKFIELD	Indians	Indians	Local production
TONGMEI	Chinese	Chinese	Reconditioning

The major causes of human resource for health (HRH) challenge in these countries of study include

1. lack of HRH policy and planning,
2. inadequate remuneration and incentive mechanisms,
3. Absolute shortages of pharmaceutical and other essential professionals,

<sup>18</sup>Dr Sam Gaizer, Chairman IPA

<sup>19</sup> PSGH 2019 AGM Magazine



4. shortage of training and skills development institutions,
5. Poor HR management (inflexible recruitment procedures, lack of career structure and incentives),
6. Lack of action-oriented research into HR interventions
7. Internal and external migration of professionals (the brain drain) and
8. The HIV/Aids epidemic.

Human resources for health (HRH) is a crucial pillar for global health security and has been included in the Sustainable Development Goals (SDG). According to the WHO's Global Strategy on HRH (Workforce 2030), 2.5 health workers per 10,000 inhabitants are needed to achieve the Millennium Development Goals. This figure is more than ten times the health workforce (HWF) currently employed by the health systems in the four countries. The problem of HWF shortage in the four countries is further exacerbated by inequitable spatial distribution, resulting in severe urban–rural imbalances. The shortage is most critical in the manufacturing sector, which requires personnel with skills in pharmaceutical product identification, formulation, production and clinical trials.

It is noted that, like in many African countries, the four countries face workforce crisis in their health systems including doctors, nurses, pharmacists and pharmacy technicians, laboratory technicians, community health workers and midwives. There was no information on the pharmaceutical manufacturing sector workforce in the four countries in the study. This may be explained by the very low-key activity in the local pharmaceutical production industry.

#### **2.4.2. Role of Universities and Training Institutions**

##### **Ghana**

In **Ghana**, universities such as KNUST, UG, UDS, CU, Ho, and Entrance Pharmaceuticals are involved with the training of pharmacists, engineers and other scientists for the sector. There are also some other training institutions which train technicians for the sector as well, including some of the polytechnics which are now universities as well. It is only KNUST that train students at both undergraduate and postgraduate levels in Pharmaceutical Technology. KNUST offers an MSc Pharm Tech program, which is designed with industry in mind. It is expected that the industry will sponsor their employees for this program. In 2019, the content of the Pharmaceutical Technology Program<sup>20</sup> was reviewed and submitted to the NAB for accreditation.

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<sup>20</sup> Prof. Marcel Bayor, Head, Pharmaceutics, KNUST

The following preliminary recommendations are proposed for human research development for LLP:

1. The transformative agenda that is envisaged for pharmaceutical manufacturing must ensure that there is a pool of pharmacy technologists that can be tapped from to sustain and drive the sector. In Nigeria and India, National Institute for Pharmaceutical Research and Development (NIPRD)<sup>21</sup> and National Institute for Pharmaceutical Education and Research (NIPER) perform that role to ensure a continuous training and development of technologists to feed the sector. These are public-funded institutions which churn out most of the categories of personnel needed for the sector especially in the case of NIPER. Ghana and ECOWAS must copy the NIPER establishment to satisfy the supply side of the human resource requirements.
2. Training of technologists should be modelled on the 70:20:10<sup>22</sup> principles for Learning and Development by Morgan McCall. That is 70% of the training time for challenging assignments on the job; 20% for developmental relations like conferences/workshops and other networking arrangements; 10% for course and training in the classroom or other similar environments.
3. Hands-on training can be offered by existing companies for post-graduates as part of the training but this comes at a cost to the companies. In that regard, some kind of incentive may be best offered to the companies so that they can open their doors to the trainees. These incentives could be tax exemptions on expenditures used for students training. Importantly, the numerous pharmacy tertiary training schools should be assisted to have their own in-house mini manufacturing units for hands-on teaching lessons.
4. NIPER (India) has program for all human capital developments related to pharmaceutical manufacturing which is publicly funded. The products from this institute feed the companies with the requisite human capital. This experience can be adopted in Ghana. The Ghana College of Pharmacists is a public funded institution to train specialist pharmacists in Drug Production amongst others. This college is in a position to marshal all manner of people from far and wide to help train drug production experts even if the resource persons are not part of the college faculties. The college should be involved in the conversation for the development of the human resource potentials for the manufacturing sector so that it can plan to fill the gaps.

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<sup>21</sup> [https://www.niprd.net/?page\\_id=211](https://www.niprd.net/?page_id=211)

<sup>22</sup> <https://www.growthengineering.co.uk/70-20-10-model/>

5. Additionally, the managers at the micro (firms) level of the sector must make conditions attractive for young graduates to join. In the past couple of years most young graduates who join the industries do not stay long due to poor working conditions and this should be given some attention to help retain the new recruits.

Ghanaians in the diaspora should be considered a vital investment resource to warrant priority attention from GoG because evidence shows that remittances from Ghanaians in the diaspora are substantial<sup>23</sup>; billions of USD since 2012.

### **Nigeria**

In **Nigeria**, Pharmacy as a profession has evolved much faster over the last two decades than previously experienced. In 1989, the National University Commission (NUC) in Nigeria approved minimum standards of five-year training curriculum for Pharmacy. However, the six to seven years Pharm Doctor Program remains the current global best standard for sustainable training of people who will handle a critical aspect of a nation's health care delivery system. The pharmacy curriculum has been expanded to meet up with the challenges from the clinical and industrial angles. One of such moves is the introduction of the Doctor of Pharmacy Program (Pharm.D) initiated by the University of Benin, Benin City, Nigeria.

### **Cote d'Ivoire**

In **Côte d'Ivoire** since its creation in 1977, the Pharmaceutical and Biological Sciences Faculty has trained more than 1500 pharmacists. The Biological and Pharmaceutical Sciences Faculty of Côte d'Ivoire is the only school officially dedicated to the training of pharmacists. It does not have a highly specialized training program for the pharmaceutical industry. Pharmacists trained in are not specialized in the Pharmaceutical Industry. The sector is full of pharmacists with notions in pharmaceutical manufacturing acquired during their university training but are not specialized to lead and operate a pharmaceutical industry.

To solve this issue, we recommend that Universities must adapt their curricula to modern trends in the evolution of the pharmaceutical industry. Areas such as regulation, pharmaceutical technology, drug formulation and development, and clinical studies need to be strengthened.

Secondly the regional harmonization of the curricula of training for first, second and third cycles of pharmacy studies would lead to the production of a qualified workforce and the improvement of the practice of pharmacy.

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<sup>23</sup> <https://www.theglobaleconomy.com/Ghana/Remittances/>

The Postgraduate College of Pharmacists of West Africa (in WAPCP) could play a key role in training pharmacists and pharmacy researchers who can possess the required expertise and meet the demand of the pharmaceutical market in the ECOWAS region.

### **Senegal**

In **Senegal** we have a Faculty of Pharmacy located at Dakar University Cheikh Anta Diop (UCAD). A second faculty is being built at Thies in western Senegal.

We have mainly 4 training and specializations in the Faculty of Pharmacy and among them a Master's Degree in Industrial Drug Development. However those trainings turned out to be more theoretical than practical.

Senegal has several advantages, particularly at the geostrategic and political levels. Indeed it is located in the far west of the African continent and is limited to the west by the 700km Atlantic Ocean, privileged gateway to Africa, facilitation of technology transfer. So Senegal constitutes an open door to the rest of the continent with modern and structuring infrastructure, political stability, and good institutional governance. Technology transfer, training and human resources mobility can be important milestones for helping other countries to develop their industries.

It would be important to strengthen the partnership with the University to improve the theoretical and practical training of pharmacists. The Government should offer merit scholarships to support pharmacists in their postgraduate courses which are usually quite expensive. Currently most of the training is done by university professors. It is important that some specific courses to be provided by industry professionals

### **Togo**

In **Togo**, national universities provide human resources for administrative and financial positions. Pharmacists trained in Lomé are also hired, but since there are not yet postgraduate studies in pharmaceutical industry, production and control activities are managed by technicians from abroad. The following are some of the recommendations:

1. The Training of human resources from West African countries in Côte d'Ivoire through specialized training programs oriented towards the pharmaceutical industry: A comprehensive program of short-term courses for current employees and those aspiring to join the sector
2. The creation of industrial specialty programs in neighboring countries thanks to the training experience acquired by learners in Côte d'Ivoire. Learners will benefit from short-term training for engineering teams, craftsmen and machine operators to overcome

the lack of skills and experience required in tooling, manufacturing and optimal maintenance of the installation and operations.

3. The experience of pharmaceutical industrialization acquired in Côte d'Ivoire by investors could motivate the duplication of the Ivorian model in neighboring countries through the establishment of robust pharmaceutical industries.
4. Development of quality and experienced human resources ready to drive the development of the pharmaceutical industry in their country.

Creation of a specific pharmaceutical program of long-term courses for regulators and industry in the sub-region

Since Togo's market is tiny, it will be helpful to consider the country as part of the whole regional market. That would enable Togo to provide not only human resources both from the country itself and the diaspora but logistics advantages also such as its harbour and the Asky company hub.

Togo's scientists trained abroad that are working in different scientific teams can contribute to the launching of a regional Master's degree in pharmaceutical production.

We recommend Togo's manufacturers to:

1. Take advantage of the numerous shortages of drugs to broaden their facilities and produce locally all the missing products ;
2. Merge with other companies or at national level or at regional one to be able to cope with big markets' needs ;
3. Communicate with local authorities in university and regulations about their needs in order to seek for HR development strategies ;
4. Create attractive conditions to encourage the skilled Togolese in the diaspora to come back and help them develop their activities ;
5. Create conditions to technology transfer with the companies abroad that they are working with.

### **2.4.3. Role of the Diaspora**

There is no formal engagement with the Ghanaians in the diaspora to date except through the Private Health Sector Policy of 2013. This policy shows how the private sector, in general, can be engaged with the Ghana health system through investments. However, Ghana is in the process of drafting a Diasporian Policy, an abridged form was introduced during the Ghana Diaspora Celebration and Homecoming Summit 2019, 3-5 July in Accra. Such a policy which also exists

in Zambia<sup>24</sup>, Kenya<sup>25</sup>, and Ireland<sup>26</sup> will harness broadly all the potentials of the Ghanaian diaspora in a systematic framework for national development including LPP. The Ivorian diaspora represents an important and useful financial power for local populations living in Côte d'Ivoire. In addition to its financial contribution, the diaspora also represents a pool of human resources, skills and know-how that can contribute to economic development, including through job creation. Thus, the diaspora could intervene in the development of local Pharmaceutical industry:

1. By providing qualified human resources.
2. By investing massively in training by offering scholarships to young Ivorian's wishing to pursue careers in the pharmaceutical industry on the condition that they return to Côte d'Ivoire after their training to serve the local industry
3. Contribute to the financing of a training school specialized in Pharmaceutical Industry in Côte d'Ivoire

The pharmaceutical industries in Senegal are not numerous and consequently the offer is much lower than the demand. Also the industries are not attractive in terms of innovative products, infrastructures so that the Senegalese of the diaspora are not willing to return in Senegal. However, like Rwanda in 2009, a Senegalese Diaspora policy should be established. The policy could be the guiding framework which sets out how authorities wishes to see the Senegalese diaspora contributing and being integrated into the national development of the pharmaceutical sector. So Knowledge and skills could be transferred through services like:

1. Capacity-building program, mobility-based approach which helps to mobilize competencies acquired by African nationals abroad for the benefit of Africa's development. Through its, African nationals will directly contribute to the development of their countries of origin.
2. Short-term volunteering Program to reverse the 'brain drain' by encouraging nationals to provide their expertise, transfer of knowhow and skills.
3. Short-term consultancy services or partnerships between local and diaspora professionals organizations. ([https://www.iom.int/sites/default/files/country/EEA/info\\_sheet\\_diaspora.pdf](https://www.iom.int/sites/default/files/country/EEA/info_sheet_diaspora.pdf)).

**Togo** in the diaspora is full of skilled people that should be convinced to come back and hold the strategic positions in local manufacturers. There was a foreign affairs minister's program which invited Togolese in the diaspora to an important meeting, some years back ago. Many of them

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<sup>24</sup> [http://www.mofa.gov.zm/?wpfb\\_dl=48](http://www.mofa.gov.zm/?wpfb_dl=48)

<sup>25</sup> <http://www.mfa.go.ke/wp-content/uploads/2016/09/Kenya-Diaspora-Policy.pdf>

<sup>26</sup> <https://www.dfa.ie/media/globalirish/global-irish-irelands-diaspora-policy.pdf>

are now taking part in projects but I have not found yet any such collaboration in the pharmaceutical industry.

## **2.5. Research and Development**

### **2.5.1 Status of Research & Development in the pharmaceutical sector.**

R&D activities occupy a central position in the development of a vibrant, sustainable and socially inclusive local manufacturing pharmaceutical industry. This will enhance affordability of essential drugs, production, increase employment opportunities as well as reduce dependency on foreign support.

In West Africa, unlike in many developed countries with well-established pharma industry, pharmaceutical companies invest very little in R&D. In some countries there is an institutional framework to support R&D but in practice not much has been achieved. This is partly due to the absence of a platform for regularly engagement between research institutes/universities and pharmaceutical manufacturers. The impact of research institutions on Local Pharmaceutical Production (LPP) is therefore minimum.

Generally financial support for R&D is low across the countries. Currently there is very little activity in R&D of pharmaceuticals and APIS in Côte d'Ivoire, Guinea, Conakry, Cape Verde, Benin and Togo. However, in Ghana, Senegal and Nigeria there are existing structures that could be made more functional to achieve set institutional objectives. The practice in Nigeria where research in public-owned universities are sponsored mainly through a special intervention fund (Tertiary Education Trust Fund (TETFUND)) is noted. TETFUND was established by the Federal Government of Nigeria in 2011 to disburse, manage and monitor education tax to government owned tertiary institutions in Nigeria and funds R&D through call for research proposals from researchers in diverse fields. In Senegal there is no pure research in the pharmaceutical sector, the tests performed are mainly the pharmacopoeia sector. The investment in research for the pharmaceutical sector is very limited. The Faculty of Medicine, Pharmacy has conducted several studies on medicinal plants with the support of Non-Governmental Organizations. Other institutions have also carried out studies including the Inter State School of Veterinary Sciences and Medicine, the Faculty of Sciences and the Fundamental Institute of Black Africa (IFAN). (*Source PNP 2014*).

### **2.5.2 Bottlenecks in starting local production of Active Pharmaceutical Ingredients (API)**

The production of active pharmaceutical ingredients is key to the growth and development of the pharmaceutical industry. API production is capital intensive and technology involved is also

relatively sophisticated. . Internationally API production companies are shifting to China and India. Very few firms, if any, have been involved in the production of APIs in West Africa.

One of such companies is the Ghana based Lagray Chemical Company Limited which was the first vertically-integrated generic pharmaceutical manufacturer in West Africa. They were involved in the development, manufacture, and marketing of APIs. Lagray produced the API erythromycin which was used as an intermediary for the production of Azithromycin. The API produced by Lagray was fully utilised by themselves only as an intermediary and none was offered for sales to other companies. From all indications the volumes of the API produced was not that high and the company folded up due to low revenue generation and mobilization. The company's products were mostly second and third line products for treatment the necessary prescription traction could not be generated in the Ghana Health System.

Senegal has a rich experience in medicinal plants and has some traditional medicine centres and Community Centre for Appropriate Technologies for Health (CCTAS). Senegal has established by ministerial decree a National Commission for Senegalese Traditional Pharmacopoeia and the National Formulary.

This commission aims to develop the Senegalese pharmacopoeia and the national form. Regulatory texts relating to the registration of Improved Traditional Medicines (MTAs) have been also developed. The updating of these documents and their adoption will allow the development of MTAs. Today, traditional healers need scientific supervision to guarantee the safety of MTAs. For this purpose centres of clinical experimentation of medicinal plants have been created in the health centre but these centres are not functional because they have no operating budget. (*Source PNP 2014*).

The local production of APIs has been hampered by the following factors:

1. Weak or absent intellectual property laws
2. Poor governance structures
3. Weak regulatory structures
4. Lack of transparency (corruption)
5. Inadequate funding
6. Lack of incentives to support R & D
7. Lack of collaboration between academia and industries
8. Instability of government policies



### **2.5.3. Role of Asian Countries, Successes and Lessons Learnt**

The Asian countries where Ghana imports pharmaceuticals in high quantities are India, China, and Bangladesh. India dominates in terms of APIs and FPP exports to Ghana. Additionally, Ghanaian companies import substantial quantities of pharmaceutical packaging materials and excipients from India too, because they find them very competitive. Total pharmaceutical imports from India have been rising steadily from 40m in 2010 to about 136.8m USD in 2017.

In **Côte d'Ivoire** the Chinese government pledged to invest \$60 billion to support the continent's development at the Forum on China-Africa Cooperation in Johannesburg in December 2015. Cooperation on health was one of the priorities of the meeting, and China encouraged its companies to support African pharmaceutical production to facilitate access to medicines exclusively to investment projects in Africa. Thus **Branch of Human well Healthcare**, a **Chinese pharmaceutical group** opened its first plant on the continent, in Mali, in early 2015. Covering an area of 69,000 m, the plant employs more than 200 Malians. All have received training in modern pharmaceutical production techniques.

In Senegal, the presence of these industries favours the transfer of technology, generates jobs, limits imports and therefore facilitates access to medicines. What is important is to have a win-win partnership. Also the industries currently in Senegal could purchase bulk generic products from these countries in order to make the secondary packaging. This could allow local industries to participate actively in international tenders.

In Togo, Asian technicians are already working in manufacturers in Togo, as said in the lines above. What needs to be done is to carry that cooperation to institutional level. That will enable the training of many national technicians and make the cooperation more fruitful.

#### **Role of the country in helping other African Countries**

Creating a Centre of excellence for training manufacturers for the region is essential.

Ghana has had a considerable length of time with pharmaceutical manufacturing experience and that could be documented to act as a learning curve for some countries who want to venture into that industry. The Ghana College of Pharmacist (GCPharm)<sup>27</sup> could be a convenient place to offer these services. The college can be asked to document the phases of Ghana's pharmaceutical manufacturing for print and audio-visuals for training purposes.

Indeed, due to the relatively advanced nature of regulation by GFDA, Ghana can offer services in regulatory science to help train other regulators in the region by co-opting regulators from other countries for joint factory inspections, etc. to develop their capacity. USP Ghana has been

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<sup>27</sup> <http://gcpharm.edu.gh/contact/>

offering training for regulators and PM from all over Africa in Accra which could complement what GFDA could do. Further, USP Ghana<sup>28</sup> has offered its facilities to UG to complement the training of pharmacists and postgraduates.

Drug analysis and laboratory services are very expensive undertakings but they become manageable when the economics of scale are applied. Ghana can act as a centre for laboratory analysis for those countries with weak infrastructure and capacity to execute this function to help build their capacity while making that service available to that country at negotiated fees.

Drugs manufactured in Côte d'Ivoire are distributed on a market that extends to all WAEMU countries and some countries in the CEMAC zone where French-speaking distribution networks are established. Côte d'Ivoire is the most important market in French-speaking West African countries. The top three countries (Côte d'Ivoire, Senegal and Cameroon) account for more than 50% of the regional pharmaceutical market. Of the top three countries, Côte d'Ivoire has the most dynamic market. The development of the pharmaceutical industry in Côte d'Ivoire could help the industry of other West African countries.

#### **2.5.4. Jumpstarting local production of APIs.**

There is need to jumpstart the production of APIs considering the importance of the local production of APIs to the growth and development of the pharmaceutical industry and its effect on access to medicines.

To achieve this goal the following factors would need to be addressed:

1. Improved infrastructure including regular supply of public power
2. Implementation of good manufacturing practices
3. Provision of adequate foreign exchange
4. Availability of competent personnel.
5. Tax incentives

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<sup>28</sup> Kwasi Boateng, USP Ghana

Initiatives such as that proposed by PMG-MAN in Nigeria could be an option for consideration. PMG-MAN has canvassed the Expedited Medicines' Access Programme (E-MAP), a proposed collaborative contractual partnership between the health ministry and local manufacturers. E-MAP is expected to combine innovative manufacturing practices with contextual logistics and supply chain management that would achieve effective, cost efficient and timely provision of high-quality medicines. It is hoped that this collaboration will directly address the challenge of producing APIs in Nigeria.

The NIPRD in Nigeria also provides services for the granting of incentives with implications for the pharmaceutical sector up to 120 per cent of expenses on research and development (R&D) being 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.

### **2.5.5. Current R& D activities**

#### **Universities**

In the University system in West Africa, there are departments and Units that are R&D oriented. These include Pharmacognosy, Pharmacology, Toxicology, Pharmaceutics, Pharmaceutical Technology, Herbal Medicine, Industrial Pharmacy, Pharmaceutical Chemistry, and Clinical Pharmacy. These departments and units conduct research in different aspects of drug research including development and elucidation of active compounds from indigenous knowledge and biodiversity. However, the level of research activity is varied across those countries with faculties of Pharmacy in their Universities. The universities in Nigeria, Ghana and Senegal are more involved than those in the other countries. There are also in country variations in depth and scope of such activities.

In Senegal there are a lot of research activities performed by the universities. The University research system is structured around a Research Department, a Scientific Advisory Board, the Cooperation Department, the Intellectual Property Department and the Valuation Department. Research results and the Research Ethics Committee. Senegal also have the Support Office for Research and Innovation (BARI) which supports the implementation of UCAD's research and innovation policy by developing support services for research structures, providing support for strategic research management and supporting innovation and knowledge transfer.

However at the University, the research carried out for pharmaceutical sector are most often focused on the therapeutic activities. Indeed due to the lack of equipment which are very expensive, they are not able to perform molecule extraction. Added to that, there is not enough collaboration between academia and industries to transfer research performed in the university to the industries for development. Indeed, local industries are mainly generic company and are not really interested to perform research and development. Due to the reasons above, the University outsources some critical tests abroad with the risk of loss of intellectual property.

Currently there is a national subvention for the Chemistry laboratory for studies on sickle cell disease. (Source Chemistry Laboratory UCAD)

#### **Research organizations**

There are research institutes in a few West African countries with specific mandates in R&D activities relating to identification, analysis of drugs as well as development of raw materials from local resources to the pharmaceutical industry.

In Nigeria, we have National Institute for Pharmaceutical Research and Development (NIPRD), Nigerian Institute of Medical Research (NIMR) in Lagos, Raw Materials Research and Development Council (RMRDC) and Nigerian Natural Medicine Development Agency (NNMDA).

NIPRD has now carried out research and development into pharmaceutical grade starch, pregelatinized starch used as pharmaceutical binder, and dextrose monohydrate marketed as glucose powder (nutraceuticals) which is a major ingredient in intravenous infusions with great advantage to local drug manufacturers.

Pharmaceutical grade starch is currently imported primarily from China and there are local companies which produce industrial grade starch.

Senegal: In addition to research performed at the University, There is the Institute of Research and Development (IRD) whose missions are carrying out scientific research within units and laboratories to produce knowledge and training and Valuation through operational applications of research (patents or expertise).

### **2.5.6. Drug Development Based on indigenous knowledge and biodiversity**

#### **Malaria**

Malaria is a real scourge and is considered a public health problem in West Africa. Transmission is stable; it represents the first reason for consultation in the country's health facilities, the first cause of morbidity and mortality

#### **Ghana: Malaria and HIV/AIDS Drug Development Based on Indigenous Knowledge**

There are several herbal preparations with crytoplepine-based extracts in especially liquid dosage forms as antimalarias on the Ghana market. Nibima preparations, as antimalarias are also products from the Centre for Research into Plant Medicine <sup>[1]</sup> at Mampong, Akwapim in the Eastern Region.

**Côte d'Ivoire:** According to the National Program for the Promotion of Traditional Medicine (PNPMT), Kroa Ehoulé, 1421 species of medicinal plants used in traditional medicine and allowing the management of patients have been identified to date by Ivorian researchers.

PNPMT points out that this feat is to be attributed to one of the greatest plant researchers in West Africa, the ethnobotanist Laurent Aké Assi, who died on 14 January 2014 at the age of 82 in Abidjan, and to the traditional medicine research laboratory, whose work has enabled these mePMPMT explains that drugs from traditional pharmacopoeia have been validated by national and international research institutes. Some drugs have already been authorized and sold in pharmacies. From now on, the offices of Ivorian traditional healers are monitored and controlled by the program.

According to PMPMT, in Côte d'Ivoire, five million patients are monitored and treated each year by traditional healers. "Traditional medicine does not compete with conventional medicine. On the contrary, it offers care and collaborates with modern medicine.

In addition, medicinal plants are generally used to treat malaria, opportunistic infections contracted by people living with HIV/AIDS, diabetes, hypertension and sickle cell disease. Software to identify practitioners

In addition, the PNPMT has developed and implemented an information and management software for traditional health practitioners (TPS) to address population health issues. The software has made it possible to identify more than 8500 traditional health practitioners in 12 administrative regions of Côte d'Ivoire.

The TPS has been adopted as a model for identifying traditional healers in the sub-region by the West African Health Organization (WAHO). For researchers, ensuring the proper practice of traditional medicine in the country requires the establishment of a regulatory and legislative framework. It must take into account the regulation of traditional medicine actors, the regulation of the practice of traditional medicine and the regulation of traditional medicines. The president of the science, research, technology and environment commission of the National Assembly of Côte d'Ivoire, for her part, believes that the software set up by the national programme of traditional medicine for mapping these practitioners and creating medical consultation pavilions in public hospitals will enable parliamentarians to acquire the knowledge necessary to pass laws in favour of the population. It should also be noted that for some time now, traditional medicine has been integrated into the Ivorian public health system.

Thus, traditional healers now work in hospitals, alongside conventional doctors and together take care of patients. The first pavilion was opened a month ago at the University Hospital Centre (UHC) in Treichville. According to the Ministry of Health and AIDS Control, coverage in modern health facilities in Côte d'Ivoire is estimated at one first contact health facility for 12,822 inhabitants, one maternity for 14,000 women of childbearing age, one hospital bed for 2890 inhabitants and one doctor for 9,000 inhabitants. Meanwhile, the country has one traditional health practitioner for every 200 inhabitants.

#### **Case study in Cote d'Ivoire: Malaria**

Researchers from the University of Bioscience and the Pharmacodynamics and Biochemistry Laboratory have identified and highlighted the antimalarial properties of plants found in central Côte d'Ivoire (Toumodi) and used by the people of the centre for malaria treatment. *Artemisia afra* (of African origin). Has been investigated and currently being used as an herbal tea to treat malaria. To date, *Artemisia* is grown in experimental fields, particularly in Grand-Bassam, not far from Abidjan, but also in the botanical garden of the University of Korhogo.

**Nigeria:** The National Institute for Pharmaceutical Research and Development (NIPRD), 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.

**Senegal:** In Senegal we have research carried out by UMR VITROME (Mixed Research Units: IRD / Aix-Marseille University) on Malaria. This work focuses on three main areas: the discovery and molecular identification of emerging pathogens, the study of insect vectors and therapeutic research. (*Source Mission UMR VITROME*).

**Mali:** Mali Malaria Research Centre: Viewed by many as model as a model for research centres in developing countries, as its research is planned, directed, and executed by African scientists. Also has a robust training program for new generation of Malian scientists critical to the success and sustainability of the program. Current training programs in biology, tropical medicine, medical entomology, and epidemiology.

Malaria research including; vaccines, diagnostics, immunology and genetics, and prevention. Mali Traditional Medicines Established in 1973 the official institute connected to the National Institute of Research in Public Health (INRSP: Institut National de Recherche en Santé Publique). Main activities include: registration of traditional practitioners, medicinal plants, research and development of Improved Traditional Medicines (ITMs). Traditional medicines World Health Organization collaborating centre.

## **HIV-AIDS**

**Ghana: ARV Herbal preparation:** There is no ARV herbal preparation which has been approved by the FDA for distribution. Those who tried to come forward with their products were disapproved because their claims could not be substantiated. However, ARV are being manufactured by Danadams Pharmaceuticals, which is the only company making ARVs for distribution in Ghana and elsewhere. The products are not WHO PQ so they do not get patronage from the MOH to be procured because MOH funding comes from the DPs. The MOH is the major purchaser of ARVs. Some of the ARVs produced at Danadams are Bivek-E Combipack (Lamivudine, Zidovudine, Efavirenz), Lamdek-100 tablets (Lamivudine). They have Danoxine (Pyrimethamine Sulphadoxine) tablets and Danmether (Artemether /Lumefantrine) tablets as antimalaria products.

## **Recommendations**

### **Nigeria:**

Funding: R & D activities in public-owned universities are sponsored mainly by the Tertiary Education Trust Fund (TETFUND). TETFUND is an intervention fund that was established by the Federal Government of Nigeria in 2011 to disburse, manage and monitor education tax to government owned tertiary institutions in Nigeria.

R&D researchers in universities receive further support by the provision of books/journal donations, travel aids/grants, staff exchange/fellowship programme, R&D facilities, sponsored participation at workshops and R&D grants/funding from some international funders.

National Drug Policy: Pooling of Resources of different SMEs t fund R&D into herbal medicines. There is a need for a Centre for Clinical Research.

### **Senegal**

The difficulties encountered in research are mainly related to the lack of funding, the valuation and popularization of the results.

The lack of very expensive research equipment, the lack of collaboration between academia and industries (mainly generic industries) for R & D, the risk of loss of intellectual property linked to the outsourcing of certain tests, justifies largely the need for funds to be able to carry out R & D locally. That's why it is important to have subvention from organization and or the national authorities to be able to buy the equipment needed to do the research locally.

Many medical research (malaria, AIDS, etc.) are also carried out with the support of organizations like IRD France. It is therefore important that pharmaceutical researchers work closely with these structures to take advantage of their subventions.

It is important to support Senegal, which is a country rich in medicinal plants, to value and to exploit the biodiversity of its local products for therapeutic activities and for molecule extraction. Research and development in biosimilar, packaging materials need to be explored also.

## 2.6. Intellectual Property (IP)

### 2.6.1. Intellectual Property Rights and Technology Transfer

Intellectual Property refers to the innovations in the form of creative ideas and expressions of the human mind that have commercial value and are entitled to legal protection using legal mechanisms such as copyrights, patents, and trademarks. Intellectual property rights enable owners to select who may access and use their intellectual property and to protect it from unauthorized use. Technology transfer is defined by the United Nations (DFID 2004) as the process of sharing knowledge, skills, expertise and know-how.

### 2.6.2. Support Structures for Management of Intellectual Property Rights

Country	Structure	Mission
Senegal	The Senegalese Agency for Industrial Property and Technological Innovation (ASPIT).	It was born from the merger between the Department of Industrial Property and the Senegalese Agency for Technological Innovation created since 2001. The new Agency has a public service mission for the promotion of Invention and Technological Innovation. Its objective is to make the productive sectors more competitive, to supervise and support industries, agricultural and / or artisan projects. Priority is given to innovative projects that generate growth with high added value and that can create new jobs.
Cape Verde	The Institute for Quality Management and Intellectual Property (IGQPI)	It is the coordinating body of the National System of Intellectual Property Protection and the National Standards Organization. Its mission is to promote the defense and protection of intellectual property at both national and international level, fully integrated by industrial property, copyright and related rights with the support of the World Intellectual Property Organization (WIPO). IGQPI is in the process of developing the National Intellectual Property Policy and Strategy (PENPI), in order to provide the Country with adequate Intellectual Property public policies, with positive impacts on the competitiveness of the national economy, innovation and dissemination of new technologies.

Nigeria	Intellectual Property Technology Transfer Offices (IPTTOs)	Established by the government of Nigeria
	The National Office for Technology Acquisition and Promotion (NOTAP)	<p>It has established forty three (43) IPTTOs in Universities, Polytechnics and Research Institutions in Nigeria.</p> <p>The offices are established to promote interaction and strengthen the linkage between University/Research Institutions and Industries, develop a robust IPR portfolio through patenting, copyright, technology licensing; to support the Institution's initiative in developing patent culture. The IPTTO also sets into motion the formal system of incentives and reward that encourages individual researchers to collaborate with industry. The IPTTOs are also to facilitate the utilization of IPR system in tertiary institutions. To further drive this process the guidelines for registration and monitoring of technology transfer agreements in Nigeria was revised and published in 2018. To that end, and in 2019, the IPTTO in Obafemi Awolowo University has registered about five patents in drug related technology field, particularly from the Drug Research and Production Unit.</p>
Nigeria	the Nigerian Intellectual Property Organization (NIPO).	<p>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. National Office for Technology Acquisition and Protection (NOTAP) is responsible for regulation of technology acquisition and protection, including Intellectual Property Rights (IPR) issues, patents, benefit sharing,</p>
Ghana	Ghana Industrial Property Office (GIPO)	Review of intellectual property acts to be compliance with the TRIPS agreement and international best practices.



Togo	Togo National Institute of Intellectual Property (INPIT)	<p>to receive, process and transmit to OAPI applications for the protection of inventions, utility models, trademarks, industrial designs, trade names, geographical indications and plant varieties;</p> <p>to sensitize the Togolese population on the importance of industrial property and technology, on the need to protect themselves against counterfeiting and unfair competition;</p>
Côte d'Ivoire	Ivorian Intellectual Property Office (OAPI)	<p>The Ivorian Intellectual Property Office, abbreviated as O.I.P.I., is the national public institution created by Decree No. 2005 112 of 24 /02/ 2005, responsible for administering the Intellectual Property system. He also represents the African Intellectual Property Organization (OAPI) and the World Intellectual Property Organization (WIPO).</p> <p>The Ivorian Intellectual Property Office has the following missions:</p> <ul style="list-style-type: none"> <li>to encourage the acquisition of technologies and applied research in the industrial field, in particular:</li> <li>to make available to inventors, researchers, research centres its documentary collection consisting of patents free of exploitation as well as patents that have fallen into the public domain;</li> <li>to act as the focal point of the Fund for Assistance to Invention and Technological Innovation (FAPI), with a view to financing industrial development projects submitted to the African Intellectual Property Organization (OAPI);</li> <li>to intervene in the field of the sale and acquisition of technology in order to make it possible to make profitable the inventions and innovations patents or registered trademarks;</li> <li>to promote and manage national intellectual property activities in liaison with the African Intellectual Property Organization (OAPI) and the World Intellectual Property Organization (WIPO), as well as with any body likely to provide assistance to Côte d'Ivoire in this regard;</li> <li>to monitor intellectual property issues at the national and international levels;</li> <li>to protect all intellectual property rights as defined by the Bangui Agreement and to fight, in liaison with the competent services, against any counterfeiting and fraud in this field</li> </ul>

West Africa	African Intellectual Property Office(OAPI )	The African Intellectual Property Office which office is located in Yaoundé, examines and grants patent applications under the Bangui Agreement. The Bangui Agreement, which as national Industrial Property Code, is the legal basis for protection in countries members. 17 countries in West Africa are members.
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### 2.6.3. Importance of intellectual property on access to Antiretroviral Drugs

The provision of antiretrovirals (ARVs) to serve public health needs particularly in sub-Saharan Africa countries is complicated due to a myriad of factors which include poverty and inadequate funding, a lack of appropriate chemical industry capacity, poor social and medical infrastructure and amenities, inadequate legislation, and the existence of patents on antiretrovirals ARVs. Patents play a significant role in limiting access to affordable ARVs because the patent holders have monopoly on the pharmaceutical products and production process for a number of years. To obtain a patent on new ARVs, a pharmaceutical company or research organization must file a patent application. Patents may be granted for new products such as medicines, or for processes for manufacturing those medicines. Product patents may be granted on new molecules (often referred to as “base” patents or “compound” patents), or on specific forms or formulations of medicines (often referred to as “secondary” patents). The latter could include, for example, a particular salt form, an oral solution or tablet formulation of a given medicine, or a fixed-dose combination that combines more than one ARV compound into a single pill. Some secondary patents (notably those related to liquid dosage forms) are applied to pediatric formulations of medicines. In practice, new ARVs are generally covered by more than one patent or patent application<sup>[1]</sup>.

Patents are territorial rights, which mean that they have effect only in the specific territory for which they were granted. Despite the territorial nature of patents, it is important to note that the existence of patents on ARVs in the countries where most ARVs are currently manufactured (e.g. Brazil, China, India, South Africa, Thailand) may be sufficient to ensure exclusivity across developing countries to the patent holders. This is because patents in manufacturing countries could be used to prevent the production and therefore prevent export of the patented medicine into other countries. Thus, in order to understand whether there are patents that may have an impact on market competition in a country that imports ARVs, it is often necessary to review the patent status in countries that are likely to manufacture the ARVs as well as the importing country.<sup>[2]</sup>

#### **2.6.4. Antiretroviral drugs (ARVs) production**

Although the countries of the Sub-Saharan Africa have limited capacity for the production of pharmaceuticals, companies in Ghana, Kenya, Nigeria, South Africa, and Zimbabwe have demonstrated that they can produce ARVs. In Ghana, Danadams Pharmaceutical Industry Ltd is the only locally-based ARVs manufacturer. Four (4) other companies; Ernest Chemist Ltd, Pharmanova, Letap, Kinapharma are involved with the exports of generics. Danadams Pharmaceutical Industry Ltd. has the ability to fulfill the government's supplemental needs and exports to Togo, Burkina Faso, La Côte D'ivoire and Gambia. During the first year of Danadams Pharmaceuticals Ltd. operations it focused on the process leading to the acquisition of regulatory approval for the production of some selected ARVs. The company managed to acquire the regulatory approval for the production of generic versions of ARVs <sup>[3]</sup>.

Danadams Pharmaceuticals Ltd. Products are not WHO –prequalified for the supply of ARVs, although it has a very modern facilities and processes. As a result of this, the procurement of ARVs from Danadams Pharmaceuticals Ltd has to be paid for from Government of Ghana resources and not with the Global Fund.

Drug Regulators from Togo and Gambia inspect the plant and approve ARVs for marketing in their respective countries. Although Danadams Pharmaceuticals Ltd has an interesting story, the company has encountered these major constraints.

1. The high cost of bioequivalence tests for each product that is required for the acquisition of WHO Prequalification
2. The high cost of APIs when purchased in relatively small quantities
3. Inadequate market share and lack of economies of scale that result from its inability to supply under the Global Fund arrangements.

#### **The journey of Danadams Pharmaceuticals Ltd. with respect to ARVs is**

2005: Received authorization for seven (7) ARVs and became a pioneer by being the first company in Ghana to produce “generic” ARVs.

2006: Seven (7) ARVs registered in the Democratic Republic of the Congo

2009: West African Health Organization (WAHO) awards USD 1.2million contract to Danadams to provide ARVs to Togo and Gambia

### **2.6.5. Licensing of Patents on Antiretrovirals**

The production of ARVs is not only research and technology-based but also patent controlled and capital intensive. During the life of the patent, the patent holder may exercise the right to block others from manufacturing, selling or importing the patented product without consent. However, the patent holder may also give consent to other manufacturers to make or sell the product under certain conditions<sup>[6]</sup>. The current trend is to manufacture ARVs under voluntary licenses which set out the conditions under which consent is given. The details of these licenses are usually confidential and there is limited information available. Licensing terms and conditions generally specify the countries in which a medicine may be made or sold. The patent holder may announce a commitment not to enforce its patents in certain countries. The practical effect of such commitments is often similar to that of licenses; the scope and certainty of these mechanisms vary.

In Ghana, The creation of the Medicines Patent Pool (MPP) by UNITAID, in 2010 with the following mission “to increase access to, and facilitate the development of life-saving medicines for low and medium income countries through an innovative approach to voluntary licensing and patent pooling”<sup>[8]</sup> The MPP’s objective is to enhance access to more affordable HIV treatment in developing countries and to promote the development of new technologies such as fixed-dose combinations and formulations suitable for children<sup>[9]</sup>. MPP provides a platform which has enlarged the geographical scope of essential medicines to beneficial countries and has also brought transparency in the essential medicines licensing agreements because they are published on the website of MPP. Major generic manufacturers such as Cipla, HETERO, Mylan, SUN Pharma, and Laurus have benefited from this arrangement.

In addition to voluntary licenses, there are also instances in which a government may intervene without the consent of the patent holder and may issue a license allowing the manufacture or importation of a given medicine despite the existence of a patent. This is called a compulsory license and it is allowed by most national patent laws. Between 2003 and 2005 a number of African countries namely Cameroon, Ghana, Guinea, Mozambique, Rwanda, Swaziland, Zimbabwe and Zambia had to invoke compulsory license regime to import ARVs into their respective countries to address public health needs. The use of the compulsory regime usually brings with it political tension and does not lend itself to the transfer of technology. The aforementioned countries seem to have used the compulsory license regime once.

### **2.6.6. The TRIPS Flexibility**

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an international legal agreement between all the member nations of the World Trade Organization (WTO). TRIPS was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) between 1989 and 1990 and is administered by the WTO. It sets down minimum standards for the regulation by national governments of many forms of intellectual property (IP) as applied to nationals of other WTO member nations. TRIPS also contain provisions that allow a degree of flexibility and sufficient room for countries to accommodate their own patent and intellectual property systems and developmental needs. Patents on medicines have been one of the most hotly debated topics since the adoption of the TRIPS Agreement because patents grant exclusivity for the duration of the patent term and result in patent holders having control over the production, supply, distribution and, by virtue of exclusivity, price.

According to Article 7 of the TRIPS Agreement, "the protection and enforcement of Intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations." In addition, WTO Members may, when implementing TRIPS rules, "adopt measures necessary to protect public health" and other public policy objectives, "provided that such measures are consistent with the provisions of the TRIPS Agreement (Article 8.1, TRIPS). The preamble to the TRIPS Agreement recognizes "the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives."

The TRIPS Agreement was therefore aimed at ensuring that legislation and regulations developed at the national level maintains a balance between the minimum standard of Intellectual Property Rights protection and the interest of the public. The Agreement establishes global minimum standards for protecting and enforcing nearly all forms of intellectual property rights, including for pharmaceutical products and processes.

#### **2.6.7. Implementing the Flexibilities in West Africa**

The use of TRIPS flexibilities is rare in West Africa pharmaceutical sector given low technology capabilities among the local firms. The rare 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 licenses.

All the signatory countries to the Bangui Agreement must plead for the revision of this agreement to allow full use to be made of the flexibilities of the TRIPS Agreement, in particular for:

1. exclude from patentability medicines for LDCs,
2. allow the use of compulsory licenses as soon as the patent is granted, and imports under compulsory licenses,
3. allow recourse to parallel imports (duty exhaustion regime),
4. to allow a substantive examination of patent applications.

#### **Ghana**

Ghana has since early 1900 in the then Gold Coast under the British used intellectual property legislations. Ghana did not have a Patent Act until 1992 when the Patent law 1992, (PNDCL 305A) was enacted. To improve the intellectual property regime globally, the World Trade Organization (WTO) adopted the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement which came into force in 1995.

The Patent Act, 2003, Act 657 governs patent protection, including protection of pharmaceutical patents, in Ghana. Ghana from 2009 under the Swiss Ghana Intellectual Property Project began implementing activities to strengthen the intellectual property regime in Ghana, one of the major activities was the review of the intellectual property acts to be further compliant with the TRIPS Agreement and international best practice. In this respect, analysis of the Patent Act, 2003, by a consultant revealed that it was necessary to fully incorporate the flexibilities and safeguards that could assist Ghana in improving innovative and research activities and further address public health concerns. The key inclusions of the reviewed Patent Act are in respect of exception to rights conferred by patent, compulsory license, voluntary license among others such as parallel importation and exhaustion of rights.

Ghana in compliance with its obligations under the WTO and the TRIPS agreement from 2003 to 2006 amended existing intellectual property acts including the Patent Act and introduce new acts to protect other aspects of intellectual property.

### **Côte d'Ivoire**

Côte d'Ivoire is a signatory to the Paris Convention of 20 March 1883, the Patent Cooperation Treaty of 19 June 1970 and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of 15 April 1994. It has also signed the Bangui Agreement establishing the African Intellectual Property Organization (OAPI): Côte d'Ivoire, which is a member of OAPI, the African Intellectual Property Office, which examines and grants patent applications under the Bangui Agreement. The Bangui Agreement is characterized by the absence of substantive examination of patent applications and the absence of patent opposition processes. It should be noted that Côte d'Ivoire has not adopted a "TRIPS plus" type measure, which is an excellent thing for access to medicines. Among the members of OAPI, all West African countries, except Côte d'Ivoire and Equatorial Guinea, are included in the current list of Least Developed Countries (LDCs). LDCs have a transitional period until 2033 to apply the standards of the TRIPS Agreement for pharmaceutical products. However, their membership of OAPI, and the absence of a specific regime for OAPI member countries with LDC status, obliges them to meet the intellectual property standards as defined by the Bangui Agreement. The Bangui Agreement therefore serves as national patent law for all these countries.

Côte d'Ivoire has still not incorporated the flexibilities of the TRIPS Agreement into its national law, but the NPSP (New Public Health Pharmacy) purchases generics from manufacturers prequalified by WHO. The local industry has limited its production to essential molecules recognized as not covered by patents. With regard to compulsory licensees and office licenses, OIPI (Ivorian Intellectual Property Office) does not in any way declare that it is aware of such flexibilities. But according to the Medicines and the law and policy database (<http://tripsflexibilities.medicineslawandpolicy.org/>), office licenses were issued in Côte d'Ivoire in June 2004, then in September 2007 and again in November 2007

## **Nigeria**

Nigeria has been a member of the World Trade Organization (WTO) since 1995 and is classified as a Developing Country (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

The Nigerian laws on IP provide remedies for the intellectual property rights owner in the event of infringement on his rights by a third party. Remedies like damages, injunctions including rendering of account of profits and other forms of relief as the court may deem fit. This tallies with the provisions of the TRIPS Agreement in Articles 45 through 46. However, the TRIPS Agreement in Article 48 provides for indemnification of the defendant where the action against turned out to be baseless and has thereby deprived him of his own rights, this provision is not replicated under any IP law in Nigeria. This is one aspect that needs attention. (Itanyi, 2016). Nigeria should not make a wholesale application of TRIPS but in a manner that upgrades Nigeria IPR regimes to international standards and also give indigenous talents opportunity to flourish.

The Nigerian intellectual property system appear to be fragmented as they are managed by three distinct agencies and three ministries. The Ministry of Industry, Trade and Investment is in charge of the patent registry, National Office for Technology Acquisition and Promotion in the Federal Ministry of Science and Technology (FMST), while the Nigerian Copyright Commission is located in the Ministry of Justice and handles copyright related matters.

## **Senegal**

The Senegalese Agency for Industrial Property and Technological Innovation (ASPIT), is the National Structure of Liaison with the African Intellectual Property Organization (SNL/OAPI). As Senegal's trade policy is resolutely oriented towards the liberalization of trade, the respect of international commitments is a priority. In this perspective, a National Committee for International Trade Negotiations (CNNCI) was established by Decree No. 2001-1072 of 12 December 2001 and a subcommittee set up within it, scrupulously ensures the respect of intellectual property rights and the implementation in accordance with national legislation and international commitments.

The NGO Yolse in collaboration with the African Union, the United Nations Development Program (UNDP), UNAIDS, the Ambassador of Senegal, the South Center organized a workshop on 23 November 2015 with a view to sensitize the representatives of the OAPI member states of the importance of integrating the flexibility of the transitional period into the Bangui Agreement. The workshop was a success due to the sensitization work of the NGO Yolse and its partners. The OAPI member states incorporated into the revised Bangui Agreement in Bamako on December 14, 2015, the decision of the Council of TRIPS of 6 November 2015 exempting Least Developed Country (LDCs) from the obligation to grant or enforce patents on pharmaceutical products and to protect data resulting from pharmaceutical-related clinical trials until 1 January 2033. (Source *Contribution from NGO Yolse at the work of the United Nations Secretary-General's High Level Panel of Experts on Access to Medicines February 28, 2015*)

Thus in 2015 Senegal participated in the revision of the Bangui Agreements to comply with the provisions of TRIPS. The Republic of Senegal deposited its instrument of ratification of the Bangui Agreement, Act of 14 December 2015, to OAPI, on March 28, 2017. After Mali and Gabon, Senegal is the third country to ratify through its parliament the Bangui Agreement. ASPIT, through its role of National Liaison Structure with the African Intellectual Property Organization (SNL / OAPI), must translate at the national level the main tasks given to it by the Bangui Agreement, namely the promotion and sensitization on the use of the industrial property system for economic and social development. And by the end of 2019 a national committee for the implementation of TRIPS will be established in Senegal. (Source *ASPIT*)

**Benin** is a member of many international/regional intellectual property agreements: Bangui Agreement (OAPI) (since 1983); Berne Convention (since 1961); Hague Agreement on Designs (since 1986); Nairobi Treaty on Olympic Symbol (since 2006); Nice Agreement on Classification of Marks (since 1979); Paris Convention (since 1967); Patent Cooperation Treaty (since 1987); WIPO Convention (since 1975); WIPO Copyright Treaty (since 2006); WIPO Performances and Phonograms Treaty (since 2006); and WTO/TRIPS (since 1996) IP legislation.

Benin also joined the union of 16 predominantly Francophone countries constituting the Organisation Africaine de la Propriété Intellectuelle (OAPI). The principles governing OAPI include:

1. the adoption of uniform legislation to create a uniform system of intellectual property rights protection with a common administrative procedure
2. the creation of a common authority to serve as a national intellectual property rights protection office for each of the member states
3. the centralization of procedures so that a single title would issue creating national intellectual property rights in the individual member countries

OAPI member countries are required to ‘renounce’ their national sovereignty in the area of intellectual property, to afford the right holder a single regional title of protection valid in each country, obtained via an OAPI application and registration procedure. Thus, in order to join OAPI, Benin had to renounce its national IP legislation. Benin is also a member of the Bangui Agreement, which provides for copyright protection. It is not clear which of the legal dispensations will apply in practice.

**Mali** is a member of the following international agreements: Bangui Agreement (OAPI) (since 1984); Berne Convention (since 1962); Hague Agreement on Designs (2006); Paris Convention (since 1983); Patent Cooperation Treaty (since 1984); WIPO Convention (since 1982); WIPO Copyright Treaty (since 2002); WIPO Performances and Phonograms Treaty (since 2002); and WTO/TRIPS (since 1995). It is also a member state of the union of 16 predominantly Francophone countries constituting the Organization Africaine de la Propriété Intellectuelle (OAPI), which requires members to ‘renounce’ their national sovereignty in the area of intellectual property. It is not clear how this legal dispensation will apply in practice.



It is observed that while the countries in question have the right to exercise the flexibilities under the TRIPS Agreement, in reality it is very difficult to make effective use of these flexibilities as a public health policy tool. Although the Doha Declaration on TRIPS and public health allows developing countries to issue compulsory licenses, they lack sufficient manufacturing capacity. Additional challenges include:

1. lack of technical expertise to effectively implement the TRIPS flexibilities
2. lack of technical and infrastructural capacities for medicines regulations
3. bilateral and other pressures not to use the TRIPS flexibilities for public health purposes and/or to adopt TRIPS-plus standards
4. difficulties in regulating anti-competitive practices and abuse of intellectual property rights;
5. difficulties in accessing pricing and patent status information

**Cape Verde** Joined the World Intellectual property Organization in 1997 and has developed the national intellectual property laws and regulations. Cape Verde is a member of the following international agreements: Berne Convention (since 1997); Rome Convention (since 1997); WIPO Convention (since 1997); WTO/TRIPS (since 2008). It has developed IP legislation on trademarks, Industrial Property Code, Patents, Industrial Property Code, Designs, Copyright and Related Rights.

The National Intellectual Property Policy and Strategy (PENPI), to be developed, should take into account national priorities, especially those identified in national innovation and development plans, as well as the multifaceted challenges facing the country in promoting an environment conducive to the creation of a social awareness about intellectual property (IP). On the other hand, they should emphasize the integration of IP system dimensions into national development planning.

#### **2.6.8. Case studies and success stories**

##### **Voluntary License for manufacture of ARVs**

**Case: South Africa:** In April 2004, the American pharmaceutical company Merck & Co Inc, announced its intention to grant a license to manufacture Efavirenz to Thembalami, a joint venture between Ranbaxy (India) and Adcock Ingram (South Africa). In early March 2005, the South African government announced that seven companies had been selected following a call for tenders launched a year earlier to supply the public sector with antiretrovirals for the next three years. Of the seven companies, Aspen is the company that has won the most contracts, providing eight of the fifteen antiretrovirals needed. Only one other generic company was selected, Cipla Medpro (Cipla's South African subsidiary), which will supply d4T. The remaining treatments will be purchased from the multinational companies Boehringer Ingelheim, Bristol-Myers Squibb, Merck Sharp & Dohme, GlaxoSmithKline and Abbott Laboratories. Thembalami had not registered the generic version it should produce under Merck's voluntary license and was unable to submit this product for tender. Lessons learned:

1. Voluntary licensing has enabled the local production of some antiretrovirals to be launched in South Africa. In general, South Africa's commitment to expanding access to antiretroviral treatment for its population could lead to a significant change in the overall dynamics of the antiretroviral market. However, it is important to note that the proliferation of commercial partnerships between multinationals and local companies in developing countries, in the form of voluntary licences, does not necessarily ensure that there is genuine competition benefiting the expansion of access to medicines. Multinational companies are increasingly developing this type of alliance. Aspen, for example, manufactures 40 % products for GSK.
2. By becoming subcontractors to multinationals, companies like Aspen are no longer necessarily in a position to play a competitive role. This is one of the disadvantages of the compulsory licensing system provided for in the TRIPS Agreement, which requires the negotiation of voluntary licences as a preliminary step before compulsory licences can be granted in the event of refusal by multinationals. Control of local manufacture and sale remains in the hands of multinationals when these licenses are granted for a fixed period of time, to certain producers only and under certain conditions, in particular pricing conditions. This then goes against the multiplication of production sources that allow competition and affordable prices to be obtained

### **Compulsory license for manufacturing of ARVs**

#### **Case 1: Ghana**

In respect to exceptions to patent rights it was proposed to include early working system (Bolar exception). With respect of compulsory license, the grounds for the grant of compulsory licenses are limited; the process for obtaining a compulsory license is cumbersome and expensive, the provisions for government use are inadequate and should be expanded to cover flexibilities available to developing countries also a legal framework in which voluntary licenses are easily negotiated for and obtained as a matter of course be incorporated. It was proposed that the act be amended to reflect the August 30th, 2003 Decision and clarify the situation for voluntary licensing. The reviewed Patent Act has been approved by Cabinet and forwarded to Parliament for consideration.

In Ghana In respect of compulsory license, the Ministry of Health and the Food and Drugs Board developed administrative guidelines for the issue of compulsory license for pharmaceutical products in Ghana. Ghana has since then used the compulsory license regime once and the conditions were as follows:

Ghana issued a government use order for public health reasons:

1. Was issued on 26<sup>th</sup> October 2005
2. Issued under the emergency situation with regards to HIV/AIDS within the National HIV/AIDS program
3. Was for the importation of Generic ARVs from India
4. The ARVs were patented by GlaxoSmithKline (GSK)
5. Duration of license was for 3 years
6. Royalties were not paid although the Government was prepared to make such payment
7. The cost of the ARVs dropped by almost 50%

The effective use of compulsory licensing as a tool for gaining access to medicines at affordable prices requires adequate technical knowledge and efficient administrative infrastructure and this has been demonstrated by Ghana.

**Case 2: South Africa in the challenge of the accessibility of anti-retroviral drugs:**

In 1997, South Africa enacted legislation allowing the import of low-cost generic medicines and establishing a price control mechanism. However, its application was blocked from February 1998 by the legal action of 39 pharmaceutical companies. They attacked the South African government on the grounds that national laws allowing the use of generic versions of patented products were not in conformity with WTO agreements. Following a legal procedure that generated strong international support, they were forced to withdraw their complaint in April 2001. In addition, under South African law, this verdict put the government in a position to grant "compulsory" licences to allow local production or import of generics. The risk of losing control over the manufacture and circulation of generic versions of their products may explain the promptness with which, following the Commission's condemnation, GSK and Boehringer-Ingelheim granted "voluntary" licences to local producers.

**Lessons learned** - *By allowing these producers themselves to manufacture and sell the three molecules, the companies avoided legal circumvention of patents by the South African State.*

Brazil was the first country in the South to implement a universal access program for antiretrovirals. The programme began in 1997 with the provision of free treatment to more than 20,000 HIV/AIDS patients. The annual budget allocated to the purchase of AIDS drugs was then \$224 million. In 2001, the number of people undergoing treatment reached over 100,000. By then, eight out of twelve drugs distributed free of charge were produced locally by Far-Manguinhos, a public research and production unit, which was free to manufacture most of these unpatented antiretrovirals in Brazil. They were discovered before 1995, the date of entry into force of TRIPS. However, health authorities started observing an increasing resistance of patients to first-line treatments composed of non-patented drugs. Therefore, second-line treatment was required, this time requiring the prescription of patented drugs. This was the case with Efavirenz, a drug patented by Merck, which alone absorbs 10% of the anti-retroviral budget. Brazil was concerned that the increasing use of patented drugs may threaten the viability of its universal access to retroviral drugs program, which allowed patients to live with the disease, reduced the number of hospitalizations and ultimately saved significant amounts of money. As a result, the country decided to obtain significant price reductions by mobilizing the legal tools available to negotiate advantageously with companies holding patents.

**Case 3: The first Brazilian offensive concerns Efavirenz:** In March 2001, Merck threatened to sue Brazil for illegally importing generics of Efavirenz, a practice that would constitute a qualified infringement of its patent. The Brazilian response is immediate. Far-Manguinhos did indeed import Indian generics. These imports are not intended for commercial exploitation. The public research and production unit has no intention of selling them on the market. In fact, Far-Manguinhos is working on samples of the Indian credits to develop and eventually produce its own copy. A perfectly legal practice since TRIPS allows patent circumvention in the case of governmental and non-commercial use: an R&D programme on a drug and/or the production of a generic of a patented drug under compulsory licence to supply a programme of universal access to essential medicines does not constitute an infringement of intellectual property. The threat of Brazilian local production very quickly finds a favourable echo. The company proposes to reduce the price of Efavirenz by 65% from \$2.09 to \$0.84 per tablet. This resulted in an announced savings of \$39 million for the Brazilian Ministry of Health. **Case 4:** A few months later, Brazil attacked Nelfinavir, a Roche patented drug. After six months of unsuccessful negotiations with Roche, the Brazilian government announces its intention to override the patent. In December 2001, the supply contract between Roche and the Brazilian Ministry of Health expired. It will not be renewed and Far-Manguinhos will be responsible for the local production of the drug. Once again, the procedure is legal since this is a public non-commercial use, a production under compulsory licence intended to feed the universal access to retrovirals program. Since a quarter of the program's 100,000 patients are on Nelfinavir, local production is expected to reduce the price of the drug by 40%, saving \$88 million. Very quickly, the Ministry launched the compulsory licensing procedure to start local production and import of Indian generics until Far-Manguinhos could ensure the ramp-up of its production to cover domestic needs. Finally, Brazil's intention to produce Nelfinavir locally under compulsory licence leads Roche to propose a 35% reduction in the price of the drug. An agreement was finally signed at the end of August: the reduction for 40% reduction. and Roche is committed to starting local production by 2002 at the latest. Brazil then interrupted the compulsory licensing procedure. In 2003, universal access to antiretroviral drugs programme covered nearly 140,000 people.

### **Recommendations**

Revision of the Bangui Agreement to allow full use of the flexibilities of the TRIPS Agreement  
Substantive examination of patent applications must be provided for, and examiners trained in pharmacology and "secondary" drug patent issues before limiting the practice of evergreening.  
Transparency must be improved by OAPI and local liaison offices in order to make the status of patent applications public and accessible.

Substantive examination of patent applications must be accompanied by the possibility for third parties to make comments during the examination procedure. It must also be accompanied by the possibility for third parties to oppose the grant of a patent before it is granted

A regional approach to the use of TRIPS flexibilities will enable similarly situated countries to address their constraints jointly by drawing on each other's expertise and experience and by pooling and sharing resources and information. It will also enhance the efforts to pursue common negotiating positions at the WTO and in other multilateral negotiations such as those on a substantive patent law at the World Intellectual Property Organization (WIPO).

In addition, a regional approach coincides with the objective of enhancing South-South cooperation on health and development.

Pharmaceutical manufacturers apart from the licenses they procure, must be assisted to make use of expired patents to help them improve their product portfolios to spur their growth. As that will be a less costly route for product development

The potentials of the pharmaceutical manufacturing sector can only be realised with a strong human capital base. The current HR situation of the LPPs in Ghana is very precarious. There is a mixture of small proportion of local and plenty Indian technologists manning the sector. There are about fifty (50)<sup>29</sup> local pharmacists in the industries which makes about 1.9% of total pharmacists registered with the PSGH of about two thousand six hundred and eighty-two (2682)<sup>30</sup>. The industrial pharmacists in the pharmaceutical manufacturing sector are mostly sourced from India under individual efforts by the companies and their Indian partners. It happens that the young pharmacists who enter the sector do not stay long enough because they do not find it attractive enough.

### **2.7. Academia-University-Industry Linkages**

Many African countries have recognized the need to advance university-industry collaboration to an even higher level by allowing industry to drive program design and delivery through partnership models that include both apprenticeship and practical training and specialized programs for employers and based on real-world practice and simulations. Most academics and leading industry representatives are on the same wavelength when it comes to collaboration. There are many benefits in strengthening research and innovation through joint research projects, providing innovative commercial products, improving the teaching, learning and enrichment of students' knowledge and employability, and providing new funding to postgraduate universities. Most African universities, like most other countries in the world, are interested in formalizing collaboration with industry in the areas of curriculum development, teaching and learning, research and development, consulting, as well as obtaining suitable industrial internships for Researchers get to collaborate with industry players to take their research products to another level — commercialization.

Collaboration with industry players benefits students in terms of acquiring skills and knowledge. Researchers will also benefit from technology transfer and commercialization.

**In Ghana**, there is evidence that university lecturers on their own have been developing formulations and doing chemical analysis to develop in-house assay methods for the industries e.g. a lecturer from KNUST was called to help solve a production problem of chloramphenicol capsules at Letap Pharmaceuticals. Also some of the lecturers own pharmaceutical manufacturing companies where they may be developing technologies for commercial purposes. However, these collaborations must be formalized and benefit both universities and industry in a win-win relationship. The creation of a more formal framework for discussion and exchange would be an asset in promoting research and innovation.

**In Côte d'Ivoire**, there are examples of partnerships between schools of excellence and the private industrial sector.

### **Case of the Partnership between the Houphouet Boigny National Polytechnic Institute and the construction and public works Company PFO-AFRICA-Cote d'Ivoire to set up a Management Chair**

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<sup>29</sup>Dr Sam Gaizer, Chairman IPA

<sup>30</sup> PSGH 2019 AGM Magazine

The partnership signing ceremony with Pierre FAKOURY Operator Africa Côte d'Ivoire (PFO AFRICA CI) on 07 September 2018 in Abidjan, the Institut National Polytechnique Félix HOUPHOUET BOIGNY. This Partnership aims at Strengthening the capacity and expertise of graduates in the fields defined in the partnership in order to conduct development projects in the industry. Financed by PFO, a major player in the construction and public works sector, this Master's degree, which began at INP-HB in September 2019, aims to combine managerial culture with technical skills for innovative project management. "It is clearly a training course with hiring as a key element (by PFO), designed to combine the acquired techniques with the managerial skills necessary to understand and solve all the major problems posed by the complexity of projects in a rapidly changing socio-economic environment". In this project, the Ivorian construction company intends to build a strong personality in each student. This master's degree aims to train engineers and managers in this company who are likely to face the many industrial challenges. It is at this cost that students will participate in the development of Côte d'Ivoire and Africa,

**Case of the partnership between the Houphouet Boigny National Polytechnic Institute And the CONAD-CI group, which includes CITRANS, Agro West Africa and Agro West Industries Citrans, Agro west Africa Abidjan and Agro west industries**

Created on 27 March 2017, CITRANS, the Ivorian Transport Company is a structure specializing in lagoon transport by boat buses in Abidjan district. Aqualines, CITRANS' trademark, offers a shipping service combining: SAFETY-COMFORT-RAPIDITY.

INP-HB and CONAD –CI group lay the foundations for the signing of a framework cooperation agreement. In this cooperation agreement; the aim is to define areas of collaboration for the implementation of a framework partnership agreement. The first part of the partnership is to recruit at INP-HB competent human resources in the fields of transport, finance, marketing, IT, production and purchasing, combining know-how and interpersonal skills, in order to resolve the question of know-how, a real problem within CITRANS organization ".

The idea is to have within CITRANS teams, employees who develop, entrepreneurial dynamism, team spirit, interpersonal skills and proven leadership.

The second part concerns the INP-HB's support resources in technical and technological terms. It is therefore to provide an answer to these difficulties that CITRANS' managers approached INP-HB, a prestigious school with multidisciplinary training offers.

This partnership also aims to recruit at 2 levels. Initially, the focus will be on operational staff likely to set up mechanisms in both technical and management fields. "For the managerial aspect, the database of INP-HB alumni from the last five years will be consulted in order to possibly recruit experienced managers.

The practical details of this strategic partnership are structured around six (06) major axes. These include, in particular:

1. Hosting HB INP students on internships or for visits to CITRANS, Agro West Africa Abidjan and Agro West Industries;
2. Training of students and faculty at INP-HB;
3. The promotion of maritime and lagoon transport professions;
4. Continuous training of employees of partner companies, namely CITRANS, Agro West Africa Abidjan and Agro West Industries;

5. The assistance, advice and expertise of the INP-HB for technical support to member companies of the CONAD-CI group (CITRANS, Agro West Africa Abidjan and Agro West Industries);
6. The provision of INP-HB facilities for activities (training, convention, socio-cultural and promotional activities, etc.) of the CONAD-CI group.

Despite these few examples concerning other sectors of the economy, partnership agreements between universities and the local pharmaceutical industry are almost non-existent.

**In Nigeria,** The pharmaceutical industry depends on research and development (R&D) for the development of the medicines that they produce. R&D could be conducted in-house, where industrial firms have their own laboratories, but research could also be contracted out to universities or research institutes. Universities have long been recognized as sources of knowledge creation, innovation, and technological advances. In order to fully utilize universities' potential, Nigerian governments are actively pursuing strategies to strengthen University and Industry Collaboration (U-IC). Oyelaran-Oyeyinka and Adebowale (2012) disclosed that a wide variety of factors combine to determine the nature of innovation, innovation capacity, research performance and collaboration in the Nigerian universities and public research institutes. FMH (2005) assured that considering the enormous cost of R&D, government shall provide support and an enabling environment to encourage such activities, specifically in developing new drugs and improving existing ones. Furthermore, R&D shall be encouraged, especially in the areas of local raw materials as sources for new drugs, traditional medicines among others.

Ssebuwufu et al (2012) showed that many African universities have undertaken efforts to foster and institutionalize linkages with the productive sector. However, such offices operate on minimal budgets in many institutions, and are not always staffed with sufficient expertise in entrepreneurialism, intellectual property rights management, and marketing strategies. Furthermore, many lack complementary and supportive policies and mechanisms for regulating interactions with the productive sector. The perceived benefits of university-industry collaboration include the following:

1. Provide alternative funding options at a time when funding is limited;
2. Access to or acquisition of state-of-the-art equipment; ---improving curriculum and training in technology and problem-solving programs;
3. Better employment opportunities for students;
4. Additional income for teachers;
5. A clearer contribution of universities to the economy, etc

### **2.7.1. Why enter into university-industry partnership?**

Ssebuwufu et al (2012) noted that in general, firms in Africa tend to make use of low technology products, operating at low technical efficiency with little interest in investing in R&D generally. In the broader literature, perceived benefits from university-industry collaboration include: providing alternative funding channels in an era of constrained financing; access to/or acquisition of state-of-the-art equipment; improved curriculum and training in technology-oriented programmes and problem-solving; enhanced employment prospects for students; supplemental income for academic staff; and clearer contribution of universities to the economy, among others.

One of the major problems facing Nigeria is graduate unemployment. A situation that has been worsened by the increasing number of universities in the country and the mismatch between the school curricula and the needs of the industrial sector of the economy. University-industry collaboration has been suggested as one of the measures that could mitigate graduate

unemployment in Nigeria. Some authors have suggested among others the need to bring in seasoned industrialists to participate in drawing curricula and also teach some practical courses on a part time basis in Nigerian Universities. This should hopefully further equip Nigerian graduates with skills needed in the industrial sector of the economy with implications for their employability (Segun et al., 2015)

Oyelaran-Oyeyinka and Adebowale (2012) studied determinants of innovation in University-Industry Collaboration in some life sciences including pharmacy in Nigeria. They found that inter-firm linkage is driven not by strategic concerns but the need to maintain production regime in order to remain competitive. Firms do not see universities regarding solutions to these sorts of immediate challenges. Learning to improve products is firms' central activity; the main actors are buyers and suppliers of components, materials and machinery. Universities play a part when firms need new knowledge that helps them move to a new and potentially higher production regime. This is precisely what firms confirm they require, but they are hardly able to pay for the services of university academics, they often are not able to spare the time and some are unable to properly define the problem that requires solution in the language of the academics. Engaging in academic-industry collaboration is a long-term endeavour for industrial partners for business growth and value creation. However, the readiness of majority of the firms for such venture is doubtful. (Jávorka et. al. (2016).

### **2.7.2. Challenges of U-I Linkages**

UNCTAD (2009) notes that in Nigeria, as in most African countries, weak interactions exist among universities, research institutes and enterprises. Jávorka et. al. (2016) noted that the inherent differences between the worlds of academia and industry – for example, working with different timescales, lack of understanding of each other's needs, structures, practices or even just the language used – can create difficulties that often seem insurmountable. Collaboration in the field of education-related activities does not create obvious short terms gains. Therefore, such collaboration must go together with a clear value proposition, where industrial partners can recognize the pay-off for their time and resources devoted to the project participation.

Obanor and Kwasi-Effah (2013) found that collaboration between university and industry is mostly by individual effort, both from the university and industry point of view. This resulted in weak collaboration since this act is informal. Most academics are driven by their conferences, technical journals and their need to publish and less driven by how technology can be effectively transferred through effective collaboration. Furthermore, some industrialists, being not well informed about the benefit of collaboration, refuse sponsorship or grants proposed by the academics as the industrialist feel it's a waste of finance and will just add a little to their expenditure.

NIRP (2014) reported that the current challenges confronting industrial development in Nigeria include low critical mass in scientific fields, inadequate equipment, inadequate information sharing, weak or no interaction between academia, industry, government and unclear commercialization path and weak intellectual property enforcement.

Oyelaran-Oyeyinka and Adebowale (2012) identified some reasons for low rate of commercialization of inventions in Nigeria to include weak or lack of interest by university researchers, poor specification of remunerations that attend researchers' job specifications, lack of information on what universities have to offer the firms, mismatch of interest and lack of complementary assets such as R&D facilities on the side of firms, lack of finance such as venture



capital to promote risky and poor support systems to assist firms to define and engage in U-I linkages.

### **2.7.3. Policy incentives supporting U-I Linkages**

The Science, Technology and Innovation (STI) Policy of Nigeria (2011) has, as one of its strategic policy objectives “Initiate, support and strengthen strategic bilateral and multilateral cooperation in scientific, technological and innovation activities across all sectors of the economy.” STI has several incentives for the support of U-I Linkage in Nigeria. UNCTAD (2009) also notes that there is a tax incentive to encourage corporate contributions to research institutes in Nigeria

### **2.7.4. Success Stories of U-I linkages**

There have been a few success stories in the U-I linkages and discussed below.

#### **Agriculture, Engineering,**

Several new crop varieties that were developed from Nigerian universities and research institutes have been successfully commercialized and are cultivated in the country. Besides crop development, agro-processing machineries have also been successfully commercialized. The list of such inventions is long, and it includes small-scale dryer, yam pounding machine, insecticide from local plant extracts, and anti-corrosion agent for cast-iron components, anti-ulcer and anti-snake bite remedies, and distillation of essential oil, among others.

#### **Pharmacy – Issues of raw materials**

NOTAP (2016) reported the following break-through of raw materials and products that require attention of government, investors and entrepreneurs.

1. Development of an effective anti-sickling phyto-medicine
2. Development of a process for the production of pharmaceutical grade starch
3. Development of a process for the production of microcrystalline cellulose for use in drug formulation
4. Development of an effective anti-malaria phyto-medicine
5. Development of an effective anti-diabetic phytomedicine
6. Development of an effective anti-fungal phyto-medicine
7. Extraction of essential oils from local plants
8. Extraction of pharmaceutical grade artemisinin from Artemisia plant grown in Nigeria

A major success story of Academic-Industry Technology transfer in the Pharmaceutical industry in Nigeria is Niprisan, a medicine that was developed for the management of Sickle Cell disease. Niprisan was developed in 1998 by Nigeria’s National Institute for Pharmaceutical Research and Development in collaboration with local traditional herbal practitioners from Nigerian medicinal plants that is used for treating the disorder in Nigeria. The drug was granted a US patent in September 1998 and had passed through clinical trials.

Niprisan, is formulated from parts of four different indigenous plants namely: Piper guineense seeds, Pterocarpus osun stem, Eugenia caryophyllum fruit and Sorghum bicolor leaves. Though Niprisan is not a cure for Sickle cell anaemia, the drug has proved to be potent in managing sickle-cell disorder in patents, as it significantly reduces the occurrence of crises without any toxicity or serious adverse effects on patients.

However, the commercialization of Niprisan got hampered by several challenges. The exclusive rights to the patent were eventually sold to a US-based, Indian-owned company Xechem International in 2003 and successfully secured an “orphan drug” status for Niprisan in the United States in 2004 and in the European Union in 2005. Xechem established a production plant in

Nigeria and the drug was launched into the Nigerian market as Nicosan in 2006. After production slowed down the exclusive license given to Xechem International for the manufacture and marketing of the drug was withdrawn in March 2009. The Nigerian government took over production through NIPRD but its commercial production was later stopped in 2015. After the patent expired in 2017, an Illinois pharmaceutical company, Xickle started to produce its own version of the drug and the company claims its drug has twice the antisickling activity of the original Niprisan. In order to reactivate the production of the drug in the country, NIPRD signed a production agreement with a Nigerian pharmaceutical company, May & Baker in June 2018. In Nigeria we have a partnership University Industry but that has never been formalized. These partnerships allow the pharmacist student to perform internship every year in these industries. This partnership has started spontaneously and so far allows students who have made industry option to benefit from an induction internship during 3 to 4 months in the pharmaceutical industry. Also it was issued during a workshop on the development of the pharmaceutical industries in Senegal organized by the Ministry of Health and Social Action (MSAS) in relation with the Premature and in collaboration with several departments such as General Directorate of Taxes and Domains (DGID), Directorate of Private Sector Support (DASP) / Customs / Taxation / Fonsis / Fongip, APIX, Operational Office for Follow-up of the Emerging Senegal Plan (BOS), Directorate of Internal Trade, Directorate of Industry, the need to Strengthen the partnership with the University to improve the theoretical and practical training of pharmacist students in option Industry .(Source MSAS)

#### **Successes and challenges relating to university industry partnership in Togo**

The only university-industry linkage recorded is the assistance provided by the national committee (precision appointed by the Ministry of Health).

There are no particular policy incentives for such linkage. Nonetheless, there is cooperation between university and traditional practitioners even if the latter don't disclose their ingredients easily.

**Senegal** has a partnership University Industry but that has never been formalized. This partnership allows the pharmacist student to perform internship every year in these industries. This partnership has started spontaneously and so far allows students who have made industry option to benefit from an induction internship during 3 to 4 months in the pharmaceutical industry. Also it was issued during a workshop on the development of the pharmaceutical industries in Senegal organized by the Ministry of Health and Social Action (MSAS) in relation with the Premature and in collaboration with several departments, the need to strengthen the partnership with the University to improve the theoretical and practical training of pharmacist students in option Industry. (Source MSAS)

#### **In Benin, Mali, Burkina Faso, Guinea, Cape Verde.**

Considering these countries there is a need to strengthen the linkages between academia, research institutions and the manufacturing industry. Health sciences training programmes and institutions need to be re-evaluated and oriented towards the industry requirements. Universities should realign their training curricula to produce the right caliber of personnel needed by the industry. Policies, legislations and structures that promote the linkages between Universities and the pharmaceutical industry are needed to develop the local pharmaceutical manufacturing sector.

## CHAPTER THREE

### 3.0. PHARMACEUTICAL SECTOR IN COTE D'IVOIRE

#### 3.1. Promotion of local pharmaceutical industries and social inclusion through Procurement Policies and Strategies

##### 3.1.1. Current Practices with respect to procurement

Ivorian manufacturers depend mainly on imports for their local pharmaceutical production. Almost all machinery and equipment, laboratory equipment and reagents, and raw production materials, including APIs, aluminum foil for blister packaging, other labelling materials, and excipients are imported. The local contribution to production inputs in the pharmaceutical sector is limited to certain starches and sugars. It is estimated that nearly 95% of API needs are covered by imports. The use of imports for inputs has real and significant financial implications. The time required for them to arrive from Asia means that credit terms offered by suppliers can be used before inputs even reach manufacturers' warehouses and well before they are processed into end products and distributed in the market. This has a significant consequence on working capital given the high cost of financing in the country. The government's intervention is required to address this cash flow problem in order to significantly contribute to the sustainability of local pharmaceutical companies.

##### 3.1.2. National Pharmaceutical Industry

To regulate the sector and promote the pharmaceutical industry, the decision-making bodies have set up the key instrument for guiding drug policy, which is the National Pharmaceutical Policy. This policy aims to promote the development of the pharmaceutical sector with the promotion and development of local industry as one of its focal points. The policy outlines main strategies for the development of the pharmaceutical industry. However, not much success has been realized. The Ivorian pharmaceutical industries benefit from various advantages granted by the Ivorian State in order to facilitate their development:

The first is the "national preference agreement" prohibiting the import of medicines with the same active ingredient, pharmaceutical formula and dosage as those manufactured locally.

However, following the devaluation of the FCFA, this agreement is only applicable in a situation where the price of the drug does not exceed the imported one by more than 16%.

The second is called: "priority approval for investment"

Procurement in the public sector is ensured by the New Public Health Pharmacy (PSP) on the basis of a National List of Essential Medicines and Medical Consumables. The NPSP is a central government purchasing office of the NPE type (National Public Establishment of an Industrial and Commercial Nature) organized according to the terms of Decree No. 2002-334 of June 13, 2002. Regulatory measures have made it possible to carry out the reform of the Public Health Pharmacy (PSP) which has changed status from an Industrial and Commercial EPN (EPIC) to a Non-Profit Association (NPO) called "New PSP-CI" by Decree N° 2013-792 of 20 November 2013. NPSP is the main supplier to public health institutions in Côte d'Ivoire. They are required to obtain 85% (university hospitals) and 100% (other health facilities) of their needs from the NPSP. NPSP therefore has a virtual monopoly on the distribution of pharmaceutical products in these health Institutions, which constitute the totality of its. NPSP also receives support for medicines from organizations such as PEPFAR, the Global Fund, United Nations agencies,

USAID etc. PSP, which does not have departmental distribution branches, has strengthened its logistics to ensure deliveries. Despite this, stock shortages are still to be deplored in some sanitary facilities. This is why these public health facilities are authorized by the NPSP under a procedure known as the Non-PSP Procedure, to source from private companies. However, it is important to note that this derogation is not always carried out in compliance with the above-mentioned procedure.

PSP's procurement procedures include tendering international and limited consultation. A limited part of the products is however, acquired by mutual agreement. The drugs are ordered under INN in the National List of Essential Medicines. Local manufacturers participate in tenders on the same basis as external suppliers. As stated in the national pharmaceutical plan, they must benefit from the advantages of national preference or sub-regional as recommended by the Ministers of Health of the CFA franc zone since December 1999(As stated in the national Pharmaceutical policy).However, we noticed that they do not really benefit from the advantages of national preference regarding tender business because of their lack of competitiveness compared to imported drugs and their inability to honor volumes of medicines ordered by NPSP

The support of the State is essential to enable the development of local industry. It must take the form of a public procurement orientation and incentive public policies, like what has been done in other countries (Morocco, Tunisia and Egypt) with conclusive results. For example, Morocco, which is the continent's second largest pharmaceutical producer after South Africa, has introduced and reinforced the principle of national preference into public tenders. Now, the country has about 40 industrial pharmaceutical units, which supply more than 70% of domestic demand and export part of it to neighboring countries.

With regard to public procurement in Cote d'ivoire, it is necessary to reinforce and to make applicable mechanisms by which public and private purchasing centers obtain their supplies primarily from local producers, and use imports only to fill volumes that cannot be served locally. Expectations are high in the management of public purchasing bodies, both for the reliability of their orders and for the timely payment of receivables, which, when late, can have a significant impact on the cash flow of producing companies.

Incentive policies must take into account the specific characteristics and constraints of the pharmaceutical industry. The installation and maintenance of production equipment requires significant investments. To regulate the sector and promote the pharmaceutical industry, the decision-making bodies have set up the key instrument for guiding drug policy, which is the National Pharmaceutical Policy of 2015, updated and the Strategic Plan for the Implementation of the National Pharmaceutical Policy (October 2016).

The Strategic Plan for the Development of the Local Pharmaceutical Industry (July 2017) aims to promote the development of the pharmaceutical sector with the promotion and development of local industry as one of its focal points.

This Vision is translated into strategic objectives divided into 3 steps:

### **1<sup>st</sup> Step:**

- Achieve within 5 years 30% coverage of national drug needs through local manufacturing
- Mobilize investments in the pharmaceutical industrial sector amounting to US\$100 million over these 5 years

## **2<sup>nd</sup> Step:**

- Reach 45% coverage in 10 years
- Conquering the Ivorian IPL image = quality IPL improving the accessibility and availability of medicines

## **3<sup>rd</sup> Step:**

1. Become a major drug supplier in the region

To achieve these assigned strategic objectives, a strategic action plan to promote local industries has been drawn up in 22 actions to undertake:

1. Government Commitment
2. Organization of an international symposium on the promotion of local pharmaceutical industries
3. Tax measures including VAT
4. Advantages of emerging industry and protective measures
5. Organization of partnership days (country / country)
6. Awareness note for the banking system
7. Granting of sector-specific credit lines
8. Discussion with international organizations for the implementation of support funds for study
9. Creation of an industrial zone dedicated to non-polluting industries
10. Advantages of public procurement
11. Coordination with health insurance
12. Implementation of an Anti-Dumping Monitoring Cell
13. Development of a specific investment code
14. Strengthening of the pharmaceutical regulatory authority
15. Implement WAEMU regulations
16. Increase drug registration fees and remits them to the Agency (NLSP in the meantime)
17. Review the list of imported medicines taking into account the quality/efficiency/cost ratios with local products.
18. Review the Deadline for Granting Operating Licenses
19. Increase in profit margins for local products.
20. Continue the upgrading programs
21. Evaluation of implementation of this strategic plan and assessment of sectoral developments (every three months and at each time as necessary)
22. Implement a strategy for the training of senior managers and technicians attending to work in local Pharmaceutical industries.

Despite the implementation of the strategic action plan, it must be noted that, not much success has been realized mainly due to the lack of real commitment of the actors in charge of its roll-out.

### **3.1.3. Tax incentives to promote investment in Cote d'Ivoire**

In 1986, the strategic status of the pharmaceutical industry was already recognized by the Côte d'Ivoire authorities and the first local pharmaceutical manufacturing units were already given priority approval. This approval granted local Pharmaceutical manufacturing (LPM) full exemption from customs duties and VAT on investments (industrial equipment, spare parts,

materials and construction costs for industrial buildings). A 10-year exemption from income tax on industrial and commercial profits had also been granted. Other benefits that investors in the pharmaceutical industries can benefit from include:

- a. Tax exemptions ranging from 50% to 75% over a period of five (5) to fifteen (15) years depending on the investment areas.
- b. Tax exemptions relate to income tax, including the flat-rate minimum tax, the contribution of patents and licenses, the contribution payable by employers, the tax on income from securities for dividends paid to national shareholders and the tax on property assets.
- c. Tax credits determined as a percentage of the amounts invested. At the end of the implementation of their investment programs, the rates set by the new code vary between 25% and 50%.

### **3.1.4. Local content**

Since August 2018, Côte d'Ivoire has had a new investment code; since August 2018, Côte d'Ivoire has had a new investment code. The investment code established by Order No. 2018-646 of 1 August 2018 is a set of incentives put in place to adapt the private investment regime to new economic conditions, including growth prospects.

The main objective of this investment code is to:

1. To encourage and promote productive investment, green and socially responsible investment in Côte d'Ivoire towards the processing of local raw materials
2. Encourage the creation and development of activities aimed in particular at The creation of sustainable and decent jobs
3. Production of competitive goods for domestic and export markets
4. Technology promotion, research and innovation

International investors are invited to rely on local companies in the conduct of their operations in order to benefit from the facilities offered by the new legal framework. The objective is of course to open up spaces of opportunity for SMEs and to give a more inclusive character to Ivorian economic growth. Thus, large foreign companies eligible for tax benefits, particularly those entitled to tax credits, must favour an approach resolutely focused on promoting Ivorian industry in terms of job creation, opening up share capital to nationals and subcontracting.

For local employment, an additional tax credit of 2% is granted to foreign investors whose number of Ivorian executives and supervisory staff represents 90% of the total number of these two categories of employees. The same rate is applied to companies that subcontract to national companies, the realization of goods intended to be incorporated into a final product in Côte d'Ivoire and abroad as well as for companies that open their share capital to nationals. The implementing decree of 18 December 2018 identifies the conditions for access to the tax credit. Companies in agriculture, agro-industry, health and hotel sectors as well as companies in other sectors of activity excluding companies in the trade and liberal professions, the banking and financial sectors and the non-industrial construction sector. These companies must also open at least 15% of their share capital to Ivorian nationals.

### **Impacts of the Ivorian Investment Code**

1. Rebuilding human capital
2. The reduction of production and transaction costs in its economy as a whole.

3. The repositioning of its industry in a difficult global geopolitical context with low growth, a latent crisis in the global financial system and major constraints (common industrial policy, international agreements such as EPAs, GATT, WTO, etc.).
4. diversification and densification of its existing industrial fabric, which remains one of the most important more sophisticated in the region in terms of consistency with the country's comparative advantages in through:
  - a. The attraction of massive FDI in a global recession context
  - b. Maximizing its market share in a context of strong economic growth of the Nigerian and Ghana economies.
5. Drastic improvement in capacity domestic entrepreneurial

### **3.1.5. Regional Programs on public procurement and local industries**

Regional pharmaceutical production is very low and the regional market has no harmonized regulation. As a result, the cost of access to essential medicines remains high, leading to the massive importation of medicines. The WAHO (West African Health Organization) and the West African Producers' Association work together to promote pharmaceutical Manufacturing. The objective of this collaboration is to promote and support competitive and efficient regional pharmaceutical production to ensure the supply of 30% to 60% of essential drugs produced in the region by 2020. To this end, several actions are underway, in particular through WAHO: Harmonization of registration procedures in collaboration with NEPAD, the revision of the TEC for pharmaceutical products, advocacy missions at the level of the country and the level of the partners, and a program to strengthen the capacity of regional pharmaceutical industries in terms of GMP (Good Manufacturing Practices. WAHO guidelines on procurement strategies play a vital role in promoting the pharmaceutical industry:

1. Advocate for a zero-tariff policy on pharmaceutical raw materials within the framework of the ECOWAS Common External Tariff (CET)
2. Advocate for finished pharmaceutical products and other inputs to be exempt from VAT
3. Identification of API manufacturers, help them build their capacity to enable them to supply the pharmaceutical production sector
4. Identify manufacturers of EXCIPIENTS; help them to build their capacity to develop their products to supply the pharmaceutical production sector

### **3.1.6. Experiences, best practices and success stories from those countries that have implemented such policies on the impact [Plan de fabrication pharmaceutique pour l'Afrique, 2012]**

Countries with a thriving pharmaceutical industry, such as India, China and Brazil, provide significant government support to their producers in the form of incentives and protectionist policies. Policy instruments that have been used to protect the pharmaceutical sectors in these regions include.

- 1. High customs duties on imported products:** For example, India applies customs duties on formulas up to 56% on import tariffs. Brazil 15% on formulas and China has recently imposed import tariffs of up to 37% on sulfamethoxazole (SMZ) imported from India.
- 2. Purchasing preferences:**

- a. Brazil enjoys preferential prices of 25%
- b. Russia has introduced measures to ensure that 70% of the products purchased by the state are manufactured locally and this has apparently led many Indian companies to consider building manufacturing plants in Russia.
- c. South Africa benefits from preference points for local production in tenders and is currently replacing this system with another in which a percentage of designated products will be purchased only from domestic producers. Legislation on purchasing preferences is in place in a number of other countries in Africa, but it is not always implemented.

These examples highlight that some emerging countries have taken active measures to protect and support their pharmaceutical industries. Manufacturers often also benefit from other types of support. In India, producers of drug formulations receive substantial government support to promote exports, including Duty-free imports of equipment and raw materials for the products to be exported. Others include ten years of tax relief if located in Special Economic Zones (SEZs); and export credits; low utility rates; working capital loans and valued depreciation allowances

### **India**

[Catching up in pharmaceuticals: a comparative study of India and Brazil, Samira Guennif, Shyama Ramani]

When India attained its independence in 1947, its pharmaceutical industry was of a very modest size with market sales of about \$28.5 million (Ahmad, 1988). Western multinationals (MNCs) held about 80% of the market with the remainder being served by several Indian owned companies operating on a much smaller scale. No Indian company had manufacturing capabilities in either bulk drugs or formulations. There was heavy dependence on imported drugs, which were marketed directly by the MNCs established in India and local agents of MNCs that did not have a local presence. MNCs mainly formulated their drugs in India, importing the bulk drugs from their home countries; their contention being that the locally available bulk drugs were not of the desired quality. In the process, not only were technological externalities and knowledge transfer absolutely minimal but Indian drug prices were among the highest in the world (Ramani and Venkataramani, 2001; Greene, 2007). Thereafter, the evolution of the Indian pharmaceutical industry can be divided into four phases:

1. First attempts to reduce dominance of foreign firms.

After twenty years of the 'License Raj' and an import substitution policy, 80% of the market share was still held by foreign controlled firms in 1970. Indian firms had capabilities only in formulations. Prices of drugs remained among the highest in the world, partially due to import duties, but mostly because firms were focused on brand competition and promotional activities (Lall, 1974a, 1974b). Indian consumers suffered from a shortage of essential drugs and a crisis in terms of healthcare provision. MNCs on the other hand fared well: they were in India "not only the most profitable among manufacturing firms in the country generally but also among all types of foreign controlled enterprises, including those in non-manufacturing sectors" (Lall, 1974b; p.163).



## 2. Development of re-engineering capabilities and conquest of internal markets

The change in the IPR regime coupled with the dynamic response of local firms to acquire capabilities in all stages of drugs production led to a sharp reduction in import dependence and MNC domination. But, this would not have been possible had India not been equipped already with scientific capabilities in the form of public laboratories skilled in creating new processes; and universities producing large numbers of science graduates. The demand side also supported the new trajectory as Indian consumers revealed themselves to be extremely price sensitive

## 3. Development of regulation handling capabilities and assault on international markets.

After 2000, in order to supply public health programs in developing countries supported by international organizations such as the WHO, Indian firms had to comply with a prequalification process of product-selection and regulations related to WHO-GMP. Thus, though these requirements did not affect the small and medium scale suppliers of intermediate or bulk drugs, the leading pharmaceutical firms that supplied international markets adopted GMP, even when it was not required within India. The WHO also demanded other complementary practices such as submission of 'Drug Master Files' giving details of the firm and its system for ensuring quality, documentation, validation, self-inspection and internal audit. The success of the Indian firms in acquiring regulation handling capabilities is illustrated in the fact that on antiretrovirals, out of the 85 products selected by the WHO to treat the HIV/AIDS epidemics in the developing world, Indian firms such as Ranbaxy, Cipla, Aurobindo or Matrix Laboratories prequalified for the supply of 60 products in 2009.

## 4. The quest to build new drug discovery capabilities in the post-TRIPS era.

### Comparative table of the pharmaceutical sector by country (Africa)

	Ghana	Macro	Tunisia	Cote d'Ivoire
Manufacturing Units	38	32	56 <sup>31</sup>	8
Coverage rate of needs (%)	30	70	49	6
Import taxation	Yes	No	No	No
Charges for local products <sup>32</sup>	Yes	Yes	Yes	Yes
Tax exemption <sup>33</sup>	Yes	NO	Yes	Yes

<sup>31</sup> Including veterinary and medical devices manufacturing factories

<sup>32</sup> Charges for local products (VAT and other taxes)

<sup>33</sup> Tax exemption on raw materials and packaging articles

### **3.2. Human Resource Development for the Pharmaceutical Manufacturing Sector**

#### **The current human resource situation in the pharmaceutical industries in Cote d'Ivoire and what coping strategies the industries have adopted.**

The main problems highlighted by the analysis of the situation of human resources for health concern:

1. Weak institutional capacity for human resource management for health.
2. Insufficient coordination, planning, programming and monitoring and evaluation at the central, decentralized and decentralized level,
3. The imbalance between the production of health professionals and the needs of human resources in quantitative terms,
4. The imbalance between the profiles and skills of health professionals and the needs of the health system,
5. Shortcomings in the evaluation and accreditation of training institutions,
6. The inadequacy between the people trained by the training institutions and the real needs of the system,
7. The low capacity of central and decentralized structures in charge of human resources management for health
8. Poor development of human resources in terms of their remuneration, career profile and continuous reinforcement of their skills,
9. The weakness of the strategic information system and operational research,
10. Insufficient budgetary allocations to meet human resource needs.

#### **3.2.1. The Status of Human Resource for the LPP in Côte d'Ivoire**

One of the most fundamental aspects of the long-term sustainability of the pharmaceutical industry in Côte d'Ivoire is the development of the human resources necessary to fulfil the various functions within the pharmaceutical production system. In addition to academic qualifications, the pharmaceutical workforce needs specific practical training to be productive. In Côte d'Ivoire, the shortage of skilled labour is one of a major obstacle to the growth of pharmaceutical production. The pharmaceutical manufacturing system requires specialized skills in a number of disciplines, including pharmacy, chemistry (analytical, organic, synthetic, therapeutic), biological sciences (biochemistry, microbiology, molecular biology), engineering (mechanical, electrical, chemical, industrial processes), life sciences (medicine, pharmacology, toxicology), and management (strategy, financial management and operations, logistics, commercial law, etc.) and information and communications technology, among others. The pharmaceutical industry has a need for university graduates and highly qualified professionals in a wide range of disciplines, including science, engineering, technology, management, law and ICT.

The system requires a strengthening of human capital within regulatory functions, technical aspects of manufacturing, trade and manufacturing management aspects, and the sphere of policy development. The local pharmaceutical industry suffers from a shortage of qualified workforce. Local manufacturers are forced to call on skills from other countries to fill this gap. Manufacturers are often forced to recruit industrial pharmacists and technicians trained in Western countries to palliate this lack of qualified human resources

### **3.2.2. The role played by the national universities and other training institutions in Cote d'Ivoire to address the human resource challenge.**

The following below summarizes the human resource training and deployment in Cote d'Ivoire:

1. As the development of qualified human resources is one of the major conditions for achieving the objectives of the National Development Plan for Health (PNDS), the government has put in place a human resources development strategy to train human resources capable of meeting the various health challenges. This process, which was carried out in collaboration with other relevant departments, institutions and authorities, in order to define the Government's vision, career plan, staff retention strategies (skills development and strengthening, benefit definitions, motivations, recruitment plan, etc.). Unfortunately, this strategy is not specific to the promotion of the local pharmaceutical industry.
2. Since its creation in 1977, the Pharmaceutical and Biological Sciences Faculty has trained more than 1500 pharmacists. The Biological and Pharmaceutical Sciences Faculty of Côte d'Ivoire is the only school officially dedicated to the training of pharmacists. It does not have a highly specialized training program for the pharmaceutical industry. Pharmacists trained in are not specialized in the Pharmaceutical Industry. The sector is full of pharmacists with notions in pharmaceutical manufacturing acquired during their university training but are not specialized to lead and operate a pharmaceutical industry. To solve this issue, we recommend that Universities must adapt their curricula to modern trends in the evolution of the pharmaceutical industry. Areas such as regulation, pharmaceutical technology, drug formulation and development, and clinical studies need to be strengthened.
3. Secondly The regional harmonization of the curricula of training for first, second and third cycles of pharmacy studies would lead to the production of a qualified workforce and the improvement of the practice of pharmacy.
4. The Postgraduate College of Pharmacists of West Africa (WAPCP) could play a key role in training pharmacists and pharmacy researchers who can possess the required expertise and meet the demand of the pharmaceutical market in the ECOWAS region.
5. Pharmacists wishing to acquire this expertise are moving to Western countries to train. At the end of their training, they are hired by the pharmaceutical industries of the host countries. Also, the lack of availability of qualified human resources among the wide range of identified disciplines is a major constraint and that the resources and expertise required are insufficient to improve the skills of those working in this industry.
6. The proposed access to the required know-how is limited to implement international GMPs.
7. In order to strengthen the competence of its human resources as part of its support to the local pharmaceutical industry, representatives of the Ivorian Government have formed a partnership with VCU (Virginia Commonwealth University) officials to provide Ivorian researchers with the necessary skills to establish world-class pharmaceutical practices. VCU's Medicines for All Institute, part of the College of Engineering and funded by the

Bill & Melinda Gates Foundation, is directly involved in this partnership. The institute is working to improve the accessibility and availability of life-saving drugs for a multitude of diseases. Students will come from Côte d'Ivoire to this school and learn the techniques... and bring them back to Africa to improve the production of these drugs in a place where they are really needed. This Agreement with the Ivorian government will enable the University to work closely with scientists in the country, helping them to strengthen their expertise in the production of these drugs in their home countries. Students from Côte d'Ivoire regain valuable skills and abilities; this could then follow them home, allowing them to develop pharmaceutical technologies. VCU will also provide its research and planning expertise to help the Ivorian government establish a research institute at the National Polytechnic Institute Félix Houphouët-Boigny in Côte d'Ivoire, as well as the construction of a new drug treatment center. VCU was founded in 1838 as the medical service of Hampden-Sydney College, becoming the VCU Medical Center in 1854. With a record \$256 million in subsidized research funding in fiscal 2011, VCU is designated as a research university with a very strong activity in this field.

### **3.2.3. Role the people from Cote d'Ivoire in the diaspora can play to provide the required human resource expertise in the pharmaceutical industries.**

The Ivorian diaspora represents an important and useful financial power for local populations living in Côte d'Ivoire. The estimation of the economic power of the diaspora is based mainly on the amounts of financial transfers made from abroad to Côte d'Ivoire. Reducing poverty in the country is a major challenge. In addition to its financial contribution, the diaspora also represents a pool of human resources, skills and know-how that can contribute to economic development, including through job creation. The diaspora has a spirit of initiative that allows it to occupy a strategic place in the overall social structure. Thus, the diaspora could intervene in the development of local Pharmaceutical industry:

1. By providing qualified human resources.
2. By investing massively in training by offering scholarships to young Ivorian's wishing to pursue careers in the pharmaceutical industry on the condition that they return to Côte d'Ivoire after their training to serve the local industry
3. Contribute to the financing of a training school specialized in Pharmaceutical Industry in Côte d'Ivoire
4. Strengthen the partnership with European and American universities for training and capacity building for managers and the local workforce

### **3.2.4. Collaboration with countries from Asian countries can help to support the sector**

The Chinese government pledged to invest \$60 billion to support the continent's development at the Forum on China-Africa Cooperation in Johannesburg in December 2015. Cooperation on health was one of the priorities of the meeting, and China encouraged its companies to support African pharmaceutical production to facilitate access to medicines exclusively to investment projects in Africa. Thus **Branch of Human well Healthcare**, a **Chinese pharmaceutical group** opened its first plant on the continent, in Mali, in early 2015. Covering an area of 69,000 m, the plant employs more than 200 Malians, including executives. All have received training in

modern pharmaceutical production techniques. "This plant will benefit the population by ending the lack of drug production in Mali. As a result, the whole of West Africa now has access to its range of medicines, including serums and syrups.

### **3.2.5. Support of Cote D'Ivoire to help other French speaking West African countries to develop their local pharmaceutical industries**

Drugs manufactured in Côte d'Ivoire are distributed on a market that extends to all WAEMU countries and some countries in the CEMAC zone where French-speaking distribution networks are established. Côte d'Ivoire is the most important market in French-speaking West African countries. The top three countries (Côte d'Ivoire, Senegal and Cameroon) account for more than 50% of the regional pharmaceutical market. Of the top three countries, Côte d'Ivoire has the most dynamic market. The development of the pharmaceutical industry in Côte d'Ivoire could help the industry of other West African countries through the following recommendations:

#### **Recommendations**

1. The Training of human resources from West African countries in Côte d'Ivoire through specialized training programs oriented towards the pharmaceutical industry: A comprehensive program of short-term courses for current employees and those aspiring to join the sector
2. The creation of industrial specialty programs in neighboring countries thanks to the training experience acquired by learners in Côte d'Ivoire. Learners will benefit from short-term training for engineering teams, craftsmen and machine operators to overcome the lack of skills and experience required in tooling, manufacturing and optimal maintenance of the installation and operations.
3. The experience of pharmaceutical industrialization acquired in Côte d'Ivoire by investors could motivate the duplication of the Ivorian model in neighboring countries through the establishment of robust pharmaceutical industries.
4. Development of quality and experienced human resources ready to drive the development of the pharmaceutical industry in their country.
5. Creation of a specific pharmaceutical program of long-term courses for regulators and industry in the sub-region.

### **3.3. Research and Development**

#### **3.3.1. National, regional and international R&D activities in the pharmaceutical sector in Cote d'Ivoire.**

The majority of R&D projects for people in the South are public-private partnerships (PPPs). These partnerships are considered essential in the discovery and development of products needed for millions of patients in markets that are not commercially viable. They involve multiple stakeholders, including public and academic institutions, the pharmaceutical and biotechnology industries, private foundations and NGOs, whose skills are complementary.

Public bodies have an important role in fundamental research and the advancement of scientific knowledge, from genome to structural biology, which are at the origin of many active

ingredients. The pharmaceutical industry has an essential function, which is to convert scientific discoveries into effective and safe products through clinical research.

Many programmes (Global Fund, Melida and Bill Gates Foundation, EGPAF, PEPFAR, Ect...) have been implemented to organize the fight against the main pandemics (AIDS, malaria, tuberculosis), tropical diseases and other neglected diseases in Côte d'Ivoire. However, due to a lack of sufficient resources and a lack of a specific pharmaceutical R&D support programme, Ivorian producers are unable to develop R&D capacities in the direction of diseases or to supply local markets fully with medicines.

The model developed in Côte d'Ivoire is that of an industrial activity of generic drug formulation. It is the creation of industrial added value from (imported) components whose quality compliance with international standards must be checked on site. The transformation activity must be carried out by qualified and competent human resources, based on processes and procedures defined in the specific pharmaceutical regulatory framework.

Research and development of new molecules, chemical synthesis of components and the manufacture of biotechnology-derived drugs are not currently part of the activity of local industries. In terms of research and development in the pharmaceutical sector in Côte d'Ivoire, we note:

1. Lack of coordination of research and development activities;
2. Insufficient operational research activities in the pharmaceutical sector;
3. Insufficient exploitation of research results;
4. Lack of research and development policy for improved traditional medicines.

### **3.3.2. R&D activities on drug development targeting treatment of malaria and HIV-AIDS based on indigenous knowledge and biodiversity in Cote d'Ivoire.**

#### **Malaria**

Malaria is a real scourge and is considered a public health problem in Côte d'Ivoire. Transmission is stable; it represents the first reason for consultation in the country's health facilities, the first cause of morbidity and mortality. The fight therefore appears to be a vital issue for this country, which is emerging from a decade of successive socio-political crises that have weakened it in many areas.

Researchers from the University of Bioscience and the Pharmacodynamics and Biochemistry Laboratory have identified and highlighted the antimalarial properties of plants found in central Côte d'Ivoire (Toumodi) and used by the peoples of the centre for malaria treatment. This study identified 26 plant species that may have antimalarial effects. After the Analyses 8 of the 26 plants have proven their antimalarial properties. The latter have been used in malaria control treatment and have proven effective at various doses.

This study was carried out with a view to photochemical, pharmacological and toxicological experiments and the implementation of innovative initiatives that could lead in the future to the manufacture of improved traditional medicines (ATMs).

Other Ivorian scientists are raising public awareness on Artemisia or wormwood, a natural remedy considered effective against malaria, and whose popularization could help eradicate this disease from the country. It is a plant that comes in the form of: Artemisia Annuua (of Chinese origin), and Artemisia afra (of African origin). Artemisia has several therapeutic virtues, but most of the studies are focused on malaria, especially in Côte d'Ivoire, where the disease burden

is very high. Since the remedy does not contain any toxic products, it does not cause any side effects in the patient and has not yet been subjected to resistance. The researchers are training half a dozen people with their team, who have come voluntarily to learn how to grow wormwood. This plant is consumed as an herbal tea to treat malaria. An important advantage of Artemisia is its accessibility. "It can be grown anywhere, even at home, and at home. It is within everyone's reach. To date, Artemisia is grown in experimental fields, particularly in Grand-Bassam, not far from Abidjan, but also in the botanical garden of the University of Korhogo.

### 3.3.3. Performance of Local Pharmaceutical Production

Turning to the industrial angle of the pharmaceutical sector, the share of local production represents about 6% of drug consumption in Côte d'Ivoire, unlike Ghana where it is above 35% and above 45% in Nigeria. The number of pharmacies in Côte d'Ivoire is 1105 and the market share is estimated at more than 200 billion CFA francs. Figures considerably below targets and lower than those of countries such as Ghana (400 billion CFA francs) and Nigeria (1350 billion CFA francs). Currently there are nine production units listed in the Table below.

Local Pharmaceutical manufacturing	Inception Date	Geographic Address
GALEFOMY	1989	BOUAKE
S-TERRE	2000	ABIDJAN
ROUGIER PHARMA	2009	ABIDJAN
PHARMIVOIRE NOUVELLE SA	1999	ABIDJAN
OLEA	2007	ABIDJAN
CIPHARM	1988	ABIDJAN
LPCI	1997 ACTIVITY 2004	ABIDJAN
DERMOPHARM	1992	ABIDJAN
LIC PHARMA	1998 ACTIVITY 2002	

Out of nine production units listed in the country, five are active. At the local market level, Olea hold 35% of the market, Cipharm (33% of the market), Lpci (26%), Lic pharma (18%), Pharmivoire Nouvelle (12%). At the sub-regional level, Cipharm is ahead with more than 50% market share (below are the market shares of the various companies).

In terms of turnover (See Table below) CIPHARM is leading followed by OLEA then LPCI, LIC PHARMA and finally PHARMIVOIRE Nouvelle (Excluding public procurement). PHARMIVOIRE Nouvelle benefits from a higher increase in turnover due to the majority hospital use of its production (50 to 80%) made up of injectable massive solutions. This turnover from public structures was of lesser importance for the other three IPLs (Cipharm, Oléa, Lic Pharma). However, the New PSP, which restarted operations in 2014, allows IPLs to achieve a significant increase in their domestic revenue.

#### Turnover achieved by the four IPLs on the sub-regional market

IPL	Revenue (Billion FCFA)	%
CIPHARM	7	50%
OLEA	3,7	26%
LPCI	1,5	11%
LIC PHARMA	1	7%
PHARMIVOIRE NVL SA	0,8	6%
TOTAL	14	100%

It should also be noted that Ivorian pharmaceutical production is highly competitive on its domestic market with generics mainly from India and China. In order to compensate for the shortfall and not to remain below critical production thresholds to ensure their survival, IPLs rely on traditional purchasing groups well established on the French-speaking market to export their production to the sub-region. This strategy is essentially adopted by CIPHARM, which exports more than 50% of its production to the region, while the other 3 companies sell their production on the local market. On another level, and due to the relocation of purchasing groups to France, IPLs incur an export charge that represents approximately 15% of their turnover. Apart from the impact on the price of locally produced medicines, the relocation of traditional power plants extends the time required to make IPL production available on the regional market. The model developed in Côte d'Ivoire is that of an industrial activity of generic drug formulation. The trend prospects are as follows:

1. Local production under license guaranteeing international quality standards,
2. Direct or custom production of generics, whose technology is available or transferable,
3. The improvement of traditional medicines

#### **3.3.4. Locally produced pharmaceutical forms**

The locally produced pharmaceutical forms are described here below:

- 1. Dry forms (tablets and capsules):** They are the most accessible in terms of production and are the main drug form in Côte d'Ivoire. About 40% of the drugs marketed in the private sector are in the dry form. 4 units locally produce 15% of these dry forms consumed in the country but the available production capacity is underused and represents 30% in dry form units. The production of dry forms in the medium term can be increased to 70% of needs in order to promote better accessibility of medicines.
- 2. Liquid forms:** The high import costs of these forms make it necessary to have local production. Syrups and other oral liquid forms represent 25% of pharmaceutical forms in the private sector. 3 units produce locally about 19% of syrups and suspensions. The available production capacity represents 32% for Oral Liquid forms and the medium-term production potential can be increased to 60% of unit needs for accessibility.
- 3. Injectable forms:** Injectable forms are essentially hospital-based drugs with a significant impact on health safety. Injectable products are high-tech but represent only 8% of all drugs sold in the private sector. 2 units produce massive injectable solutions for about 30% of the national needs of the private sector but only partially covers the demand of the public sector. The production of solid solutes should be encouraged as this is a major health and safety issue. Import transport costs for intravenous solution are high.

#### **3.3.5. Case study: Specific case of CIPHARM**

**CIPHARM** was created in December 1986 and inaugurated in May 1988; CIPHARM is a public limited company with a board of directors with a capital of 600 million CFA francs. CIPHARM, Market Leader in local pharmaceutical production, produces 50% of the medicines manufactured in Côte d'Ivoire (in terms of production) with a market share of 32%. Since its creation, CIPHARM has invested 13.5 billion CFA francs in its production facilities. **The company is 80 % owned by Ivorian private pharmacists.** The remaining 20 % is shared



between Laborex CI and COPHARMED. The company's core business is to manufacture and market pharmaceutical products; whereas its activities include: manufacturing and custom packaging (manufacturing, packaging) of pharmaceutical products for third parties; manufacture on site essential specialities; make these specialities available throughout the year; control manufacturing costs and therefore sales prices; and make generic DC products available to the most disadvantaged. The following points are worth noting under this case study:

**Strategy:** Ivorian pharmaceutical production represents between 6 to 10% of local consumption. 90 and 94% of consumption is imported from Europe and Asia by large international groups that flood the Ivorian market. CIPHARM has had to deal with this as follows:

1. To fill this gap and produce in large quantities on the national territory, CIPHARM has had a new manufacturing unit since 2017. In order to meet the quality requirements of the pharmaceutical industry, Cipharm has set up a modern and efficient laboratory equipped with state-of-the-art equipment (UV-visible spectrophotometer, spectrophotometer, computer-controlled infrared, HPLC chains, potentiometer, etc.). Highly qualified technicians ensure the various controls on inputs and manufactured drugs.
2. Built to the highest standards and equipped with modern equipment, Cipharm (3,400 m<sup>2</sup> of construction) meets the international requirements of Good Manufacturing Practices (GMP). The plant has been validated by the DPML and by major international laboratories, which have entrusted it with manufacturing. All materials in contact with the drug are made of stainless steel (inertia of the material, high washability). A total of 750,000 tablets are produced each year from the production lines. But also injectable solutions, skin powders, syrups, ointments, suppositories, capsules.
3. These products are manufactured for the Ivorian market and 16 countries in the sub-region where they are marketed. In 2018, the company achieved a turnover of 4 billion CFA francs. Since 2017, CIPHARM has had a new production unit for injectable solute: production of Glucose, salt and paracetamol in bags (a first in Côte d'Ivoire). CIPHARM produces 3 million bags per year but is far from the minimum 25 million recommended by the WHO to make Ivory Coast self-sufficient. The company would like to expand its production capacity but is struggling to amortize the loan contracted to launch this unit. (5.7 billion CFA francs).

**Other challenges:** Despite all the efforts made, the company is facing many challenges:

1. **Raw material supply:** 100% of the chemical components and raw materials come from abroad because they are not produced in Côte d'Ivoire. As a result, CIPHARM has to import raw materials worth CFAF 2 billion from abroad on a highly speculative international market. Once in port, these raw materials can be blocked for several days: The cause: excessively long administrative procedures and without raw materials, no medicines. The cumbersome administrative procedures penalized production, which takes 4 months from the purchase of raw materials to the release of the drug. This extension of production times has a cost that is difficult to compress.

2. **Financing gap:** Financing is needed to increase production capacity: Slow start-up, very long-term credit, unfavorable bank interest rates (12 to 13%) instead of preferential rates at 5-6%.
3. **Compliance:** with manufacturing and safety standards, while important, adds to the cost. For example, in order to meet the quality requirements of the pharmaceutical industry, Cipharm has set up a modern and efficient laboratory with cutting-edge equipment (UV-visible spectrophotometer, spectrophotometer, computer-controlled infra-red, HPLC chains, potentiometer, etc.). Highly qualified technicians carry out the various controls on inputs and manufactured drugs. A warehouse with a capacity of approximately 1,500 pallets, on four storage levels, with different areas: quarantine of inputs, storage of accepted inputs, quarantine of finished products, storage of finished products, storage of rejected items
4. **Competition with the Sector's Giants and other Chinese and Indian pharmaceutical industries:** To protect himself from this competition, the CEO of CIPHARM pleads for a national preference called BLACK LIST prohibiting the import of drugs already manufactured by the local industry. Countries like Ghana, which developed a local pharmaceutical industry later than Ivory Coast consumes 30% of local production. Nigeria is above 40% and the Maghreb countries such as Morocco and Tunisia are at more than 70%, the Ivory Coast is barely at 7%. While waiting for the black list, CIPHARM faces fierce competition on the Market.

### **3.4. World Health Organization (WHO) Certification**

#### **3.4.1. Status of Pharmaceutical Companies in Cote D'Ivoire on WHO certifications.**

In Côte d'Ivoire, Artemisinin-based Combination Therapies (ACTs) have been the rule in the treatment of simple malaria since 2005. Artesunate-Amodiaquine (AA) is recommended as a first-line treatment, in conjunction with Artemeter-Lumefantrine (A-L) since 2012. Until now, of the 10 laboratories registered with the Directorate of Pharmacy and Medicines (DPM), 3 produce CTAs, and one was refurbishing them from 2010 to 2014. They provide the private market. The public market being closed to them since it is supplied by the Global Fund, which requires WHO prequalification, which none of them have obtained to date. Nevertheless, among the two laboratories producing dry forms of A-L, one of them (LICPHARMA) holds the majority of the market shares at the national level (private therefore) while the second (CIPHARM) 2nd national market share, develops a larger production than the latter, having outlets in the sub-region. A third (OLEA) producing powders for A-A suspension has just developed a dry form of A-L, and the fourth (LPCI) reconditioning A-A microspheres, which it has just abandoned. As we can see, local firms are moving towards the production of A-L.

#### **3.4.2. Support provided by government and other organizations**

Although pharmaceutical production has existed in some ECOWAS member countries for several years, none of the pharmaceutical manufacturing companies has so far been able to obtain WHO prequalification or Good Manufacturing Practices (GMP) certification for a given product. This is an essential condition for success, as antiretroviral drugs, antimalarial drugs and anti-tuberculosis drugs are mainly purchased by donors who require that the companies that produce the products they purchase have international certification.

WHO has selected and approved five pharmaceutical manufacturing units in Nigeria and two in Ghana, which have expressed interest in WHO pre-qualification. These units will be supported to enable them to obtain certification within the next two to three years. Thus, as a strategy to facilitate regional trade in quality assured pharmaceuticals, an ECOWAS/WHO certification system for finished products, pharmaceutical raw materials and pre-qualification criteria documents, intended to be used for the evaluation of pharmaceutical manufacturers for marketing authorization, were developed in 2011. This is an opportunity for countries and pharmaceutical manufacturing companies to participate in the process to demonstrate their ability to source drugs from certified sources in the region and to gain access to the regional market. To achieve the assigned objectives, the following activities are carried out:

1. Publication of a call for expressions of interest document to allow interested companies to indicate their desire to participate in the ECOWAS pre-qualification and certification mechanism.
2. Carrying out an audit of the selected companies and identifying their shortcomings
3. Establishment of an incentive system for progress in terms of compliance criteria with certification and pre-qualification mechanisms.
4. Development of a GMP roadmap for manufacturers in the region.
5. Provision of technical support and capacity building to companies that have expressed interest in obtaining international certification.
6. Provision of technical and financial support for the updating of the Regional Centre for Bioequivalence and Biopharmaceutical Research (CBBR) in Ghana

### **3.5. Academia-University – Industry Linkages**

#### **3.5.1. The current successes and challenges relating to university industry partnership in Cote d'Ivoire.**

Science and technology are the essential drivers of industrial, economic and social development and, in this process, university-industry cooperation is fundamental. The Partnership for the Development of Applied Science, Engineering and Technology Skills (PASET) is an initiative launched in 2013 and led by 5 African countries (Côte d'Ivoire, Ethiopia, Kenya, Rwanda and Senegal) jointly with the World Bank. It aims to fill systemic gaps in skills and knowledge in the fields of applied science, engineering and technology (ASET). It also aims to strengthen the capacity of African higher education institutions to train high-level technicians, engineers and scientists to meet the demands of African economies.

In Côte d'Ivoire, there are examples of partnerships between schools of excellence and the private industrial sector. These partnerships generally aim to:

1. Strengthen the capacity and expertise of graduates in the fields defined in the partnership in order to conduct development projects in the industry concerned: this is the case of the Partnership between the Houphouët Boigny National Polytechnic Institute and the construction and public works company PFO-AFRICA-Cote d'Ivoire to set up a Management Chair
2. Assistance, advice and expertise from schools of excellence to propose solutions to the partners' technical teams and the provision of schools' technical facilities for certain

partner activities: Case of the partnership between the Houphouët Boigny National Polytechnic Institute of Citrans, Agro west Africa Abidjan and Agro west industries

3. Launch of a Training Program Adapted to the needs of the industrial fabric: Launch of a new Master's program in Data Science in Côte d'Ivoire by INPHB and Orange Cote d'Ivoire Telephone Company.

Despite these few examples concerning other sectors of the economy, partnership agreements between universities and the local pharmaceutical industry are almost non-existent

### **3.5.2. Best practices and lessons learned from successful developing countries that have excelled in academia pharmaceutical linkages (India, China, Brazil, and Indonesia) as well as developed countries such as Germany and USA.**

#### **Case of China**

Fangyuan Pharmaceutical has created an institute (Institute of Jiangsu Microbiology), two R&D antennas (Nanjing University - Chen Hongyuan University Antenna and China Pharmaceutical University - Wang Guangji University Antenna) and three R&D centers (Engineering Research Center for Semi-synthetic Jiangsu Antibiotics), Jiangsu Microbial Pharmaceutical Engineering Research Center, Jiangsu Business Technology Center), and has called upon foreign specialists, who will collaborate with the company and the various R&D units, to jointly develop innovative drugs in one of the most advanced scientific fields in the world. After almost ten years of effort, Fangyuan Pharmaceutical's international R&D team has finally developed the process for the development of arbekacin sulfate and will submit an application for clinical research authorization. The drug is expected to be produced in 2020.

#### **Case of USA**

The discovery and development of a new drug is the result of close collaboration between academic and industrial researchers. In this process, the public and private sectors pursue distinct but complementary objectives. While the public sector's role is focused on increasing basic knowledge about the disease, the private sector's role is more focused on applied research to convert this knowledge into effective treatments. The benefits that flow from public subsidies to university research can only be realized once effective treatments have been developed. This last role, only the pharmaceutical industry is able to fulfill it

Pharmaceutical R&D (research and development) funding is the result of a complex combination of public and private sources. Governments mainly support basic and preliminary research. This funding is provided through direct budget allocations, research grants, through public research institutions and by funding higher education institutions. The pharmaceutical industry translates and applies the knowledge generated by basic research to product development and invests in the large clinical trials necessary to obtain market authorization. The sector also receives direct R&D subsidies or tax credits in many countries.

### **3.6. Intellectual Property Rights and Technology Transfer**

#### **3.6.1. Review of the progress made in implementing the TRIPs flexibilities policy and guidelines developed by Cote d'Ivoire.**

Côte d'Ivoire is a signatory to the Paris Convention of 20 March 1883, the Patent Cooperation Treaty of 19 June 1970 and the Agreement on Trade-Related Aspects of Intellectual Property

Rights (TRIPS) of 15 April 1994. It has also signed the Bangui Agreement establishing the African Intellectual Property Organization (OAPI): Côte d'Ivoire, which is a member of OAPI, the African Intellectual Property Office, which examines and grants patent applications under the Bangui Agreement. The Bangui Agreement is characterized by the absence of substantive examination of patent applications and the absence of patent opposition processes. It should be noted that Côte d'Ivoire has not adopted a "TRIPS plus" type measure, which is an excellent thing for access to medicines. Among the members of OAPI, all West African countries, except Côte d'Ivoire and Equatorial Guinea, are included in the current list of Least Developed Countries (LDCs). LDCs have a transitional period until 2033 to apply the standards of the TRIPS Agreement for pharmaceutical products. However, their membership of OAPI, and the absence of a specific regime for OAPI member countries with LDC status, obliges them to meet the intellectual property standards as defined by the Bangui Agreement. The Bangui Agreement therefore serves as national patent law for all these countries.

However, Côte d'Ivoire and all signatory countries to the Bangui Agreement must plead for the revision of this agreement to allow full use to be made of the flexibilities of the TRIPS Agreement, in particular for:

1. exclude from patentability medicines for LDCs,
2. allow the use of compulsory licenses as soon as the patent is granted, and imports under compulsory licenses,
3. allow recourse to parallel imports (duty exhaustion regime),
4. to allow a substantive examination of patent applications.

Côte d'Ivoire has transferred its competence in the examination of patent applications to OAPI, whose office is located in Yaoundé. The OAPI is responsible for conducting patent application examinations. To the extent that patent law is a territorial law, it is possible for courts in Côte d'Ivoire to challenge the validity of a patent, or for public prosecutors to issue ex officio licenses. Many patents have been granted, although a majority of countries among OAPI members are LDCs that theoretically have until 2033 to implement the TRIPS Agreement and grant patents on pharmaceutical products. Unfortunately, this flexibility offered by the TRIPS Agreement was not used by Côte d'Ivoire when the country was classified as an "LDC".

OAPI does not examine patent applications and issues them almost systematically. Côte d'Ivoire does not have national laws on intellectual property, none of which cover patents. The reference text thus remains the revised 1977 Bangui Agreement establishing OAPI.

Côte d'Ivoire has still not incorporated the flexibilities of the TRIPS Agreement into its national law, but the NPSP (New Public Health Pharmacy) purchases generics from manufacturers prequalified by WHO. The local industry has limited its production to essential molecules recognized as not covered by patents. With regard to compulsory licensees and office licenses, OIPI (Ivorian Intellectual Property Office) does not in any way declare that it is aware of such flexibilities. But according to the Medicines and the law and policy database (<http://tripsflexibilities.medicineslawandpolicy.org/>), office licenses were issued in Côte d'Ivoire in June 2004, then in September 2007 and again in November 2007.

### **3.6.2. Success stories and best practices from elsewhere in Africa and outside Africa**

#### **Case of South Africa in the challenge of the accessibility of antiretroviral drugs**

**Case 1:** In 1997, South Africa enacted legislation allowing the import of low-cost generic medicines and establishing a price control mechanism. However, its application was blocked from February 1998 by the legal action of 39 pharmaceutical companies. They attacked the South African government on the grounds that national laws allowing the use of generic versions of patented products were not in conformity with WTO agreements. Following a legal procedure that generated strong international support, they were forced to withdraw their complaint in April 2001. In addition, under South African law, this verdict put the government in a position to grant "compulsory" licences to allow local production or import of generics. The risk of losing control over the manufacture and circulation of generic versions of their products may explain the promptness with which, following the Commission's condemnation, GSK and Boehringer-Ingelheim granted "voluntary" licences to local producers. **Lessons learned** - *By allowing these producers themselves to manufacture and sell the three molecules, the companies avoided legal circumvention of patents by the South African State.*

**Case 2:** In April 2004, the American pharmaceutical company Merck & Co Inc, announced its intention to grant a license to manufacture Efavirenz to Thembalami, a joint venture between Ranbaxy (India) and Adcock Ingram (South Africa). In early March 2005, the South African government announced that seven companies had been selected following a call for tenders launched a year earlier to supply the public sector with antiretrovirals for the next three years. Of the seven companies, Aspen is the company that has won the most contracts, providing eight of the fifteen antiretrovirals needed. Only one other generic company was selected, Cipla Medpro (Cipla's South African subsidiary), which will supply d4T. The remaining treatments will be purchased from the multinational companies Boehringer Ingelheim, Bristol-Myers Squibb, Merck Sharp & Dohme, GlaxoSmithKline and Abbott Laboratories. Thembalami had not registered the generic version it should produce under Merck's voluntary license and was unable to submit this product for tender. Lessons learned:

- a. Voluntary licensing has enabled the local production of some antiretrovirals to be launched in South Africa. In general, South Africa's commitment to expanding access to antiretroviral treatment for its population could lead to a significant change in the overall dynamics of the antiretroviral market. However, it is important to note that the proliferation of commercial partnerships between multinationals and local companies in developing countries, in the form of voluntary licences, does not necessarily ensure that there is genuine competition benefiting the expansion of access to medicines. Multinational companies are increasingly developing this type of alliance. Aspen, for example, manufactures 40 % products for GSK.
- b. By becoming subcontractors to multinationals, companies like Aspen are no longer necessarily in a position to play a competitive role. This is one of the disadvantages of the compulsory licensing system provided for in the TRIPS Agreement, which requires the negotiation of voluntary licences as a preliminary step before compulsory licences can be granted in the event of refusal by multinationals. Control of local manufacture and sale remains in the hands of multinationals when these licenses are granted for a fixed period of time, to certain producers only and under certain conditions, in particular pricing conditions. This then goes against the multiplication of production sources that allow competition and affordable prices to be obtained

### **3.6.3. The wise use of compulsory licensees:**

Brazil was the first country in the South to implement a universal access programme for antiretrovirals. The programme began in 1997 with the provision of free treatment to more than 20,000 HIV/AIDS patients. The annual budget allocated to the purchase of AIDS drugs was then \$224 million. In 2001, the number of people undergoing treatment reached over 100,000. By then, eight out of twelve drugs distributed free of charge were produced locally by Far-Manguinhos, a public research and production unit, which was free to manufacture most of these unpatented antiretrovirals in Brazil. They were discovered before 1995, the date of entry into force of TRIPS. However, health authorities started observing an increasing resistance of patients to first-line treatments composed of non-patented drugs. Therefore, second-line treatment was required, this time requiring the prescription of patented drugs. This was the case with Efavirenz, a drug patented by Merck, which alone absorbs 10% of the anti-retroviral budget. Brazil was concerned that the increasing use of patented drugs may threaten the viability of its universal access to retroviral drugs program, which allowed patients to live with the disease, reduced the number of hospitalizations and ultimately saved significant amounts of money. As a result, the country decided to obtain significant price reductions by mobilizing the legal tools available to negotiate advantageously with companies holding patents.

**Case 1:** The first Brazilian offensive concerns Efavirenz. In March 2001, Merck threatened to sue Brazil for illegally importing generics of Efavirenz, a practice that would constitute a qualified infringement of its patent. The Brazilian response is immediate. Far-Manguinhos did indeed import Indian generics. These imports are not intended for commercial exploitation. The public research and production unit has no intention of selling them on the market. In fact, Far-Manguinhos is working on samples of the Indian credits to develop and eventually produce its own copy. A perfectly legal practice since TRIPS allows patent circumvention in the case of governmental and non-commercial use: an R&D programme on a drug and/or the production of a generic of a patented drug under compulsory licence to supply a programme of universal access to essential medicines does not constitute an infringement of intellectual property. The threat of Brazilian local production very quickly finds a favourable echo. The company proposes to reduce the price of Efavirenz by 65% from \$2.09 to \$0.84 per tablet. This resulted in an announced savings of \$39 million for the Brazilian Ministry of Health.

**Case 2:** A few months later, Brazil attacked Nelfinavir, a Roche patented drug. After six months of unsuccessful negotiations with Roche, the Brazilian government announces its intention to override the patent. In December 2001, the supply contract between Roche and the Brazilian Ministry of Health expired. It will not be renewed and Far-Manguinhos will be responsible for the local production of the drug. Once again, the procedure is legal since this is a public non-commercial use, a production under compulsory licence intended to feed the universal access to retrovirals program. Since a quarter of the program's 100,000 patients are on Nelfinavir, local production is expected to reduce the price of the drug by 40%, saving \$88 million. Very quickly, the Ministry launched the compulsory licensing procedure to start local production and import of Indian generics until Far-Manguinhos could ensure the ramp-up of its production to cover domestic needs. Finally, Brazil's intention to produce Nelfinavir locally under compulsory licence leads Roche to propose a 35% reduction in the price of the drug. An agreement was finally signed at the end of August: the reduction for 40% reduction. and Roche

is committed to starting local production by 2002 at the latest. Brazil then interrupted the compulsory licensing procedure. In 2003, universal access to antiretroviral drugs programme covered nearly 140,000 people.

### 3.6.4. Recommendations

<b>Strategic Themes</b>	<b>Actions to be undertaken</b>
Political, legal and regulatory reforms at the national level	Provide key regulatory bodies (DPM, ANRP) with a solid legislative framework, financial, material and human resources to accomplish their mission to promote the local pharmaceutical Manufacturing
	Implement Measures to launch the new Pharmaceutical Industrialization Programme in Côte d'Ivoire
	Create an interdepartmental unit to monitor the process, quickly remove any obstacles and promote free competition between investors and avoid interventionist attitudes
	Adequacy of pharmaceutical legislation: <ul style="list-style-type: none"> <li>● Reforms and adaptation of certification fees</li> <li>● Status of legislative bodies (independence of the DPM and the ANRP)</li> </ul>
	Implementation of a master plan for the local pharmaceutical sector
	Review pharmaceutical regulations to allow the possibility for non-pharmacists to manage pharmaceutical industrial companies while guaranteeing technical professional liability in these establishments by a Responsible Pharmacist
Réformes Douanières, Fiscales et Mesures Incitatives	Reaffirm the exemption from customs duties on raw materials, packaging items and equipment for the pharmaceutical industry
	To grant a VAT credit to Local Manufacturer insofar as this VAT is not passed on to the final consumer and therefore becomes a tax for IPLs
	Exempt from tax (BIC) any project to extend or modernize a plant, aiming to increase the national turnover of units in activity for 5 years as well as future units during the first 5 years of operation
	Negotiate favourable credit lines for the benefit of the new units, which will make it possible to purchase equipment of a certain quality. Encourage financial partners to get involved in the pharmaceutical industrialization process.
	Consider the pharmaceutical industry as a nascent industry and put in place a 7-year protection measures (import



	stop/correlation) for the products to be placed on the market
	Grant an additional profit margin for wholesale distributors and pharmacies provided that the locally manufactured product has a price at least 30% lower than the most expensive imported similar product, and a verified and assured quality
Human Resources	Implement capacity building activities for regulators in partnership with USP
	Cooperation with partner universities for the training of industry stakeholders and regulators
	Assist professional associations to assess the training needs of the pharmaceutical industry, and help pharmacy students gain experience in the field so that they can benefit from more mandatory internships in the Industrial Pharmaceutical sector
R&D	Valorization of university research
	Strengthening Private Research local and institutional (Creation of a public research laboratory)
	More intensive use of traditional medicine
	valorization of local products in the elaboration of Pharmaceutical raw materials
IP&TT	Revision of the Bangui Agreement to allow full use of the flexibilities of the TRIPS Agreement
	Substantive examination of patent applications must be provided for, and examiners trained in pharmacology and "secondary" drug patent issues before limiting the practice of evergreening.
	Transparency must be improved by OAPI and local liaison offices in order to make the status of patent applications public and accessible.
	Substantive examination of patent applications must be accompanied by the possibility for third parties to make comments during the examination procedure. It must also be accompanied by the possibility for third parties to oppose the grant of a patent before it is granted
Other Recommendations	Substantially increase registration fees for imported products and increase those required for local Manufacturers
	Guarantee the quality approach of locally manufactured products
	The NPSP must conduct national tenders each time a product is manufactured locally.

## **Conclusions**

Côte d'Ivoire has the necessary foundations to quickly become a power industrial at the regional and continental levels. Despite the economic slowdown of the past 10 years, the country continues to enjoy significant natural and structural comparative advantages. However, these assets must be systematically developed through the New Industrial Policy to achieve the Ivorian Government's vision of emergence.

The development of the local Pharmaceutical Manufacturing sector remains one of the Ivorian government's main priorities in its Global Economic Development Plan.

It is therefore becoming essential to strengthen local pharmaceutical production by defining a new national policy of attractive pharmaceutical internalization following the example of all countries in the world.

The development of the local pharmaceutical industry in Côte d'Ivoire is hampered by several issues that are structural problems on the one hand (legislative and regulatory framework, lack of import customs approval for international tenders, insufficient share of public procurement in local production, illegal sale of medicines, no protection of local industries against the dumping of large international firms, the absence of a master plan), and on the other hand important problems related to the attractiveness of the business climate ,the cost structure of the industrial economy, the quality and capacity of its technical education system, the development and implementation of structural programmes.

To succeed in this challenge, several reforms of the Pharmaceuticals sector must be put in place to allow the emergence of a pharmaceutical industry that meets the expectations of governments.

## CHAPTER FOUR

### 4.0. PHARMACEUTICAL SECTOR IN NIGERIA

#### 4.1. Promotion of local pharmaceutical industries and social inclusion through Procurement Policies and Strategies

##### 4.1.1. Overview

UHC and health care and healthcare for all can only be achieved when essential medicines are affordable and accessible to the general populace irrespective of their income status in a country or region. The World Health Organization in 2004 estimated that about half the population in Africa lack regular access to essential medicines (WHO, 2004, Jitta *et al.*, 2003). Having access to affordable medicines remains a big challenge in developing countries, including Nigeria (DFID, 2004, Nyanwura, and Esena, 2013)

A study of elderly patients in plateau state, Nigeria showed adequate access among the elderly to be as low as 10.5%. Elderly patients in that state were found to pay between 0.23 to 36 times international reference prices for their medicines in all sectors (Erhun & Azoji, 2017). The results of the national survey on medicine prices undertaken in Nigeria in 2006 indicated that ninety 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. Affordability poses a major barrier to access to medicines for a reasonable population of Nigerians and some segment of the population with chronic diseases do not take medications due to affordability issues (FMH, 2010). This trend is also based on the fact that out-of-pocket expenditure makes up about 95.9 per cent of all private expenditure on health in Nigeria.

##### 4.1.2. National Health Insurance Scheme

The NHIS was introduced in 2007 and targets the formal sector which consists of the Public Sector, Organized Private Sector and the Armed Forces, Police and other Uniformed Services. Employees of the public sector and organized private sector organizations employing ten (10) or more persons are expected to participate in the Programme. Contributions are earnings-related. For the Public (Federal) sector programme, the employer pays 3.25% while the employee pays 1.75%, representing 5% of the employee's consolidated salary. For the private sector programme and other tiers of Government, the employer pays 10% while the employee pays 5% representing 15% of the employee's basic salary. However, the employer may decide to pay the entire contribution. The contributions paid cover healthcare benefits for the employee, a spouse and four (4) biological children below the age of 18 years. More dependents or a child above the age of 18 is covered on the payment of additional contributions by the principal beneficiary as determined by NHIS. Principals are entitled to register four (4) biological children each, however a spouse or a child cannot be registered twice. The scheme by reason of a presidential directive was expected to have achieved universal coverage by 2015. This is yet to be achieved. The scheme is yet to be extended to the informal sector in Nigeria.

The public sector contribution to healthcare has been on the ascendancy since the introduction of the NHIS. The intervention of Public Bureau for Public Procurement has facilitated bulk purchase of medicines and other products, lowering the cost of medicines for NHIS. The Federal Government is expected to procure medicines for the Federal University Teaching Hospitals and

Federal Medical Centres; who are at the tertiary levels whereas the state and local governments cater for the healthcare in their sub-units respectively. This fragmentation of drug procurement also affects the affordability, quality and quantity of drugs dispensed at each level of healthcare in Nigeria. State and cooperative organizations health insurance schemes are being established in different locations in Nigeria to bridge the coverage gaps left by the NHIS. Nineteen states are at various stages of their implementation of health insurance schemes as indicated in the Figure 1 (PwC, 2019). The sub-national schemes just like NHIS establish a government agency for the implementation and management of the scheme. The State Governments commit funds to the scheme to offer premiums for the poor and vulnerable in their various states.

#### 4.1.3. 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.

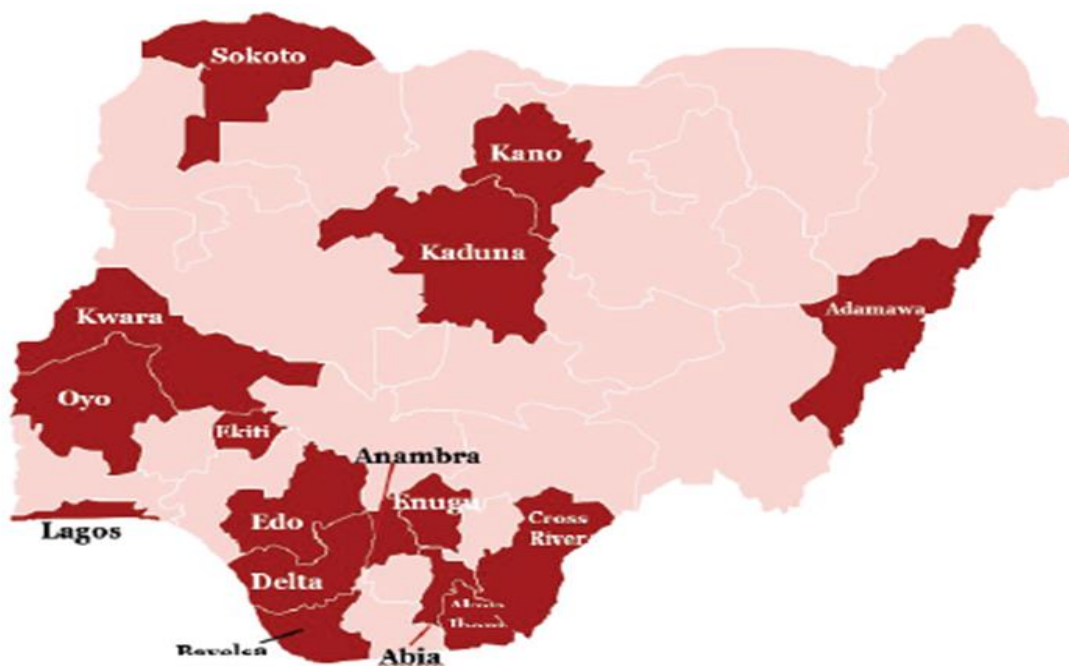


Figure: Map of Nigeria Showing States Having Health Insurance Schemes

#### **4.1.4. Public Procurement Act 2007**

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 to time set the limits and compute the margins of preference and determine the contents of goods manufactured locally. On the procurement of medicine/drugs in Nigeria, preference is given largely to the local pharmaceutical manufacturing company and if any foreign firm intends to bid for drug supply, it has to be done in collaboration with the local firm(s) show proof of local presence and that bulk of the drugs will be manufactured in the country using local materials. The Nigerian government aims to use the procurement policy to stimulate innovation and competitiveness in the pharma industry. This is also in line with the Local Content Act and Executive Order 5 signed by the Federal Government in February 2019. For local firms, they must however meet the set out criteria for suitability of bidders to be considered. These include registration of firm by Corporate Affairs Commission, obtain license for the registration of premises by PCN, production of quality products, presence of a superintendent pharmacist among other requirements.

Moreover, the Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria (PMG-MAN) is also intensifying advocacy to remind government MDAs to abide by the dictates of the National Drug Policy, Procurement Act and Executive Orders to patronise medicines that are manufactured in Nigeria. There is also the need to review the NHIS Policy to lay more emphasis on the use of locally manufactured medicines.

#### **4.1.5. 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 2004 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 revealed that:

1. patients pay between 2-64 times the international reference prices for medicines at various health facilities in both the private and public sectors
2. prices in the public sector were almost identical to those in the private pharmacies
3. private health clinics charge about 184 per cent more than the public health facilities and about 193 per cent more than private retail pharmacies

4. innovator brands cost between 2-7 times the lowest priced generic equivalents
5. affordability was largely dependent on choice of therapeutic class, product or sector from which the medicine was purchased. For example: - A worker would pay 0.7 days' wages to treat an infection with amoxicillin but would pay an additional 18.8 days' wages when using ceftriaxone injection to treat the same infection.
6. while innovator branded medicines compared well with prices in other countries, generic medicines were up to 825% more expensive in Nigeria than in other 7 countries

Medicine distribution in Nigeria is done under the supervision of relevant agencies of the FMOH in compliance with the National Drug Distribution Guidelines 2012 (NDDG). For instance, the PCN is responsible for providing appropriate license to pharmaceutical premises whether manufacturing plants, wholesale premises and retail outlets. This provides the Ministry with overall control of pharmaceutical products production and distribution in the country. Essential drugs for the national and teaching hospitals are procured through a bulk purchase by the Federal government' revolving fund scheme. The bulk purchase by the Federal Medical Stores, located in Lagos and now another one in Abuja, afford the government to buy at better prices which trickles down to the state and local distribution centres. To make the drugs more affordable and to promote local production in the country, the Federal government gives tax holiday to producers and drugs are VAT-free commodity in the country.

In addition, the Nigerian government has put strategies in place to enhance affordability of all essential medicines. One of such is the Revolving Fund Scheme (RFS) which operates within the public health sector. This fund, as explained in an interview with the Food & Drug Services of the Ministry of Health is a one-time investment of the Federal Government, which is expected to be recycled over a period of time. The fund is used to purchase drug in bulk directly from manufacturers or importers as the case may be. This is to reduce long chain movement of drugs from one point to another which consequently account for increased cost price at the long run. For private sector, government provided some palliatives in form of tax relieve. No VAT is paid on medicine or drug produced in Nigeria. These strategies are to reduce the eventual cost of drugs to enhance affordability.

#### **4.1.6. 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:

1. Increased funding of the health system

2. Expansion of information communication technologies in the Department of Food and Drug Services, Federal Ministry of Health
3. Promotion of local production of essential medicines
4. Improved consumer awareness
5. Promotion of effective partnership collaboration and coordination
6. Revitalisation of the primary health care (PHC) system
7. Strengthening of regulatory mechanisms

The Federal Ministry of Health, through its Food and Drug Services department is responsible for monitoring and inspection of drug distribution across the states of the Federation. Government established the Presidential Committee on the Pharmaceutical Sector Reform (PCPSR) and charged it among others to develop strategy towards the institutionalization of a well ordered drug distribution system in Nigeria. The strategies adopted by the Committee to achieve this include the development of the National Drug Distribution Guidelines which provides guidance to drug distribution in Nigeria (FMoH, 2019). The Guidelines recommended that each State is to establish the State Drug Distribution Centres (SDDCs) to be supervised by a Standing Committee while the private sector is to establish the Mega Drug Distribution Centres (MDDCs) which will be represented in the six geopolitical zones before they can be registered as MDDC. The guideline provided direction in respect of source of drugs to every level of pharmaceutical practice including primary health care facilities, private health care facilities and the patent and proprietary medicine vendor (PPMV). It is also important to mention that The NHP 2005 has now been revised and will soon be made available to the public after ratification by the stakeholders.

#### **4.1.7. Impact of Subsidy on the development of local pharmaceutical industries**

According to UNIDO in 2011 healthcare subsidy policies are expected to affect the growth of the local pharmaceutical industry in Nigeria. However there is presently no clear policy on this in Nigeria.

## **4.2. Human Resources Development**

### **4.2.1. Availability of human resource for the Local Pharmaceutical Industry**

Pharmaceutical industry is a knowledge-intensive sector which requires highly specialized skills and critical infrastructure for its development and survival. Therefore, human resource is an integral element of a vibrant pharmaceutical manufacturing industry. The pharmaceutical industry plays key role in attaining the goal of universal health coverage and equitable access to essential health services, particularly in relation to access to medicines. The pharmaceutical manufacturing system requires specialized skills in a number of disciplines, including pharmacy, natural and life sciences, engineering, management, and Information and Communications Technology (Anyakora *et al.*, 2017). It could be reasoned that the growth of any pharmaceutical manufacturing company is hinged on the quality as well as quantity of its knowledge base (Trauth, 2012). There are 21,892 registered

pharmacists in Nigeria, however, the data suggest that only 13, 020 are in active professional practice as indicated by the number of licensed pharmacists in 2016 (Ekpenyong *et al.* 2018).

Recent information from the Pharmacists Council of Nigeria revealed improvement and decline in the number of registered and licensed pharmacists in the country. The number of registered pharmacists increased from 23,437 in 2017 to 24,830 in 2018 while those who were licensed to practice declined from 13,457 in 2017 to 13,304 pharmacists in 2018. The decline could be as a result of brain drain in the sector. Also, there is consistent increase in the number of registered pharmacy technicians and those who had permits to operate between 2015 and 2018. The figure for 2019 is still being finalised by the planning, research and statistics department of the PCN as at the time of this report.

### **Distribution of Registered and Licensed Pharmacists and registered premises in Nigeria**

<b>Year</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
Registered Pharmacists	20,507	21,892	23,437	24,830
Licensed Pharmacists	11,837	13,020	13,457	13,304
Registered Pharmacy Technicians	2,653	3,131	4,179	5,793
Technicians with annual Permits	249	676	992	2,204

Source: PCN (2019)

Furthermore, a breakdown of 2018 statistics revealed an interesting pattern of the gender and geo-political distributions of the licensed Nigerian pharmacists. The geopolitical distribution shows that majority are from the South-West (5,507 pharmacists) while South-East has the least number of pharmacists in the country with 516. The 115 pharmacists who were trained abroad have been inducted and licensed to practice in Nigeria after successful completion of Foreign Graduate Orientation Programme and necessary examinations. There is a slight gender disparity as about 42% of the licensed pharmacists are females.

### **Distribution of Licensed Pharmacists in Nigeria by Geopolitical zones and Gender**

<b>Geopolitical Zone</b>	<b>Gender</b>		<b>Total</b>
	<b>Male</b>	<b>Female</b>	
North-Central	1,785	1,113	2,898
North-East	389	127	516
North-West	662	257	919
South-East	776	500	1276
South-South	1,096	977	2,073
South-West	2,996	2,511	5,507
Abroad	66	49	115
<b>Total</b>	<b>7,770</b>	<b>5,534</b>	<b>13,304</b>

Data collected from the PCN during the field survey. This data is for a period of January to December, **2018**.

Most of the licensed pharmacists with known area of practice in Nigeria are in community and hospital practice, with a limited number in academia, industry and administrative pharmacy. There is therefore a significant deficit in some key areas of practice in the country. Efforts are on-going to bridge human resource deficits by...

More has to be done to absorb available pharmaceutical professionals into the workforce, particularly in sectors where there are significant deficits such as industrial and academic



pharmacy. Despite the fact that the number of graduates produced in Nigeria is on the increase, the overall density of pharmacy graduates per 10,000 populations remains significantly low, indicating continuing deficit in pharmaceutical manpower compared to developed countries (FIP, 2013). However, with the addition of more pharmacy schools in the country, there will be an increment in the number of qualified and registered pharmacists to fill the gap. (Ogaji and Ojabo, 2014).

Another great challenge facing the availability of skilled personnel in the Nigerian pharmaceutical industry is the problem of brain-drain. A recent survey on the financial cost of medical personnel, pharmacists inclusive, emigrating from sub-Saharan Africa revealed that a large number of medical personnel in sub-Saharan countries are, in fact, working in the United Kingdom, Australia, Canada and the United States. The actual numbers are estimated by various parties to be in the thousands and account for an estimated loss of return on investment for these West African countries of almost US\$2.17bn while the net gain for the developed countries to which they emigrated was estimated at US\$4.55bn (Mills *et al.*, 2011).

Some organizations such as African Capacity Building Initiative and Carnegie African Diaspora Fellowship program are trying to address the problem of brain drain and harness the capacity of Africans (Nigerians inclusive) in the diaspora by guiding and building the research expertise of African diaspora and capacity training towards the continent.

PCN is also expediting actions on the accreditation of faculties and department, including specialized institutions providing pharmacy-related courses in the country. For instance, the foreign graduate orientation programme is run twice in a year to accommodate those pharmacists who graduate from various foreign universities in September and March of every year. During our visit to the Council, we witnessed the induction of about one hundred and fifty (150) pharmacists who were trained abroad. In addition, more universities have approached the PCN for accreditation of their Faculties of Pharmacy.

#### **4.2.2. Training of Pharmaceutical Professionals**

In Nigeria, Pharmacy as a profession has evolved much faster over the last two decades than previously experienced. In 1989, the National University Commission (NUC) in Nigeria approved minimum standards of five-year training curriculum for Pharmacy. However, the six to seven years Pharm Doctor Program remains the current global best standard for sustainable training of people who will handle a critical aspect of a nation's health care delivery system. The pharmacy curriculum has been expanded to meet up with the challenges from the clinical and industrial angles. One of such move is the introduction of the Doctor of Pharmacy Program (Pharm.D) initiated by the University of Benin, Benin City, Nigeria. It is presently a six years program to better equip the pharmacists with the challenges of the twenty first century and position them in line with global best practice. Appropriate quality assurance measure of performance at short, medium, and long term should be instituted in all the sectors and at all level.

Professional pharmaceutical associations in Nigeria also play key roles in training and re-training of pharmacists in Nigeria. For instance, Nigeria association of Industry pharmacists (NAIP) now known as Association of industrial pharmacists in Nigeria provide sponsorship for her members in post-graduate programs in production pharmacy at the University of Ibadan (UI). Four of such

are undergoing Masters programme while others are running post graduate diploma programs. The aim of the training is to equip them more and as well train others within the manufacturing firms. The facilitators of the program are experts from United States of America who are production pharmacists partnering with UI. The duration of the program is two years. A similar program is also taken place at King Emmanuel School of Pharmacy in Tanzania.

Nigerian Association of industrial Pharmacists (NAIP) that has an academy has made a number of advocacies with some state governments in Nigeria and they have come up with a Project called Pharmaceutical manufacturing parks (PMP) in six states within the country. The aim of the park is for massive production of pharmaceutical products for exportation and also to make Nigeria to be able to participate maximally in the continental trade agreement coming up next year in the country. NAIP is planning massive training of production pharmacists in year 2020 who will be able to work in these PMP. In addition, in 2012 the association provided research funds for R&D activities to researchers from NAPPA. The organisation now relates directly with NAPPA to sponsor commercialisable pharmaceutical R&D studies.

The training of pharmacists in Nigeria is regulated by the 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. 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.

### **Roles of NAPPSA**

Pharmaceutical Society of Nigeria (PSN) stated that they are also working with Nigeria Association of Pharmacists and Pharmaceutical Scientists in the Americas (NAPPSA). This collaboration has resulted in the commencement of a Special Doctor of Pharmacy programme in Nigeria. The PSN is organising a fellowship programme; whereby NAPPSA members would visit and work in Nigeria to help build local capacity and transfer knowledge to the industry and academia.

### **Roles of NIROPHARM**

Nigerian Representatives of Overseas Pharmaceutical Manufacturers (**NIROPHARM**) is a body consisting of overseas representatives of pharmaceutical manufacturers committed to promoting professional healthcare delivery in the pharmaceutical health sector. The organization was established around 2004 for the purpose of self-regulation. Their aim is to make sure that only standard pharmaceutical products are imported into the country. They also do contract manufacturing in partnership with Nigerian firms and in this process, the firm is brought up to the standard of the international company being collaborated with. E.g GSK collaborating with Fidson, Sanophl collaborated with May and Baker etc.

### **Roles of ACPN**

Association of Community Pharmacists of Nigeria (ACPN) has a Drug information Centre (DIC) which is located at the National office is involved with the production of information for dissemination for their member through production of periodic journal for drug use distributed to members on annual basis. Production of Newsletter to members quarterly, information pamphlets directly needed by the primary consumers of health are sold to patients at community pharmacy level. Information from international bodies e.g. International Pharmaceutical

Federation (FIP) like drug development and discoveries are transferred to members through these periodicals of DIC. The association also serve as window of information between the regulators like NAFDAC and the general public.

### **4.3. Research & Development**

#### **4.3.1. Production of Active Pharmaceutical Ingredients**

The manufacture of active ingredients is considered the most expensive aspect of pharmaceutical production. Apart from the initial huge capital investment required, it also requires that process development and quality assurance systems should be in place. The more sophisticated the products to be produced, the greater the technology base, capabilities and skills required developing and maintaining the production processes. Local production of drugs in developing countries has been perceived as a potential way to earn foreign exchange, facilitate technology transfer, create jobs, stimulate exports to neighboring countries, increase access to cheaper medicines, achieve independence from international suppliers and promote self-sufficiency in drug supply (Kaplan and Laing 2005; WHO, 2011). The production of active pharmaceutical ingredients (APIs) remains concentrated in the high-income, R&D entrenched countries, while most low- and middle-income countries with pharmaceutical industry carry out only the relatively late-stage steps of formulation and packaging. Several issues have impeded the growth and development of pharma industry (including pharmaceutical industry) in sub-Saharan Africa. Schiffer and Weder (2001) reported a dearth of competent personnel; a weak financial sector (banking/non-banking); coupled with the fact that smaller firms face more problems than larger firms with financing, taxes and regulation, inflation, corruption as contributing to poor industrial development.

Although the potential capacity of many African countries including Nigeria to produce APIs has been established (WHO, 2004), as at 2010 all APIs used in Nigeria are imported, mainly from India and China. Lack of adequate infrastructure, inability to implement good manufacturing practices, lack of foreign exchange, high production cost, unavailability of highly skilled staff (UNIDO, 2011) non implementation of enabling policies and unfavorable global politics are some of the reasons that have been adduced. Recent information from stakeholders such as NAFDAC, and Food and Drug services of the FMOH revealed that no pharma firm in Nigeria is currently producing APIs. They argued that the production of APIs is a capital intensive which requires huge infrastructure and are out of reach for Nigeria. Some synthetic materials from petroleum industry are needed but with dysfunctional oil industry, there is no way this can happen. The human capabilities required for the production of APIs are enormous and required great commitment from national government and cooperation of international communities. However, with the hope of Dangote refinery, it is believed that APIs can be produced locally in the near future.

Consequently, many pharmaceutical firms in Nigeria still repackage medicines and/or produce pharmaceutical products from imported raw materials. In a bid to promote local manufacturing capacity of the pharmaceutical industry, the Nigerian Government has canvassed many initiatives including developing the petrochemical industry for pharmaceutical raw materials (FoH/WHO, 2002).

NIPRD is one of the agencies that has demonstrated strong capability for the production of APIs from both natural and synthetic sources in Nigeria. For instance, the institute has successfully extracted and isolated pure Artemisinin from Artemisia plant. In addition, there is an established production plant in the institute capable of production of various APIs from synthetic sources.

The latter is largely dependent on the presence of a viable and active petrochemical industry. To this end, the institute has approached the Nigeria National Petroleum Corporation as well as the up-coming refinery being built by Dangote group in a bid to establish a relationship to bring this to a lime light (NIPRD, 2019).

The Pharmaceutical Manufacturing Group of the Manufacturers Association of Nigeria (PMG-MAN) has praised the Federal Government for supporting local production of vaccines. PMG-MAN has canvassed the Expedited Medicines' Access Programme (E-MAP), a proposed collaborative contractual partnership between the health ministry and local manufacturers. E-MAP is expected to combine innovative manufacturing practices with contextual logistics and supply chain management that would achieve effective, cost efficient and timely provision of high-quality medicines. This collaboration of MAN and the Federal government if implemented will directly address the challenge of producing APIs in Nigeria. (The Nation, 2017)

#### **4.3.2. Pharmaceutical R&D and Challenges**

Research and development (R&D) as well as funding of the same are essential ingredients for new product development. The African Union countries over a decade ago committed to investing at least 1 percent of Gross Domestic Product (GDP) on R&D. This goal remained unrealized hitherto, as the average share of GDP in 2015 devoted to R&D activities by many African countries was only 0.4 percent (R&D Magazine, 2016). UNESCO (2015) also reported that Africa accounted for only 1.1percent (US\$22.3 billion) of global investments in R&D.

In the health sector, Simpkin *et al.* (2019) identified the three major players involved in funding research in many African countries as; the public (government), private sector, and international institutions. Given that the recovery ratio of funds invested in the pharma R&D is often low with unpredictable outcomes, most African governments find it difficult to prioritise investment in health over education, infrastructure and other areas. In addition, investment in pharmaceutical R&D in many African countries by the private sector is hampered by unstable political environments, weak or absent intellectual property laws, poor governance, weak regulatory structures and corruption (West and Schneider, 2017). Consequently, many African countries rely heavily on research grants and/or aids from foreign and international organisations. Therefore, R&D activities for diseases that disproportionately affect African countries and address Africa's unmet health needs are poorly funded (Gedye, 2013).

R&D activities occupy a central position in the development of a vibrant, sustainable and socially inclusive local manufacturing pharmaceutical industry. This will enhance affordability of essential drugs, productivity, increase employment opportunities as well reduce dependency on foreign support. In many developed countries with well-established pharma industry, pharmaceutical companies are among the top investors in R&D in the health science sector. This is not the case in Africa, as few African companies have R&D units or R&D directors to oversee product development and technology transfer (UNECA, 2013). Nigeria is no exception in this regard. Successful production capabilities by most pharmaceutical firms in developing countries therefore require endorsement and support in form of joint venture initiative from multinational companies into R&D licensing arrangements.

Broadly speaking, all Nigerian centres of excellence visited in this study lamented shortage of fund for R&D activities. They therefore seek for additional funding from states government, and other external funding/donor partners. These bodies include, the global fund, NIH, WHO, STEP B, Governments of some countries, etc. For instance, Government of India, through the Indian I-Tech (India International Technical and Economic Co-operation Commission) programme is

currently offering technical training in India to some research fellows from NIPRD to enhance their activities. Fellows are expected to return to their home institute after the training programme. Other supports provided by these bodies are in the form of establishment of state-of-the-art facilities, staff exchange /training programmes, support for institutional capacity. Moreover, the capacity for improved Drug Production and Research in the Obafemi Awolowo University has waned over time due to poor research funding and inadequate infrastructure.

#### 4.3.3. Institutional Support/Base for Pharmaceutical R&D

The two main institutions involved in pharma R&D activities in Nigeria are the universities and research institutes. As at 2019, there are twenty-one (21) universities in Nigeria with Faculty of Pharmacy. (Table 1). The various R&D oriented departments within which drug research and development are entrenched in the faculty include: Pharmacognosy, Pharmacology, Pharmaceutics, Pharmaceutical Technology, Herbal Medicine, Industrial Pharmacy and Pharmaceutical Chemistry. These departments and units conduct research in different aspects of drug research including development and elucidation of active compounds from indigenous knowledge and biodiversity.

Apart from the research done in universities, Nigeria currently has over a hundred ministries, departments and agencies with various mandates and domiciled within various Federal ministries. Of these, four research institutes stand out with mandate in R&D activities relating to identification, analysis of drugs as well as development of raw materials from local resources to the pharmaceutical industry. These are: The National Institute for Pharmaceutical Research and Development (NIPRD), The Nigerian Institute of Medical Research (NIMR) in Lagos, The Raw Materials Research and Development Council (RMRDC), The Nigerian Natural Medicine Development Agency (NNMDA). The parent ministries, mandates as well as thematic areas of activities of these pharmaceutical research institutions are documented (UNIDO, 2011). In addition to these, there are other cognate agencies of paramount importance to the pharmaceutical industry in Nigeria with regulatory and/oversight functions (Table 2). For instance, NAFDAC ensures standardisation and WHO's compliance of all pharmaceutical products imported into Nigeria by ascertaining the safety, efficacy and proof of manufacturing and use in country of origin.

Table: Nigerian Universities with Faculty of Pharmacy

S/N	Universities
1.	Ahmadu Bello University, Zaria, Kaduna State
2.	Obafemi Awolowo University, Ile-Ife, Osun State
3.	University of Benin, Benin City, Edo State
4.	University of Ibadan, Ibadan, Oyo State
5.	University of Jos, Jos, Plateau State
6.	University of Lagos, Akoka, Lagos State
7.	University of Nigeria, Nsukka, Anambra State
8.	Olabisi Onabanjo University, Ago-Iwoye, Ogun State
9.	University of Uyo, Uyo, Akwa-Ibom State
10.	Niger-Delta University, Wilberforce Island, Bayelsa State
11.	Madonna University, Okija, Rivers State

12.	Nnamdi Azikwe University, Awka, Anambra State
13.	University of Maiduguri, Maiduguri, Borno State
14.	Usmanu Danfodio University, Sokoto, Sokoto State
15.	Delta State University, Abraka, Delta State
16.	University of Port-Harcourt, Port-Harcourt, Rivers State
17.	Igbinedion University, Okada, Benin City
18.	University of Ilorin, Ilorin, Kwara State
19.	Kaduna State University, Kaduna, Kaduna State
20.	Gombe State University, Tundun Wada, Gombe State
21.	Bayero University Kano, Kano State

#### **4.3.4. R&D Centres of Excellence in Nigeria and their Activities**

##### **Nigerian Institute of Medical Research (NIMR)**

Nigerian Institute of Medical Research (NIMR) is a research institute under the Federal Ministry of Health. The institute has conducted a number of research in combating malaria and HIV-AIDS in the country.

##### **Malaria**

In the area of malaria, in 2018, the institute worked with the FMOH on efficacy testing on recommended anti-malaria drugs in some states. The aim of the study is to ascertain the present efficacy of recommended antimalarial drugs in treating malaria. It has also conducted clinical trial to determine the efficacy and safety of some antimalaria drugs. The result will determine whether to continue or discontinue the use of such drugs. In addition, the Institute had tested the effectiveness of some insecticide-impregnated nets. The study revealed that the insecticide previously impregnated on the nets were not effective in killing the mosquitoes. The study guided the FMOH on the selection of insecticide to use for impregnating nets. Furthermore, the institute carried out an entomological survey for FMOH on malaria elimination programme through eradication of mosquito in 5 states. The study paid closer attention to the effectiveness of available insecticides on the mosquitoes for reduction of malaria transmission and possible roadmap for mosquito eradication.

##### **HIV-AIDS**

Realizing the vulnerability of Nigerian youths to HIV-AIDS infection, the institute on a programme sponsored by the NIH is working on a strategy to enhance self-testing by Nigerian youths. The project aims to improve and adopt self-testing for HIV-AIDS. Another ongoing project in the institute involves a surveillance to determine the resistant strains among the HIV-AIDS positive individuals. The institute also trains researchers on the peculiarities of management of women with HIV-AIDS. This training programme is sponsored by NIH. In collaboration with Lagos State AIDS control programme, the Institute assessed HIV prevalence and pattern among people working in garages.

##### **Medicinal Plant Research**

A Centre for Traditional Complementary and Alternative Medicine to develop emerging local herbs with anecdotal evidence of antimalarial and HIV-AIDS treatment was established about one-and a half years ago. The institute is working with the Council of Physician of Natural Medicine and training the members on how to improve their products and advise them to bring

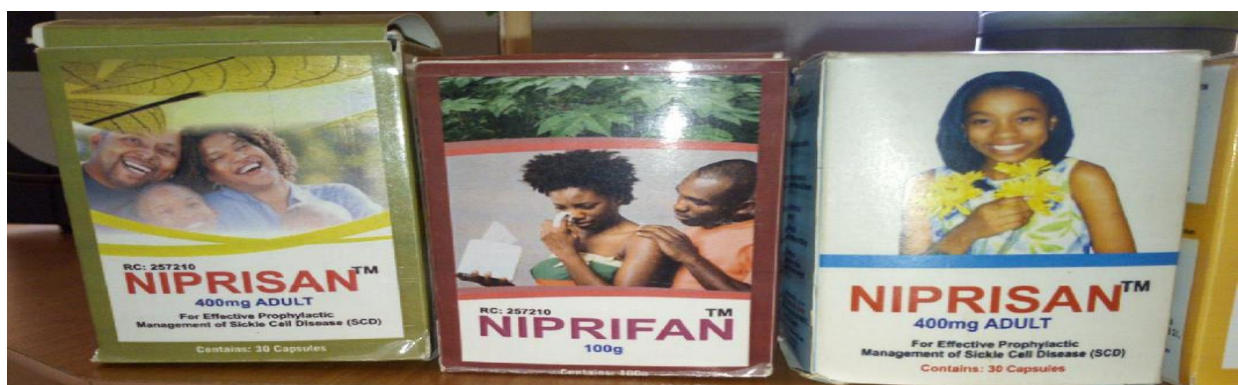
their products that are proved to be efficacious forward for safety testing; after when efficacy testing could be done.

### **The National Institute for Pharmaceutical Research and Development (NIPRD)**

NIPRD is a dedicated pharmaceutical R&D Agency with core competence in drug development targeting treatment of malaria and other diseases based on indigenous knowledge and biodiversity in Nigeria.

In addition to the popular sickle cell anaemia drug- NIPRISAN, the institute has developed another six (6) drugs, including:

1. NIPRIMAL -treatment of malaria,
2. NIPRD OIL (an eucalyptus product from natural sources for the treatment of catarrh & cough
3. NIPRIFAN - Treatment of fungal diseases
4. NIPRIMUNE - An immune booster. The product has successfully undergone clinical trial up to phase II
5. NANOMET : An antidiabetic
6. NIPRIBOIL: A cocktail of agents from medicinal plants with antiviral activities specifically formulated for the cure/treatment of Ebola virus
7. Studies are on-going on other 22 plants for various pharma formulations targeting treatment of various diseases. Of these, 3 are targeted at the treatment of malaria with better activities than previously formulated NIPRIMAL
8. Successes have been made in developing pharma compositions targeting various components of HIV-AIDS virus from natural sources among other.



Apart from pharma products development, the institute also conduct research into the process improvement to improve and optimise known production processes, as well as developing new diagnostic kits.

NIPRD in collaboration with RMRDC & SHETSCO has also developed and produced pharmaceutical grade starch from non-food sources such as weed (Tacca). However, they are yet to be commercialised.

#### Linkages

- a. NIPRD recently signed MoU with about 7 universities to enhance pharma R&D, including University of Ibadan, University of Jos, University of Abuja and Federal university, Dutse.
- b. The institute has collaboration with other Research Institutes in Nigeria (RMRDC), SHETSCO
- c. The institute has collaboration with many pharma firms in the area of product development, staff and product development among others.

Top funders of R&D activities at NIPRD are government subvention, NIH, STEP-B and WHO. Other forms of support received by the institute from donor partners include technical assistance, infrastructural support, institute strengthening and staff training.

#### **The Nigerian Natural Medicine Development Agency (NNMDA)**

NNMDA is carrying out research & development on identification of natural products/indigenous plants with medicinal values in Nigeria. It has mapped all natural medicines indigenous to the six geo-political zones in Nigeria. It has documented all the medicinal indigenous plants that can serve as raw materials for drug development in Nigeria. NNMDA has developed a herbal anti-malaria drug, herbal mosquito repellents, herbal mosquito treated nets, formulations effective as HIV drug supplements, among other drugs, Currently NNMDA are carrying out R&D on drugs for treatment of cancer.

#### **Raw Materials Research and Development Council (RMRDC)**

RMRDC has drafted a national strategy for competitiveness in raw materials and products development. This document will assist the government to focus and target appropriate raw materials needed by the pharmaceutical industry which can be produced locally in the short, medium and long term. In addition to this, the council is targetting the establishment of at least a resource-based industry in each geopolitical zone in Nigeria. Such industries will target adequate production of locally source material for pharmaceutical industry. Some success stories emanating from R&D activities in RMRDC include:

1. A project on ‘Development of lovastatin from king Oyster mushroom and related species’. this study is in collaboration with InterCeed, which is a member of Bio-resources Development Group (BDG). The study aims to obtain lovastatin from locally cultivated Oyster mushroom. Lovastatin is used in the treatment of cardiovascular diseases. The research is currently in the advance phase.
2. Another project by the Council in collaboration with Usmanu Danfodiyo University is aimed at ‘Development of anti-diabetic nutraceutical supplement for the management of Diabetes mellitus. The project is at the clinical trial stage and patent has been obtained for work done so far.
3. Another ongoing project in collaboration with NIPRD is on ‘development of phytomedicine for the treatment of tuberculosis’. Patent has been obtained for some of the breakthrough made so far on the project.
4. Again, in collaboration with NIPRD and SHETSCO, a standardised binder which can serve as pharmaceutical excipient has been obtained



Another success story is a project on ‘Development of water-based thermo-stable vaccine for control of new castle disease in rural poultry. This was done in collaboration with NCRI Vom, Plateau state.

Table: Regulatory Agencies/Bodies for the Nigerian Pharmaceutical Industry

S/N	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)	<ul style="list-style-type: none"> <li>• Inspection and registration of pharmaceutical retail, wholesale and manufacturing premises</li> <li>• Registration of pharmacists</li> <li>• Regulation of the practice of pharmacy</li> <li>• Inspection of manufacturing premises</li> </ul>
6.	National Agency for Food and Drug Administration and Control (NAFDAC)	<ul style="list-style-type: none"> <li>• Evaluation and registration of pharmaceutical products</li> <li>• Post-market surveillance and risk analysis of registered products</li> <li>• Control of product import and export</li> <li>• Regulation of product promotion and public education</li> </ul>
7.	National Office for Technology Acquisition and Protection (NOTAP)	Regulation of technology acquisition and protection, including Intellectual Property Rights (IPR) issues, patents, benefit sharing, etc.

#### 4.3.5. Other organizations that support Pharmaceutical R&D

There are numerous local, regional and international professional bodies, with important oversight function such as licensing, certification, training and development and other professional roles which could indirectly affect the R&D efforts in Nigeria. One of such is the Pharmacists’ Council of Nigeria, which accredits undergraduate pharmacy programmes and ensures adequate training of pharmacists as well as other professional practices.

The Federal government of Nigeria is displaying positive attitude towards the development of qualitative and functional higher education and research with improved budgetary allocation to the sector (Makoju *et al.*, 2005). R & D activities in public-owned universities are sponsored mainly by the Tertiary Education Trust Fund (TETFUND). TETFUND is an intervention fund that was established by the Federal Government of Nigeria in 2011 to disburse, manage and monitor education tax to government owned tertiary institutions in Nigeria. TETFUND also funds R&D through call for research proposals from researchers in diverse fields. (Bamiro, 2012). The availability of self-sponsorship as well as research fund from Nigerian /indigenous pharmaceutical firms, though at a very low level were also reported for pharmaceutical R&D in Nigerian universities (Siyabola *et al.*, 2012). In addition, the same study reported that pharmaceutical R& D researchers in universities receive further support by the provision of books/journal donations, travel aids/grants, staff exchange/fellowship programme, R&D

facilities, sponsored participation at workshops and R&D grants/funding from some international funders.

#### **4.3.6. Success stories in Nigeria**

It has already been established that Nigerian pharmaceutical sector is populated by very small firms; how does this impact their research and development capability? In Nigeria, compared with other West African countries, a huge percentage of patents granted by the patent registry belong to foreigners. The 1999 – 2002 data shows that of the 2544 patents issued, 1,458 are foreign and 986 are to local applicants in which case some of the local grants are made under license from foreign owners (Adewopo, 2011). Most of these patents are not coming from the local institutions and only few ones are in the pharmaceutical related fields. Information from the National Office for Technology acquisition and promotion revealed that about ten patents are granted recently in the areas of pharmaceuticals while two were recorded from the research institutions. It was also discovered that a Federal University of Technology just developed snake vaccine which is yet to go through necessary scrutiny before production.

Obviously, not much research and development have been going on in the sector and this is most likely because their small size makes it practically impossible for them to mobilize the huge resources required. The implication is that they sell mostly products whose patents have expired since they do not have much patents of their own and this ensures that they will always play second fiddle to firms that have the capacity to engage in research and development.

Despite these challenges, in the recent past, Nigeria has documented the following success stories in this sector:

1. The National Institute for Pharmaceutical Research and Development (NIPRD), 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.
2. In Nigeria, 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.
3. It is important to note that increase in 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 phyto-medicines from Nigeria's abundant indigenous biodiversity and traditional medicines. 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 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.

4. 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 sub-region, 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 such as realistic measures to boost research and development of local sources of pharmaceutical raw materials, including active pharmaceutical ingredients and excipients. Also the promotion of research and development of new medicines targeting the treatment of malaria and HIV/AIDS based on indigenous medical knowledge and biodiversity.

### **Recommendation**

Research and development of new herb-based products may not be as expensive as that of conventional medicine. Until firms in the Nigerian pharmaceutical industry become large enough to engage in research and development independently, they should consider research and development venture. This would enable a number of firms to pool their resources together with the understanding that they would all share in the costs and benefits of the venture.

#### **4.4. World Health Organization (WHO) Certification**

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).

As a result of policy, legal and regulatory initiatives, the capacity utilization of installed facilities in Nigeria 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.

The harmonization of medicine registration within ECOWAS and WHO certification and prequalification of some Nigerian pharmaceutical manufacturers are some of the major

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

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.

The WHO Certification Scheme for finished pharmaceutical products is an international voluntary agreement to provide assurance to countries participating in the Scheme, about the quality of pharmaceutical products moving in international commerce (World Health Assembly resolution WHA22.50(1969), World Health Assembly resolution WHA28.65 (1975), World Health Assembly resolution WHA41.18 (1988), World Health Assembly resolution WHA45.29 (1992), World Health Assembly resolution WHA50.3 (1997).

The WHO prequalification process has been listed to have the following advantages.

1. Improved public health outcomes and value for money through quality assurance of generic medicines,
2. Increased uptake of medicines designed specifically to meet low-income country needs
3. Strengthened regulatory capacity in low-income countries (LIC)
4. Developed an effective mechanism that significantly reduces registration time for prequalified finished pharmaceutical products (FPPs);
5. Improved capacity to manufacture FPPs and active pharmaceutical ingredients to international standards;
6. Increased the availability of medicines testing services through prequalification of QCLs;

In Nigeria WHO has worked with eleven pharmaceutical firms to achieve international good manufacturing practices (GMP) standards and to have products pre-qualified by WHO (AUC-UNIDO, 2012). Available records show that only four drug manufacturing companies have been pre-qualified by WHO. The companies are: Swiss Pharma Nigeria Limited, Evans Pharmaceutical Ltd, May & Baker Pharmaceutical Ltd and Chi Pharmaceutical Ltd. (Chukwu, 2014).

## **4.5. Academic/ Industry Linkages**

### **4.5.1. Overview**

The pharmaceutical industry depends on research and development (R&D) for the development of the medicines that they produce. R&D could be conducted in-house, where industrial firms have their own laboratories, but research could also be contracted out to universities or research institutes. Universities have long been recognized as sources of knowledge creation, innovation, and technological advances. In order to fully utilize universities' potential, Nigerian governments are actively pursuing strategies to strengthen University and Industry Collaboration (U-IC). Oyelaran-Oyeyinka and Adebawale (2012) disclosed that a wide variety of factors combine to determine the nature of innovation, innovation capacity, research performance and collaboration in the Nigerian universities and public research institutes. FMH (2005) assured that considering the enormous cost of R&D, government shall provide support and an enabling environment to encourage such activities, specifically in developing new drugs and improving existing ones.

Furthermore, R&D shall be encouraged, especially in the areas of local raw materials as sources for new drugs, traditional medicines among others.

Ssebuwufu *et al* (2012) showed that many African universities have undertaken efforts to foster and institutionalize linkages with the productive sector. However, such offices operate on minimal budgets in many institutions, and are not always staffed with sufficient expertise in entrepreneurialism, intellectual property right management, and marketing strategies. Furthermore, many lack complementary and supportive policies and mechanisms for regulating interactions with the productive sector. There are universities where the Directorate of Linkages have been created to drive U-IC amongst other collaborations. For example, at the Obafemi Awolowo University there is a Director of Linkages and Sponsored Research (OAU, 2019).

#### **4.5.2. Why enter into university-industry partnership?**

Ssebuwufu *et al* (2012) noted that in general, firms in Africa tend to make use of low technology products, operating at low technical efficiency with little interest in investing in R&D generally. In the broader literature, perceived benefits from university-industry collaboration include: providing alternative funding channels in an era of constrained financing; access to/or acquisition of state-of-the-art equipment; improved curriculum and training in technology-oriented programmes and problem-solving; enhanced employment prospects for students; supplemental income for academic staff; and clearer contribution of universities to the economy, among others.

One of the major problems facing Nigeria is graduate unemployment. A situation that has been worsened by the increasing number of universities in the country and the mismatch between the school curricula and the needs of the industrial sector of the economy. University-industry collaboration has been suggested as one of the measures that could mitigate graduate unemployment in Nigeria. Some authors have suggested among others the need to bring in seasoned industrialists to participate in drawing curricula and also teach some practical courses on part time basis in Nigerian Universities. This should hopefully further equip Nigerian graduates with skills needed in the industrial sector of the economy with implications for their employability (Segun *et al.*, 2015)

Oyelaran-Oyeyinka and Adebawale (2012) studied determinant of innovation in University-Industry Collaboration in some life sciences including pharmacy in Nigeria. They found that inter-firm linkage is driven not by strategic concerns but the need to maintain production regime in order to remain competitive. Firms do not see universities regarding solutions to these sorts of immediate challenges. Learning to improve products is firms' central activity; the main actors are buyers and suppliers of components, materials and machinery. Universities play a part when firms need new knowledge that helps them move to a new and potentially higher production regime. This is precisely what firms confirm they require, but they are hardly able to pay for the services of university academics, they often are not able to spare the time and some are unable to properly define the problem that requires solution in the language of the academics. Engaging in academic-industry collaboration is a long-term endeavour for industrial partners for business growth and value creation. However, the readiness of majority of the firms for such venture is doubtful. (Jávorka *et. al.* (2016).

### 4.5.3. Challenges of U-I Linkages

UNCTAD (2009) notes that in Nigeria, as in most African countries, weak interactions exist among universities, research institutes and enterprises. Jávorka *et. al.* (2016) noted that the inherent differences between the worlds of academia and industry – for example working with different timescales, lack of understanding of each other’s needs, structures, practices or even just the language used – can create difficulties that often seem insurmountable. Collaboration in the field of education-related activities does not create obvious short term gains. Therefore, such collaboration must go together with a clear value proposition, where industrial partners can recognize the pay-off for their time and resources devoted to the project participation.

Obanor and Kwasi-Effah (2013) found that, collaboration between university and industry is mostly by individual effort, both from the university and industry point of views. This resulted in weak collaboration since this act is informal. Most academics are driven by their conferences, technical journals and their need to publish and less driven by how technology can be effectively transferred through effective collaboration. Furthermore, some industrialist, being not well informed about the benefit of collaboration, refuse sponsorship or grants proposed by the academics as the industrialist feel it’s a waste of finance and will just add a little to their expenditure.

NIRP (2014) reported that the current challenges confronting industrial development in Nigeria include low critical mass in scientific fields, inadequate equipment, inadequate information sharing, weak or no interaction between academia, industry, government and unclear commercialization path and weak intellectual property enforcement.

Oyelaran-Oyeyinka and Adebawale (2012) identified some reasons for low rate of commercialization of inventions in Nigeria to include weak or lack of interest by university researchers, poor specification of remunerations that attend researchers’ job specifications, lack of information on what universities have to offer the firms, mismatch of interest and lack of complementary assets such as R&D facilities on the side of firms, lack of finance such as venture capital to promote risky and poor support systems to assist firms to define and engage in U-I linkages.

In the opinion of PMG-MAN, academia -industry linkage is weak in the Nigerian pharmaceutical industry largely because most of the academic institutions are not equipped to fill the research gap needed by the Pharma industry. In addition, the current curriculum being adopted in Nigerian universities does not fit to industry needs. A new curriculum for pharma studies in line with industry needs was proposed during a symposium that was organized by the US Pharmacopeia in Nigeria to enable the universities produce graduates that fit into today’s pharma industry. The new curriculum, was said to have been launched by the Pharmaceutical Society of Nigeria. University lecturers also need to undergo practical industry-oriented re-training. The need to focus Ph.D. research on problem-solving for industry was also emphasised (PMG-MAN, 2019). As mentioned earlier, NIPRD recently signed MoU with about seven Nigerian universities to enhance pharma R&D and has established collaborative engagements with some pharma firms in the country. These is hoped to bring a paradigm change to what is currently observed in the country.

#### **4.5.4. Policy incentives supporting U-I Linkages**

The Science, Technology and Innovation (STI) Policy of Nigeria (2012) has, as one of its strategic policy objectives “Initiate, support and strengthen strategic bilateral and multilateral co-operations in scientific, technological and innovation activities across all sectors of the economy.” STI has several incentives for the support of U-I Linkage in Nigeria. The policy articulated strategies to develop virile and strong pharmaceutical system by strengthening demand-driven in natural and orthodox medicines, biological diagnostic tools and vaccines. The incentives given to the pharmaceutical industry in Nigeria are that government allows the pharma firms to import production plants on duty free and they are assured of government patronage. UNCTAD (2009) also notes that there is a tax incentive to encourage corporate contributions to research institutes in Nigeria.

#### **4.5.5. Support Structures for Management of Intellectual Property Rights**

Enabling environment is needed for Industry-Academia collaboration to succeed. Provision of support structure for the protection and management of Intellectual Property Rights (IPR) is one of such structures. A structure that was established by the government of Nigeria is Intellectual Property Technology Transfer Offices (IPTTOs). The National Office for Technology Acquisition and Promotion (NOTAP) has established forty three (43) IPTTOs in Universities, Polytechnics and Research Institutions in Nigeria.

The offices are established to promote interaction and strengthen the linkage between University/Research Institutions and Industries, develop a robust IPR portfolio through patenting, copyright, technology licensing; to support the Institution's initiative in developing patent culture. The IPTTO also sets into motion the formal system of incentives and reward that encourages individual researcher to collaborate with industry. The IPTTOs are also to facilitate the utilization of patent documents for research in tertiary institutions. To further drive this process the guidelines for registration and monitoring of technology transfer agreements in Nigeria was revised and published in 2018. To that end, and in 2019, the IPTTO in Obafemi Awolowo University has registered about five patents in drug related technology field, particularly from the Drug Research and Production Unit. Some of the pharma inventions include a non-invasive TB test equipment, anti-cancer drug and arthritis drug among others. It should be mentioned that the researchers/scientists were able to secure these patents with the rigorous assistance of the IPTTO in the university. The IPTTOs in the tertiary institutions have assisted a number of them to develop IP policy to promote innovation and industrial linkages.

#### **4.5.6. Success Stories of U-I linkages**

There have been a few success stories in the U-I linkages and discusses below.

##### **Agriculture, Engineering**

Several new crop varieties that were developed from Nigerian universities and research institutes have been successfully commercialized and are cultivated in the country. Besides crop development, agro-processing machineries have also been successfully commercialized. The list of such inventions is long, and it includes small-scale dryer, yam pounding machine, insecticide from local plant extracts, and anti-corrosion agent for cast-iron components, anti-ulcer and anti-snake bite remedies, and distillation of essential oil, among others.

## Pharmacy

NOTAP (2016) reported the following break-through of raw materials and products that require attention of government, investors and entrepreneurs.

1. Development of an effective anti-sickling phyto-medicine
2. Development of a process for production of pharmaceutical grade starch
3. Development of a process for the production of microcrystalline cellulose for use in drug formulation
4. Development of an effective anti-malaria phyto-medicine
5. Development of an effective anti-diabetic phytomedicine
6. Development of an effective anti-fungal phyto-medicine
7. Extraction of essential oils from local plants
8. Extraction of pharmaceutical grade artemisinin from *Artemisia* plant grown in Nigeria

A major success story of Academic-Industry Technology transfer in Pharmaceutical industry in Nigeria is Niprisan, a medicine that was developed for the management of the Sickle Cell disease. Niprisan was developed in 1998 by Nigeria's National Institute for Pharmaceutical Research and Development in collaboration with local traditional herbal practitioners from Nigerian medicinal plants that is used for treating the disorder in Nigeria. The drug was granted a US patent in September 1998 and had passed through clinical trials.

Niprisan, is formulated from parts of four different indigenous plants namely: *Piper guineense* seeds, *Pterocarpus osun* stem, *Eugenia caryophyllum* fruit and *Sorghum bicolor* leaves. Though Niprisan is not a cure for Sickle cell anaemia, the drug has proved to be potent in managing sickle-cell disorder in patents, as it significantly reduces the occurrence of crises without any toxicity or serious adverse effects on patients.

However, the commercialization of Niprisan got hampered by several challenges. The exclusive rights to the patent were eventually sold to a US-based, Indian-owned company Xechem International in 2003 and successfully secured an "orphan drug" status for Niprisan in the United States in 2004 and in the European Union in 2005. Xechem established a production plant in Nigeria and the drug was launched into the Nigerian market as Nicosan in 2006. After production slowed down the exclusive license given to Xechem International for the manufacture and marketing of the drug was withdrawn in March 2009. The Nigerian government took over production through NIPRD but its commercial production was later stopped in 2015. After the patent expired in 2017, an Illinois pharmaceutical company, Xickle started to produce its own version of the drug and the company claims its drug has twice the anti-sickling activity of the original Niprisan. In order to reactivate the production of the drug in the country, NIPRD signed a production agreement with a Nigerian pharmaceutical company, May & Baker in June 2018.

## 4.6. Intellectual Property Rights and Technology Transfer

### 4.6.1. Overview

Nigeria has been a member of the World Trade Organization (WTO) since 1995 and is classified as a Developing Country (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:

1. 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 researchers who intends to patent an invention 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 office has since 2006 started establishing technology transfer offices in the research system to ease the process of patent application and also design incentive scheme for industry collaboration.
2. 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.
3. The National Patent Registry (NPR), under the aegis of the Ministry of Commerce and Industry, is responsible for patenting inventions 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. Nigeria does not conduct substantive patent search for lack of capacity, therefore patents are granted based on formality. 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. National Office for Technology Acquisition and Protection (NOTAP) is responsible for regulation of technology acquisition and protection, including Intellectual Property Rights (IPR) issues, patents, benefit sharing, etc.

#### **4.6.2. Application of TRIPs Flexibilities**

Creativity and innovation are the hallmarks of socio-economic and technological progress of nations. Therefore, most developed and newly industrializing nations devote huge resources to the promotion of innovation and creativity in all sectors of the economy. This is achieved through deliberate investment in knowledge and infrastructure. Given huge resources required to develop new products, technologies and services, and for investors to reap maximum returns, robust intellectual property (IP) regime becomes necessary. IP law confers statutory expression to the moral and economic rights on creators and the rights of the public to access those creations (WIPO, 2009). By this, creativity and technology transfer are encouraged, or supported for the betterment of the society. Over-protection of intellectual property has resulted in chaos in several circumstances as it has been argued from the developing countries' perspectives that it keeps them perpetually underdeveloped. This is due partly to lack of access to cutting edge technologies, low production capabilities and poor scientific and technological engagements which put them at the mercy of the developed nations. This section therefore focuses on the

interaction between IP system and access to medicine in the developing country, with reference to the World Trade Organization (WTO), Trade-Related Aspects Intellectual Property (TRIPS) and how the flexibilities could be utilized.

Scientific and technological innovation has contributed to the development of new medicines, diagnostic equipment, and health monitoring and treatment devices, among others (Global Innovation Index, 2019). These innovations have significantly improved health conditions, and reduce health crises, relating in particular, to HIV/AIDS, malaria, tuberculosis and avian influenza which constitute major problems in many parts of the world (WIPO, 2019). In various national and international fora, solutions are sought in respect of the role of IPs in pharmaceutical innovations and fair and affordable access to health care.

However, since TRIPS Agreement came into force, all member states of WTO are obligated to comply with TRIPS agreement by incorporating its provisions into the national patent laws, including patent protection for product and processes. By virtue of Article 27 (1) of the TRIPS Agreement, pharmaceutical products or processes, including medicines fall within the scope of patentable subject matters. Strong patent system and its effects on essential medicines has been discussed widely at the levels of WTO, WIPO, WHO, public health institutions, civil societies and NGOs with greater emphasis on the use of TRIPS flexibilities (Sell, 2007). On this development, member states have rights to use the flexibilities to their own advantage for easy access to essential medicines and pharmaceutical products. Doha declaration also reaffirms the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for that purpose. TRIPS flexibilities came with the assumptions that all countries, including the least developed countries have the capabilities to produce essential medicines using compulsory license.

The Nigerian laws on IP provide remedies for the intellectual property rights owner in event of infringement on his rights by a third party. Remedies like damages, injunctions including rendering of account of profits and other forms of relief as the court may deem fit. This tallies with the provisions of the TRIPS Agreement in Articles 45 through 46. However, the TRIPS Agreement in Article 48 provides for indemnification of the defendant where the action against turned out to be baseless and has thereby deprived him of his own rights, this provision is not replicated under any IP law in Nigeria. This is one aspect that needs attention. (Itanyi, 2016). Nigeria should not make a wholesale application of TRIPS but in a manner that upgrades Nigeria IPR regimes to international standards and also give indigenous talents opportunity to flourish.

The use of TRIPS flexibilities is rare in the Nigerian pharmaceutical sector given low technology capabilities among the local firms. Also, the Nigerian intellectual property systems appear to be fragmented as they are managed by three distinct agencies and three ministries. The Ministry of Industry, Trade and Investment is in charge of the patent registry, National Office for Technology Acquisition and Promotion in the Federal Ministry of Science and Technology (FMST), while the Nigerian Copyright Commission is located in the Ministry of Justice and handles copyright related matters. On the application of TRIPS flexibilities in the Nigerian pharma sector, the government has never applied the popular compulsory license at all. Pharma firms obtain relevant licenses to produce their drugs in the country (FMoH, 2019).

## CHAPTER FIVE

### 5.0. PHARMACEUTICAL SECTOR IN SENEGAL

#### 5.1. Promotion of local pharmaceutical industries and social inclusion through procurement policies and strategies

##### 5.1.1. General situation

In Senegal, the PNA (National Pharmacy Supply) has a monopoly on supply, storage and distribution of essential drugs and products to the country's public health establishments, such as hospitals, districts, non-governmental organizations., special programs, para- public structures, and even private wholesale distributors (on some molecules). Currently, there are two tenders programs established to support local industries:

**National Preference during international tender:** The PNA proceeds mainly by international tender for the procurement of medicines by following the public procurement code. There is a policy governed by the public procurement code applicable to the local pharmaceutical industry. According to this code, WAEMU local industries benefit from a national preference of 5-15% during international tenders organized by the PNA (*source DPM, article 50 public procurement code*). The national preference does not apply only to Senegalese' industries but concerns all WAEMU member countries due to the fact that all WAEMU member countries must respect the economic and free movement of medicines agreements.

**National tender:** To promote the local pharmaceutical industry, PNA in collaboration with the industries has developed a national tender program (all WAEMU countries) in 2017. For that purpose a list of 60 products has been established and only the local industries had the right to bid with a contract over 3 years to the winner. However, this operation was not successful as expected due to the fact that the industries could not have in their portfolio the 60 requested products. (Source PNA).

##### 5.1.2. Policy incentives to support local pharmaceutical industries

There are several policy incentives that the Government of Senegal has put in place. These include the special economic zones, export free company, and industry labelling.

##### **Special economic zone (ZES)**

The Senegal Emergent Plan (PSE) has planned the realization of two or three large-scale industrial platforms designed as an ecosystem of high-performance services and incentives, with the aim to promote industrial development. (*Source Ministry of Investment Promotion of partnerships and development of teleservices of the Government Decret 2017 2189*). In this perspective, Senegal currently has 3 special economic zones (Diass, Diamniadio, Sandiara) in Senegal which are spaces for the reception of economic activities. The purpose is to offer to companies a set of infrastructures and services which ensure them better conditions for carrying out their activities. The ZES constitute investment opportunities for new industries.

Companies and promoters can benefit from an incentive package that entitles them to tax and customs exemptions. (*National Agency for the Promotion of Investments and Major Works APIX*). As provided in Law No. 2017-07 of 06 January 2017 on the incentive scheme applicable in ZES and the decree n ° 2017-1174 implementing the law n ° 2017-07 of January 06, 2017, the exempt companies will benefit Over a period of 25 years' renewable:

1. the right of admission free of all duties and taxes levied, excluding Community levies on raw materials, equipment and other goods, and the duty free of export outside the national territory,
2. an exemption from payment of any income tax,
3. a tax rate of 15% on corporation tax,
4. the possibility of concluding fixed-term contracts for a period of five years,
5. an exemption from the lump sum contribution from the employer or any other tax based on salaries,
6. an exemption from the flat rate minimum tax on companies

### **Export Free Company**

We also have export free companies that are individually licensed companies. These companies have the following advantages: Exemption VAT import and exemption duties and taxes of customs. *Decree approving the status of free enterprise of exploitation February 2018*. The creation of these areas is a real advantage for local industries. Currently, several pharmaceutical industries take benefit of privileges granted to these areas, like Medis, Parenterus, West Africa Pharma (WHAPHA). (Source APIX) The new company Teranga Pharma has acquired the former Pfizer site in the Export Free Zone

### **Industry Labelling « PSE »**

PES is a new model of development that Senegal has put in place to accelerate its progress towards emergence. This strategy is the guidance for economic and social policy in the medium and long term. (*Senegal Emergent Plan*).

This labeling concerns more the creation of new industries. It helps to reduce administrative delays, and helps companies to have the right administrative information or support for business start-ups.

### **5.1.3. Regional Programmes which promote the use of procurement policy as a tool to promote local pharmaceutical industries in the region.**

Aside PNA program, we did not find regionally other program which try to promote the use of procurement Policy in Senegal. However, on May 2018 UNIDO and West African Health Organization (WAHO) agreed to collaborate and support the development of the pharmaceutical industry across the ECOWAS region. This project is more linked to GMP aspect which is crucial in order to have quality medicines and a guarantee of safety to promote the export of products. The aim of this cooperation is to develop a regional Good Manufacturing Practices (GMP) Roadmap Framework and national initiatives to upgrade the pharmaceutical industry in the ECOWAS region. This program would enable local industries to meet WHO quality standards to meet local and international standards. Indeed, UNIDO at the sub-regional level has put in place an evaluation plan of all pharmaceutical industries in all countries, a roadmap to develop them and allow them to be more competitive internationally. (*Source DPM*).

The West African Health Organization (WAHO) has developed the ECOWAS Regional Pharmaceutical Plan (ERPP). This describes a comprehensive approach to improving access to essential medicines in the region. A central element of the plan is to reduce reliance on imported products from outside the region. WAHO has been working with UNIDO since 2017 to develop a regional GMP roadmap framework for the ECOWAS pharmaceutical manufacturing industry to comply with internationally recognized GMP standards. In summary, the work was described as a draft framework for the ECOWAS GMP Regional Roadmap.

This approach provides a comprehensive framework that has been developed using data from all countries and technical approaches at the national level.

It is also important to note that upgrading manufacturing standards is very complex because that requires not only knowledge and technical expertise, but also the combination of many other factors such as environment that encourages investments, technologies and human resources. Manufacturers need support and advice to develop their business and time to implement the resulting upgrade plans. (*Source DPM*). This work has been already started in some countries like in Senegal where 2 pharmaceutical companies Medis and ValdAfrique have been evaluated as drug manufacturing.

#### **5.1.4. Experiences, best practices and success stories from those countries that have implemented such policies**

When we talk about access to medicines in Africa, Morocco is often an example. Moroccan production covers nearly 60% of the country's needs. Morocco has been able to lay the foundations of a pharmaceutical industry since the sixties. The Government has instilled a regulatory dynamic; it has introduced a very strong regulation and developed a political will to ensure therapeutic sovereignty. These are the first steps to put in place for a local industry which is a strategic sector. However, it was only the private sector that has invested in this sector. After the sixties, the Government prohibit the importation of medicines that could be manufactured in Morocco. Tablets, suppositories, syrups, drinkable ampoules, were banned on import to promote local manufacturing. This allowed the multinationals that were established in Morocco to move to the production stage. This implantation contributed to provide expertise and technology transfer. Subsequently, training was put in place with pharmacy studies in 1986-1987. (*The drug in Africa: how to better respond to the issues of accessibility and quality? April 3, 2018 French Development Agency*)

#### **5.1.5. How Donor healthcare subsidy policies affect the growth of the local pharmaceutical industries in Senegal.**

The government has set up the Universal Health Coverage (CMU) program to enable medical coverage of populations, in particular, the rural population and the informal sector through community health. It is also noted the remarkable efforts made in the management of existing free policies including the care of caesarean section, dialyze, people aged at least 60 years (SESAME Plan) and children 0-5 years. In addition, there are other health care program for tuberculosis, malaria, AIDS, diabetes in the sector. (*Ministry of Health and Social Action 2017-2021 SECTORAL INVESTMENT PROGRAM*). We have development partners who are also involved in financing health programs for the purchase of vaccines, antiretroviral, contraceptives, antimalarial, and medicines for neglected tropical diseases. We also have free chemotherapy to facilitate the medical treatment of women living with cancer of the cervix or breast and 60% reduction for chemotherapy of other cancers. This initiative took effect on October 1st, in all the public health structures (Source Ministerial Circular MSAS September 2019).

The interviews were conducted allowed to conclude that the major part of the subsidy programs' medications are either not locally produced or if they are locally manufactured does not fully comply with all the criteria required to take advantage of these programs. Indeed, the drugs that benefit from the various subsidy programs (Roll back Malaria, IMF, WHO ...) must most often

meet the WHO Prequalification. Today the only known prequalified drug in Senegal is the yellow fever vaccine manufactured by the Pasteur Institute for UNICEF.

#### **5.1.6. Government initiatives that support local pharmaceutical industries in Senegal.**

In Senegal we do not have a direct subsidy from the Government to local industries. However, the following initiatives support the local pharmaceutical industries in one way or the other.

- 1. Sovereign Strategic Investment Fund (FONSIS):** FONSIS is a sovereign investment fund that governs the operation of the largest international sovereign wealth funds of the member countries of the International Monetary Fund (IMF). The mission of FONSIS is to promote the role of the Government of Senegal, as an investor, partner and complement of the private sector, with the aim of supporting direct investments in order to accelerate the economic and social development of the country by creating wealth and jobs for present and future generations. In a globalized world where investors are looking for new emerging markets and niches with strong potential for growth and profitability, FONSIS will contribute its capital in well-structured projects alongside domestic and foreign investors. Several pharmaceutical industries have benefited from the support of FONSIS. Moreover, Investments in the pharmaceutical industry represents 25%. (Source FONSIS).
- 2. Deposit and Consignment Fund (CDC):** Senegal's CDC, a special-status public institution created in 2006, is expected to play a major role in the Senegalese economic environment. This instrument, which positions itself as a public institutional investor, constitutes a kind of financial arm of the Government, capable of responding to economic and social issues. (Source CDC). The new manufacturing site Parenteral was supported by CDC during his creation.
- 3. Priority Investment Guarantee Fund (FONGIP):** FONGIP has been set up to act incomplementarity with other public entities in the financial ecosystem in order to mobilize public and private financial resources for MSMEs by providing greater comfort to financial institutions. It is therefore an innovative response adapted to the social demand by allowing:
  - a. Mitigate the risks associated with granting credit to SMEs by generally reluctant financial institutions;
  - b. Complement the intervention mechanism of financial institutions for MSMEs;
  - c. Improve interest rates currently applied by financial institutions. (Source FONGIP)

#### **5.1.7. Recommendations**

It has been noted that local manufacturers have not sufficient capacity to outperform during international tenders despite the 15% national preference and even during national tender. To succeed, local industries should regroup to submit together. Manufacturers will be able to divide the products portfolio so that each manufacturer has its own list of products for submission.

They could be able to make partnerships with Indian industries to receive bulk products and make secondary packaging. This will help to have at least the finish goods packaged in Senegal and to increase their portfolio during the bidding and to meet PNA needs.

To face products importation, It would also be preferable for African countries to create regional markets and avoid having units that manufacture the same thing. It is important to have

centralizations, poles of excellence. This would limit costs for economies of scale and compete with the Indian model.

African countries lack the industrial capacity to face Indian competition should think of targeting the ECOWAS market which is the 17th largest economy in the world and have a 385 potential consumers with the recent adhesion of Morocco (Moroccan Media 360).

To facilitate this, there is a need for regulatory harmonization and therefore a reduction in the number of regulatory registrations.

The ongoing ECOWAS program «Regulatory Capacity Building Program and Regional Harmonization Process in the ECOWAS region», will be very helpful to succeed to this ECOWAS market.

The subsidy programs could have been a great way for industries to grow because of the large amounts allocated. So It is important that medicines that fall under health subsidies, including essential drugs, to be manufactured locally and pre-qualified WHO to benefit from international subsidy programs. Once manufacturers have the capacity to produce essential medicines, the authorities could implement a patient reimbursement policy that can only concern locally manufactured products.

## **5.2. Human Resources Development**

### **5.2.1. Current human resource situation and coping strategies**

It is noted that in Senegal until 2017, apart from Valdafrique, we mainly had Pfizer and Sanofi Aventis for the manufacture of drugs. The industrials have benefited from high quality standards, technology transfer, global training and "on the job training" of these multinationals. However Pharmacists do not have a strong representation in pharmaceutical industries; we can note a maximum ratio of 22% of the total number of senior staff. (Source Local industries)

### **5.2.2. Role played by the national universities and other training institutions in Senegal to address the human resource challenge**

In Senegal we have a Faculty of Pharmacy located at Dakar University Cheikh Anta Diop (UCAD) A second faculty is being built at Thies in western Senegal.

We have mainly 4 training and specializations in the Faculty of Pharmacy (*Decree on the training of the faculty of medicine, pharmacy and odontomatology approved by the university assembly*)

1. Bachelor's degree in physicochemical science applied to drugs, cosmetology and agribusiness
2. Masters in Pharmaceutical Sciences
3. Masters in Biototoxicology Applied to Industry, Environment and Health
4. Master in Industrial Drug Development
5. Master in Hospital Pharmacy and Communities
6. Master in Herbal Medicine and Cosmetology
7. Master in physicochemical sciences
8. Master in physico-chemical analysis and quality management of health products and food  
University degrees in pharmaceutical sciences
9. University degree in risk analysis and management of sanitary and phytosanitary quality

To face these challenges of human resources, the University of Dakar is in close collaboration with other foreign universities for knowledge sharing. In that respect we have a direction of cooperation which have mission to support the international strategy of the establishment and to contribute to the implementation of the guidelines defined by UCAD.

It works closely with the various components of the university to provide students, research professors or universities and partner organizations with the following services:

1. Development and monitoring of cooperation agreements with partner universities ;
2. The coordination of incoming and outgoing mobility
3. The development of a policy of international mobility grants according to financial support of the partners ;
4. The financial management of research projects related to cooperation, mobility and the management of grants awarded.

Currently the Cooperation Department monitors more than 300 agreements with partner universities worldwide, but also with companies, local authorities, foundations, NGOs, etc. Conscious of the interest and the importance of an international stay, it is a strong support for research professors and students going abroad or coming from abroad. (*Coopération Direction UCAD*). So, the Faculty of Medicine and Pharmacy is currently in cooperation with several countries including (*source : List active agreements June 2019*) :

1. Romania: University of Medicine and Pharmacies Grigore T. Popa de Lasi. This indeterminate agreement aims to promote the exchange of teachers, researchers and students
2. R.D. CONGO Brazzaville: Marien Ngouabi University, Pharmacy. This five-year agreement aims to facilitate student and teacher mobility, co-supervision or co-supervision of doctoral thesis, and participation in thesis' juries.
3. R.D. CONGO Brazzaville University of Kinshasa. This three-year agreement aims to organize teacher missions, teacher and student internship; exchange documentation, organize joint research project.

### **5.2.3. Role the Senegal in the diaspora can play to provide the required human resource expertise in the pharmaceutical industries and recommendation?**

The pharmaceutical industries in Senegal are not numerous and consequently the offer is much lower than the demand. Also the industries are not attractive in terms of innovative products, infrastructures so that the Senegalese of the diaspora are not willing to return in Senegal. However, like Rwanda in 2009, a Senegalese Diaspora policy should be established. The policy could be the guiding framework which sets out how authorities wishes to see the Senegalese diaspora contributing and being integrated into the national development of the pharmaceutical sector. So Knowledge and skills could be transferred through services like:

1. Capacity-building program, mobility-based approach which helps to mobilize competencies acquired by African nationals abroad for the benefit of Africa's development. Through its, African nationals will directly contribute to the development of their countries of origin.
2. Short-term volunteering Program to reverse the 'brain drain' by encouraging nationals to provide their expertise, transfer of knowhow and skills.



3. Short-term consultancy services or partnerships between local and diaspora professionals' organizations.

#### **5.2.4. Collaboration with countries from Asian countries to support the sector**

The desire to have local industries should not exclude the presence of multinationals or Asian giants. Instead, the presence of these industries favours the transfer of technology, generates jobs, limits imports and therefore facilitates access to medicines. What is important is to have a win-win partnership. Also the industries currently in Senegal, could purchase bulk generic products from these countries in order to make the secondary packaging. This could allow local industries to participate actively in international tenders.

#### **5.2.5. Support of Senegal to help other West African countries to develop their local pharmaceutical industries**

Senegal has several advantages, particularly at the geostrategic and political levels. Indeed it is located in the far west of the African continent and is limited to the west by the 700km Atlantic Ocean, privileged gateway to Africa, facilitation of technology transfer. So Senegal constitutes an open door to the rest of the continent with modern and structuring infrastructure, political stability, and good institutional governance. Technology transfer, training and human resources mobility can be important milestones for helping other countries to develop their industries.

#### **5.2.6. Recommendations**

It would be important to strengthen the partnership with the University to improve the theoretical and practical training of pharmacists. The Government should offer merit scholarships to support pharmacists in their postgraduate courses which are usually quite expensive. Currently most of the training is done by university professors. It is important that some specific courses to be provided by industry professionals

### **5.3. Research and Development**

In Senegal there are a lot of research activities performed by the universities and some research organization. The UCAD research system is structured around a Research Department, a Scientific Advisory Board, the Cooperation Department, the Intellectual Property Department and the Valuation Department. Research results, and the Research Ethics Committee. Senegal also have the Support Office for Research and Innovation (BARI) which supports the implementation of UCAD's research and innovation policy by developing support services for research structures, providing support for strategic research management and supporting innovation and knowledge transfer. Its mission is to provide support for documentation, editing research projects, communication and publication of scientific results. It is intended to support access to international research at UCAD, to make international tenders more visible, to encourage PhD students and young professors of UCAD to respond to them. (Source UCAD). There is also the Institute of Research and Development (IRD) whose missions are:

1. Scientific research within units and laboratories to produce knowledge.
2. Training through the reception of students, post-docs or researchers in activities. The goal is capacity building to achieve or maintain a level of excellence.

3. Valuation through operational applications of research (patents or expertise).

### **5.3.1. Existing national, regional and international funding programs for R&D in the pharmaceutical sector in Senegal**

In Senegal there is no pure research in the pharmaceutical sector, the tests performed are mainly the pharmacopoeia sector. The investment in research for the pharmaceutical sector are very limited. The Faculty of Medicine, Pharmacy has conducted several studies on medicinal plants with the support of Non-Governmental Organizations. Other institutions have also carried out studies including the Inter State School of Veterinary Sciences and Medicine, the Faculty of Sciences and the Fundamental Institute of Black Africa (IFAN). (Source PNP 2014). Currently there is a national subvention to the Chemistry laboratory for studies on the sickle cell disease. (Source Chemistry Laboratory UCAD)

### **5.3.2. R&D Activities of universities, research organizations and centres of excellence on developing local pharmaceutical raw materials to support local industries**

There is no formal activities that are striving to develop raw material for local pharmaceutical. However, some senegalese pharmaceutical actors have participated earlier this year to « Africa Sante Expo at Abidjan ». During this meeting, it has been shared the partnership between the Virginia Commonwealth University (VCU) and Institut national polytechnique Félix Houphouët-Boigny (INP-HB) for:

1. The development of low-cost drugs to increase access to global health
2. The development partnership in an effort to foster a regional collaboration towards pharmaceutical process development in West Africa. The training of doctoral students and researchers, and for orientation programs and continuing education opportunities in scientific, medical, and pharmaceutical fields

The outcomes of this collaboration will be:

- a. The development of a public-private partnership with pharmaceutical Industries for the implementation of the manufacturing of the active pharmaceutical ingredient (API).
- b. The Institute will serve as technical support to the building of a Pharmaceutical Manufacturing in Cote d'Ivoire, using the research results from both INP-HB and VCU.
- c. This Pharmaceutical Manufacturing will adopt new technological approaches like Continuous Flow Chemistry. (Source *Africa Sante expo February 2019*)

### **5.3.3. Challenges facing Senegal companies in starting local production of Active Pharmaceutical Ingredients (API)**

Existing activities around drug development targeting treatment of malaria and HIV-AIDS based on indigenous knowledge and biodiversity in Senegal. In Senegal we have research carried out by UMR VITROME (Mixed Research Units: IRD / Aix-Marseille University) on Malaria. This work focuses on three main areas: the discovery and molecular identification of emerging pathogens, the study of insect vectors and therapeutic research. (Source Mission UMR VITROME)

Most of the research on HIV / AIDS and malaria focuses on the pathogen, the modes of transmission or the therapeutic course. We could not find a study on drug research targeting these diseases. However at the University, there is research carried out but its focuses most often

on the therapeutic activities. Indeed due to the lack of equipment which are very expensive, they are not able to perform molecule extraction. Added to that, there is no enough collaboration possibility between academia and industries to transfer research performed in the university to the industries for development. Indeed, local industries are mainly generic company which are not really interested to perform research and development. So some critical tests are outsourced abroad but there is a risk of loss of intellectual property.

Senegal has a rich experience in medicinal plants and has some traditional medicine centres and Community Centre for Appropriate Technologies for Health (CCTAS). Senegal has established by ministerial decree a National Commission for Senegalese Traditional Pharmacopoeia and the National Formulary.

This commission aims to develop the Senegalese pharmacopoeia and the national form. Regulatory texts relating to the registration of Improved Traditional Medicines (MTAs) have been also developed. The updating of these documents and their adoption will allow the development of MTAs. Today, traditional healers need scientific supervision to guarantee the safety of MTAs. For this purpose centres of clinical experimentation of medicinal plants have been created in the health centre but these centres are not functional because they have no operating budget. (Source PNP 2014)

#### **5.3.4. Recommendations**

The difficulties encountered in research are mainly related to the lack of funding, the valuation and popularization of the results.

The lack of very expensive research equipment, the lack of collaboration between academia and industries (mainly generic industries) for R & D, the risk of loss of intellectual property linked to the outsourcing of certain tests, justifies largely the need for funds to be able to carry out R & D locally. That's why it is important to have subvention from organization and or the national authorities to be able to buy the equipment needed to do the research locally.

Many medical research (malaria, AIDS, etc.) are also carried out with the support of organizations like IRD France. It is therefore important that pharmaceutical researchers work closely with these structures to take advantage of their subventions.

It is important to support Senegal, which is a country rich in medicinal plants, to value and to exploit the biodiversity of its local products for therapeutic activities and for molecule extraction. Research and development in biosimilar, packaging materials need to be explored also.

### **5.4. Intellectual Property Rights and Technology Transfer**

#### **5.4.1. Voluntary License for manufacture of ARVs**

Currently there is no industry producing ARVs. Most of the generic products manufactured by Senegalese industries and exported to neighbouring countries are destined either to public procurement centres or to private wholesalers. For exportation of generic drugs both in the case of a winning bid or an order from a private wholesaler, the main requirement for exporting to these countries is to have market authorisation and the certificate of manufacturing.

For Prequalification, it most often linked to drugs subsidized by international organizations such as UNICEF. For the moment only the Institute Pasteur, with the WHO prequalified yellow fever vaccine is concerned by this case. Some companies in Senegal are manufacturing using voluntary license for some products. Indeed voluntary licensing arrangements between a patent holder and another party in a country, or serving the country's market, may afford opportunities for significant cost-containment. As with negotiated discounts, the benefits of voluntary licensing arrangements depend crucially on the terms of the licence. This license can be

delivered on an exclusive or nonexclusive basis, the right to manufacture, import, and/or distribute a pharmaceutical product. Depending on the terms of the licence, the licensee may act entirely or effectively as an agent of the patent holder; or the licensee may be free to set the terms of sale and distribution within prescribed markets, contingent on payment of a royalty. Either option, or arrangements in between, may allow for substantial price reductions. However, terms in a voluntary licence may set price ranges, or include other terms, that maintain prices at or near the same level as those offered by the patent holder

#### **5.4.2. Review also the progress made in implementing the TRIPs (Trade-Related Aspects of Intellectual Property Rights) flexibilities policy and guidelines developed by Senegal.**

The Senegalese Agency for Industrial Property and Technological Innovation (ASPIT), is the National Structure of Liaison with the African Intellectual Property Organization (SNL/OAPI). ASPIT was born from the merger between the Department of Industrial Property and the Senegalese Agency for Technological Innovation created since 2001. The new Agency has a public service mission for the promotion of Invention and Technological Innovation. Its objective is to make the productive sectors more competitive, to supervise and support industries, agricultural and / or artisan projects. Priority is given to innovative projects that generate growth with high added value and that can create new jobs. The Bangui Agreement, which is considered the Senegalese Industrial Property Code, is the legal basis for protection in Senegal.

As Senegal's trade policy is resolutely oriented towards the liberalization of trade, the respect of international commitments is a priority. In this perspective, a National Committee for International Trade Negotiations (CNNCI) was established by Decree No. 2001-1072 of 12 December 2001 and a subcommittee set up within it, scrupulously ensures the respect of intellectual property rights and the implementation in accordance with national legislation and international commitments.

The NGO Yolse in collaboration with the African Union, the United Nations Development Program (UNDP), UNAIDS, the Ambassador of Senegal, the South Center organized a workshop on 23 November 2015 with a view to sensitize the representatives of the OAPI member states of the importance of integrating the flexibility of the transitional period into the Bangui Agreement. The workshop was a success due to the sensitization work of the NGO Yolse and its partners. The OAPI member states incorporated into the revised Bangui Agreement in Bamako on December 14, 2015, the decision of the Council of TRIPS of 6 November 2015 exempting Least Developed Country (LDCs) from the obligation to grant or enforce patents on pharmaceutical products and to protect data resulting from pharmaceutical-related clinical trials until 1 January 2033. (Source *Contribution from NGO Yolse at the work of the United Nations Secretary-General's High Level Panel of Experts on Access to Medicines February 28, 2015*)

Thus in 2015 Senegal participated in the revision of the Bangui Agreements to comply with the provisions of TRIPS. The Republic of Senegal deposited its instrument of ratification of the Bangui Agreement, Act of 14 December 2015, to OAPI, on March 28, 2017. After Mali and Gabon, Senegal is the third country to ratify through its parliament the Bangui Agreement. ASPIT, through its role of National Liaison Structure with the African Intellectual Property Organization (SNL / OAPI), must translate at the national level the main tasks given to it by the Bangui Agreement, namely the promotion and sensitization on the use of the industrial property

system for economic and social development. And by the end of 2019 a national committee for the implementation of TRIPS will be established in Senegal. (Source *ASPIT*)  
Currently only yellow fever vaccine produced by Institut Pasteur of Dakar is certified WHO.

## **5.5. Academia-University - Industry Linkages**

### **5.5.1. Policy incentives to support university-industry linkage**

We have a partnership University Industry but that has never been formalized. This partnership allows the pharmacist student to perform internship every year in these industries. This partnership has started spontaneously and so far allows students who have made industry option to benefit from an induction internship during 3 to 4 months in the pharmaceutical industry. Also it was issued during a workshop on the development of the pharmaceutical industries in Senegal organized by the Ministry of Health and Social Action (MSAS) in relation with the Premature and in collaboration with several departments such as General Directorate of Taxes and Domains (DGID), Directorate of Private Sector Support (DASP) / Customs / Taxation / Fonsis / Fongip, APIX, Operational Office for Follow-up of the Emerging Senegal Plan (BOS), Directorate of Internal Trade, Directorate of Industry, the need to Strengthen the partnership with the University to improve the theoretical and practical training of pharmacist students in option Industry .(Source MSAS)

### **5.5.2. Institutional Policy and support structures for the management of intellectual property rights**

For the management of the intellectual property rights, In addition to the *ASPIT* mentioned above, we have a Draft Order on the regulation of intellectual property at the Cheikh Anta Diop University in Dakar. The systematic exploitation of research results, based on rigorous management of intellectual property, is one of the means for UCAD to establish a harmonious work environment favoring invention and creation and to obtain a financial return on investment in research by promoting the transfer of these results to companies.

This policy of UCAD in the management of its intellectual property could support companies which can thus receive technologies legally better secured and protected for the purposes of exploitation. The purpose of this Regulation is to specify the rules and procedures applicable to UCAD concerning intellectual property and valuation.

## CHAPTER SIX

### 6.0. PHARMACEUTICAL SECTOR IN CAPE VERDE, MALI, GUINEA & BENIN

#### 6.1. Overview of the pharmaceutical sector in Benin, Mali, Cape Verde & Guinea Conakry

At the heart of the health systems crises in many African countries' is lack of access to medicines due to challenges of availability and affordability. For the poor and vulnerable people, who use out-of-pocket payments to purchase medicine, the drugs, which are not always available in adequate quantities, are just too expensive. As part of a broader strategy to address the challenge of affordability of medicines, the West African Health Organization (ECOWAS) Regional Pharmaceutical Plan (ERPP) (2014) was developed to promote local production of medicines.

The purpose of local manufacturing is to enhance self-sufficiency in drug supply with a view to addressing the twin problems of availability and affordability. Besides, local manufacturing would save foreign exchange and stimulate exports, transfer technology, create jobs, alleviate poverty and promote social development. The geographical proximity of local production enables a better understanding of the local health needs, allows buyers to evaluate the manufacturing and quality control procedures of the manufacturer and facilitates enforcement of regulations through timely inspections by the Regulatory Authorities.

Currently, only a few local pharmaceutical manufacturing plants with limited production for domestic markets exist in the four countries in this study. Cape Verde, Benin and Guinea Conakry have one local pharmaceutical manufacturing plant each, while Mali has two. Mali's first pharmaceutical factory is experiencing financial difficulties and is undergoing privatization and the second factory was inaugurated in May 2018. Some of the main constraints inhibiting the establishment of local pharmaceutical industries in the countries under the study include:

1. Dependence on imported raw materials, especially active pharmaceutical ingredients (API), which are costly due to high tariffs, complex customs clearance procedures and uncertain delivery times
2. High cost of capital for investment in plant infrastructure and pharmaceutical research, development and technology
3. Inadequate Human Resource as a result of lack of relevant training programs in academia which can meet the pharmaceutical industry needs.

#### 6.2. Promotion of local pharmaceutical industries and social inclusion through procurement policies and strategies

The high costs of medicines in the four countries have contributed to significant geographic and socio-economic inequities in access to essential health services at the expense of the poor populations. The high cost of drugs is attributed to:

1. The expensive original brand and generic drugs imported by powerful global pharmaceutical firms which dominate in the local markets. The high costs are due mainly to patent protections which provide sellers of innovative pharmaceuticals with a monopoly on the market and opportunities to maintain relatively high prices where there are no alternatives.

2. Limited public funds and the heavy reliance on out-of-pocket private payments to finance public health facilities. Introduction of cost recovery policy which advocates for user fee charges led to increased cost of overall health service provision
3. Weak pharmaceutical supply and distribution chain structures, coupled with ineffective regulatory systems, leading to proliferation of counterfeits and illegal medicines, which make the cost of health services very high.

### **6.2.1. Benin**

According to the United Nations COMTRADE database on international trade, Benin Imports of Pharmaceutical products was US\$110.38 Million in 2018, comprising over 90% of total demand. About 66% was imported from France, followed by India 13%, Denmark 4.4%, Belgium 3.8%, Germany 3.1% and China 2.3%

Due to the cost recovery policy in Benin, drug prices in government health facilities are usually high. Funding from the Ministry of Health (MoH) is limited, hence there is overreliance on user fee charges as a major revenue source for health facilities. Under the universal health coverage policy, children under five years, pregnant women and people aged 70 years and above are provided with free medicines in public hospitals. However, the availability of medicines in public facilities is limited due to poor warehousing and inventory management practices; acute shortage of qualified health workers and; inadequate pharmaceutical system governance, pharmacovigilance, and regulatory capabilities. Moreover, even where drugs are to be provided free, health workers are reluctant to prescribe them and often solicit for illegal payments.

### **6.2.2. Mali**

Mali imports numerous pharmaceutical products due to lack of factories, expertise, and infrastructure. Imports of international non-proprietary name generics constitute 80 percent of drug supply in Mali. Since U.S. companies, the main exporters, enjoy a competitive advantage in the pharmaceuticals sector, Mali will continue to import large quantities of all kinds of pharmaceuticals in the next several years. However, imports of illegal and counterfeit pharmaceutical products represent about 55% to 60% of the market and pose significant problems, according to the Order of Pharmacists of Mali (Ordre des Pharmaciens du Mali). In addition to traditional wholesalers and retailers, Mali's large informal sector imports and sells pharmaceuticals without authorization. Although imported drug prices are controlled through a gentleman's agreement between the government, wholesalers and retailers, they are still relatively high.

The Bamako Initiative promulgated jointly by UNICEF and WHO in 1989 advocated for cost-recovery model based on user fees to supplement the low public spending. The cost recovery policy however, resulted in exclusion of most vulnerable people, over time, who could not pay the user fees. The policy was reversed in the early 2000s and user fees abolished. However, the user fee charges continued since it had become a major revenue to cover operating budgets of the health facilities. By 2015, user fees represented 50% of the revenues in primary health care facilities despite the universal health coverage policy. The charges became a major financial barrier to healthcare access. According to the 2017 EMOP survey, 46 percent of the population in need of health care stopped using health services because it was too expensive.

The government recently introduced universal health coverage (UHC), which advocates for free healthcare at the point of use for pregnant women and children under five. Through the UHC policy, tax legislation and price control, the Government has managed to reduce prices of some international nonproprietary name essential medicines. However, their availability in public facilities is limited due to frequent stock outs.

### **6.2.3. Cape Verde**

In Cape Verde, high price of medicines in the legal markets and distance to the pharmacy stores has led to the emergence of a parallel illegal market. A market which is highly permeable to the distribution of counterfeit, falsified, spurious and substandard medicines. Approximately one in four people purchase medicines outside the legal circuit and the Praia municipality is the most problematic, reaching one in three people. The problem is compounded by lack of awareness of the risks involved in counterfeits.

However, Cape Verde is among the countries which have implemented universal health care in the recent past. All Cape Verdeans are entitled to a basic package of health services, which covers antenatal care; emergency treatment; and treatment and prevention of HIV/AIDS, tuberculosis and malaria. Some other medicines and consultations involve a US\$ 1 surcharge, a fee that is substantially less than the actual cost of the treatment provided. For patients requiring treatment beyond the capacity of Cabo Verde's health care system, such as tertiary care for some types of cancer, the Government provides flights to Portugal and covers the treatment costs there. Between 600 and 700 people receive this sort of health care each year.

### **6.2.4. Guinea Conakry**

Guinea Imports of Pharmaceutical products was US\$109.21 Million in 2017 according to the United Nations COMTRADE database on international trade. About 50% was from India, followed by China 22%, France 20% and Belgium 1.7%. In Guinea, health service is paid for through out-of-pocket payments, making it unaffordable, particularly for indigent households, most of whom are in remote parts of the country. The government finances only one-third of health expenditures, the rest is paid by the private sector, 92 percent of which comes from the out-of-pocket payments of user fees. Insurance programs to provide financial protection for poor households are largely nonfunctioning or nonexistent. In theory, indigent people are entitled to an exemption from user fees, but in reality, the limited public financing and the tendency of health workers to augment their incomes from charge fees, lack of transparency, accountability, and the challenge of identifying who is indigent, limit the effectiveness of this policy.

## **6.3. Human Resource Development**

The major causes of human resource for health (HRH) challenge in the four countries of study include

1. lack of HRH policy and planning,
2. inadequate remuneration and incentive mechanisms,
3. Absolute shortages of pharmaceutical and other essential professionals,
4. shortage of training and skills development institutions,



5. Poor HR management (inflexible recruitment procedures, lack of career structure and incentives),
6. Lack of action-oriented research into HR interventions
7. Internal and external migration of professionals (the brain drain) and
8. The HIV/Aids epidemic.

Human resources for health (HRH) is a crucial pillar for global health security and has been included in the Sustainable Development Goals (SDG). According to the WHO's Global Strategy on HRH (Workforce 2030), 2.5 health workers per 10,000 inhabitants are needed to achieve the Millennium Development Goals. This figure is more than ten times the health workforce (HWF) currently employed by the health systems in the four countries. The problem of HWF shortage in the four countries is further exacerbated by inequitable spatial distribution, resulting in severe urban–rural imbalances. The shortage is most critical in the manufacturing sector, which requires personnel with skills in pharmaceutical product identification, formulation, production and clinical trials.

It is noted that, like in many African countries, the four countries face workforce crisis in their health systems including doctors, nurses, pharmacists and pharmacy technicians, laboratory technicians, community health workers and midwives. There was no information on r the pharmaceutical manufacturing sector workforce in the four countries in the study. This may be explained by the very low-key activity in the local pharmaceutical production industry.

### **6.3.1. Benin**

The country has a total health workforce of 10,275 (1.485 health workers per 1000 people). This is by far lower than the WHO's minimum standards of 2.3 care providers per 1,000 people needed to achieve universal coverage of needs.

The Government of Benin has prioritized the development of human resource for health in its Human Resource Development Strategic Plan (2009 - 2018) and Plan National Health Development (PNDS) (2008-2017). The plans consider the main HRH development components mentioned above. Continuing training for general health personnel is ongoing on site or abroad with the financial support of the national budget and partners. The Ministry of Health undertakes forecast of HWF to meet the need for qualified personnel. As part of these efforts, the Government, through the Administrative Decisions taken by the Council of Ministers in September 2012, launched the recruitment of 1228 health workers to fill the staffing.

### **6.3.2. Mali**

The primary HRH challenge in Mali is not health workers in absolute numbers, but maldistribution, particularly a lack of health workers in poor, remote areas far from the capital. According to Strategic Human Resources for Health Development Plan (PNS/RSS), 2009-2015), approximately 31% of physicians, and 53% of allied health workers worked outside of the capital, and over 50% of private health facilities were located in the capital. There is also low motivation among public health care workers due to insufficient financial and resource incentives, resulting in a loss of the most qualified health workers (specialists and technical staff) to the private sector. The (PSN/RSS, 2009-2015) identified the following issues as the cause of Mali's health workforce challenge:

1. a lack of recruitment from private training institutions,
2. lack of adaptation of curricula to the needs of employment,
3. inadequate planning for specialized staff,
4. inadequate coordination of HRH management and planning of training needs,
5. over-centralization of personnel management actions,
6. lack of quality staff training due to the absence of educational regulations and
7. lack of financial and physical resources at training institutions

The health workforce crisis was compounded by the declining public health expenditures, which dropped from 3.0% of GDP in 2011 to 2.3% in 2013. The budget allocation for recruitment of health workers declined progressively by 50% between 2010 and 2013 and by an additional 40% from 2013 to 2015. It is estimated that the budget needed to increase by 333% from 2015 to 2015 in order to reach the WHO-recommended minimum ratio of 2.3 health professionals for 1,000 inhabitants.

Political crisis exacerbated the maldistribution of health workers as many left the Northern provinces to find better working conditions in more stable areas. In 2009, the ratio of qualified staff to population was eight times higher in urban than in rural health centers, with a particular gap for midwives in rural areas (Ministry of Health 2009a)

In an effort to overcome these challenges, the Ministry of Public Health and Hygiene has identified HRH as a priority and approved an HRH operational plan, “Development of Human Resources for Health: National strategic plan (2009– 2015).” The plan addresses four essential HRH management functions: ·

1. Improved training to increase the number of qualified providers;
2. Needs-based deployment to place the right skill set in the right places to meet health needs.
3. Retention of health workers, particularly in rural areas where attrition rates are highest; and
4. Career development to provide mechanisms for skills improvement and provide motivation.
5. creation of a national HRH observatory and an HRH working group and
6. full participation in the County Coordination and Facilitation (CCF) process with assistance from the Global Health Workforce Alliance

Mali has completed the three phases of the CCF process:

- a. creating an HRH coordination mechanism,
- b. conducting an HRH situation analysis, and
- c. creating a fully costed HRH strategic plan,

It is currently in Phases 4 and 5. The country has begun implementing and monitoring its strategic plan and has been successful in mobilizing partner resources for HRH interventions

### **6.3.3. Guinea Conakry**

The state of the health workforce (HWF) is one of the country’s bottlenecks in advancing health outcomes. There was a long spell of underinvestment in the health sector, with limited public recruitment of workforce during the pre-Ebola outbreak period. The health workforce was characterized by serious shortages, spatial mal-distribution, poor retention and an aging workforce. This was despite the fact that the aggregate health workforce supply exceeded labor

market Demand. The main problem was limited financing to absorb all the health workers into the public health sector. As a result, a large number of health workers were unemployed and opted to set up informal or formal private practices, usually in urban areas. Besides, considerable variations in the distribution of health personnel existed. A special Division for Human Resource for Health (HRH) was created within the Ministry of health. The division recruited 2,000 health workers which were not pay until after 3 years as the health sector budget shrank from 3.5% of GDP in 2010 to 1.75% in 2013.

The Ebola Virus outbreak in 2014 aroused international attention and provided a policy window to reform the health system and invest in the HWF after many years of stagnation. The follow-up National Conference on Health prioritized the health sector and engendered a sudden boost in the agenda for HRH. National health policies and development plans were updated and health budget increased from 1.75% to 8%. The health system recovery and resilience strategy with a target to recruit 6000 staff from 2016 to 2018 and increase their salaries by 40% was developed. A total of 4,000 health workers were recruited between 2015 and 2017.

#### **6.3.4. Cape Verde**

According to Human Resources for Health (2017) by Delgado et al, there were 401 medical doctors in the database by 2017, of which 54.4% were females. The national ratio of doctors per 10 000 inhabitants was 5.25, but the reality varied significantly among islands.

Until very recently, Cape Verde has been relying on outside countries to train its health personnel. Its doctors were trained abroad, especially in Cuba, Portugal and the Union of Soviet Socialist Republic (USSR). The first in-country undergraduate medical education began in October 2015, with major support from the Faculty of Medicine of Coimbra (FMUC), Portugal, which seeks to replicate the model of medical education developed by the University of the Azores, Portugal, in the University of Cape Verde (Uni-CV).

Cape Verde provides a good illustration of the importance of international collaborations in sustaining the medical workforce. The overwhelming majority (94.3%) of the doctors graduated from 5 of the 17 countries that contributed to the training of Cape Verdean doctors. It is also an example of how this collaboration was used to equip the country with doctors in an increasingly more equitable distribution across all islands. All the islands of this archipelago country contributed to the 324 (80.8%) doctors born in the country.

### **6.4. Research and Development (R&D)**

#### **6.4.1. Mali**

Mali Malaria Research Centre: Viewed by many as model as a model for research centres in developing countries, as its research is planned, directed, and executed by African scientists. Also has a robust training program for new generation of Malian scientists critical to the success and sustainability of the program. Current training programs in biology, tropical medicine, medical entomology, and epidemiology.

Malaria research including; vaccines, diagnostics, immunology and genetics, and prevention.

Government of Mali others include; USAID, NIH, Rockefeller foundation, WHO, IAEA. Mali Traditional Medicines Established in 1973 the official institute connected to the National Institute of Research in Public Health (INRSP: Institut National de Recherché en Santé Publique). Main activities include: registration of traditional practitioners, medicinal plants,

research and development of Improved Traditional Medicines (ITMs). Traditional medicines WHO collaborating centre. WHO Drug Information Vol 19, No. 3, 2005 University of Sciences, Techniques and Technologies of Bamako (USTTB), University of Bamako, is based in Bamako, Mali. USTTB includes faculties of Medicine, Pharmacy and Basic Sciences, an Institute of Applied Science, and the research laboratories founded by the NIH/NIAID which focus on malaria, tuberculosis and retrovirology. In 2002, the NIH International Centers for Excellence in Research (ICER) program was established; today the Mali ICER at USTTB includes the Malaria Training and Research Center, the Entomology Unit of the Faculty of Medicine, Pharmacy and Dentistry, the Centre de Recherche et de Formation sur le VIH et la tuberculose and the University Clinical Research Center. In 2005, NIAID expanded the ICER program to include retrovirology and TB research. An ongoing FIC training grant with Northwestern University seeks to build capacity in HIV/TB research capacity. USTTB has collaborated with Northwestern since 2008 as a major partner of the Northwestern AITRP to train Malian researchers in clinical research and ethics

Encourage the proposed National Council for Science and Technology to work with the National University to develop a curriculum relevant to pharmaceutical trials and research (e.g. applied pharmacology, immunology, and epidemiology).

#### **6.4.2. Cape Verde**

The primary mission of the INSP is to generate and effectively disseminate scientific information of national public health importance in order to improve the lives of the people of Cape Verde.<sup>2</sup> By 2020, the INSP of Cape Verde hopes to use this knowledge to contribute positively to public health policies, strategies, and programs to achieve a fair and appropriate level of health and well-being among the Cape Verdean population. The first of these strategic areas, research, will be pivotal to the INSP both for the development and review of the National Health Research Agenda and for conducting national research on health systems and on the prevalent infectious and non-communicable diseases in Cape Verde.

Other strategic areas of the INSP include establishing means for professional public health education and training, and serving as a national reference laboratory and central coordinator for health and environmental surveillance.

In 2011, Cape Verde devoted just 0.07% of GDP to research and development, among the lowest rates in West Africa. The Ministry of Higher Education, Science and Culture plans to strengthen the research and academic sectors by placing emphasis on greater mobility, through exchange programmes and international co-operation agreements. As part of this strategy, Cape Verde is participating in the Ibero-American academic mobility Programme that expects to mobilize 200 000 academics between 2015 and 2020.

Cape Verde counted 25 researchers in 2011, a researcher density of 51 per million inhabitants. The world average was 1,083 per million in 2013. All 25 researchers were working in the government sector in 2011. There was no research being conducted in either medical or agricultural sciences.

Cape Verde published a single article in an internationally catalogued journal in 2005 and 25 articles in 2014, according to Thomson Reuters' Web of Science (Science Citation Index Expanded). In 2014, Cape Verde had the second-highest publication intensity (65 articles per million inhabitants) in West Africa after Gambia (65 articles per million inhabitants), another

country with a small population. The average for sub-Saharan Africa in 2014 was 20 articles per million inhabitants in the Web of Science (Science Citation Index Expanded).

Scientists from Cape Verde published most in geosciences between 2008 and 2014: 33 out of 78 articles (42% of output). Over this seven-year period, there were just 3 articles from this country focusing on agricultural sciences and seven on medical sciences. This is no doubt related to the fact that there were no researchers specializing in these two fields in 2011.

In the great majority of ECOWAS countries, more than eight out of ten scientific articles catalogued in the Web of Science (Science Citation Index Expanded) between 2008 and 2014 had foreign partners. In the case of Cape Verde, Guinea-Bissau and Liberia, this was even the case for the totality of articles, a situation which also correlates with a low output.

### **6.5. World Health Organization (WHO) Certification**

The need for sound and effective regulatory systems that can ensure the quality, safety and efficacy of medical products is critical. An effective regulation will promote public health and patient care and facilitate trade on medical products and socioeconomic advancement. This is because the role played by medical products in society is often shrouded with complexities and, sometimes, controversies associated with their safety, quality, efficacy and effectiveness. All countries therefore need to have effective and efficient National Medicines Regulatory Agencies (NMRAs) so that their populations are not exposed to:

1. potentially unsafe medical products of variable quality and effectiveness;
2. substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products; and
3. irrational use of medical products which may be detrimental to public health and patient safety

The WHO certification requires member states, through their NMRAs to undertake rigorous testing of medicines during development and after their release for general use. Thus, no medical products are permitted to be sold in any country unless these products have been approved by the respective NMRAs. The core functions of NMRA include:

- a. marketing authorization (MA);
- b. licensing of manufacturing establishments;
- c. imports and export control;
- d. inspection of manufacturing premises and distribution channels;
- e. market surveillance (product quality monitoring, pharmacovigilance, control of drug promotion and advertising);
- f. quality control; and
- g. oversight of clinical trials on drugs

Quality Control aims to verify that products comply with the specifications of MA and testing of post-marketing samples serves as a deterrent against negligent or fraudulent manufacturing and trading practice. NMRAs' access to well-resourced quality control laboratories, which operate according to established standards and organizational frameworks is key for quality surveillance of products circulating in the market. The Quality Management System (QMS) ISO 17025 and the WHO Guidance on Good Laboratory Practice are global benchmarking tools for measuring standards for quality control laboratory performance. Achieving either WHO Prequalification or

ISO 17,025 accreditation status ensures that a laboratory has demonstrated technical competence to produce precise and accurate data, and that it meets internationally accepted standards of quality and reliability.

Member countries of the World Trade Organization (WTO) are required under the Agreement on Technical Barriers to Trade (TBT Agreement) to report to the WTO all proposed technical regulations that could affect trade with other Member countries.

### **6.5.1. Benin**

The Department of Pharmacy and Medicines (DPMED) is the competent authority responsible for regulating the pharmaceutical sector in Benin, including the registration of medicines. Essentially, the market is composed of products that are imported by the Central Purchasing Office for Essential Drugs and Medical Consumables (CAME) and five private wholesalers. Pharmaceutical companies submit applications to DPMED to license and register medicines, who then assess cases and submits them to the Committee of Experts and the National Committee for Pharmaceutical Products for review.

Benin has a fairly comprehensive legislative framework that encompasses the licensing of pharmaceutical products and the authorization of pharmaceutical establishments. It has well-structured legislative and regulatory frameworks for the marketing authorization (MA) with medicines registration process that includes a National Committee for Pharmaceutical Products and a functional Committee of Experts for the review of MA applications. It has a regulatory framework that specifies the main requirements to register medicines and details the procedures that must be followed to obtain various types of authorization.

However, a few challenges exist including:

1. Shortage of qualified staff to carry out preliminary technical evaluations of MA application packages at the DPMED and at the department responsible for registration.
2. Lack of clear job descriptions for staff involved in the medicines registration system. This results in the absence of clear distinctions in the responsibilities held by each staff member leading to the execution of incompatible regulatory tasks by individuals.
3. Lack of specific regulations and procedures for priority medicines (essential medicines, vaccines, and prequalified medicinal products by the WHO).
4. Insufficient information available for pharmaceutical sector stakeholders. Notably, there is no up-to-date list of all licensed pharmaceutical products in Benin.
5. Inefficient information management systems. Data is incomplete and quality is inconsistent Users can make errors in data entry and correcting this information would require time and effort.
6. Difficulties in ensuring that regulation is followed. For example, the renewal rate for expired MAs is low. This goes hand in hand with the absence of an automated mechanism that monitors the validity of MAs.

### **6.5.2. Mali**

In Mali, medicine regulatory functions are carried out by separate institutions that are independently mandated by law to execute the different responsibilities:

*The Directorate of Pharmacy and Medicine (Direction de la Pharmacie et du Medicament) DPM.*

DPM is the agency responsible for granting medicine MA. In addition, it supports LNS and CNAM in their functions of surveillance and control of medicines, and monitoring the safety of medicines on the markets, respectively. DPM's performance is hampered by insufficient human resources, lack of financial autonomy, and lack of a quality management system (QMS) to efficiently perform its functions. Use of manual procedures coupled with the lack of a monitoring and evaluation mechanism makes delivery of services lengthy and unpredictable. The role of DPM in control of imports and exports needs to be strengthened, including enhanced collaboration with Customs.

The legal framework mandating the regulation of medicines and granting MA is in place.

However, the regulations require revision and updating to address the identified gaps such as handling of major variations.

#### *The Laboratoire Nationale de la Sante (LNS)*

Surveillance and control of medicines on the market is carried out by both DPM and LNS. Mechanism to control the circulation of substandard and falsified medicines (SFs) needs to be strengthened by involving all stakeholders with a clear, documented strategy. Decisions of the National Medicine Commission need to be implemented in a more pragmatic manner

#### *Centre National d'Appui à la Lutte contre la Maladie (CNAM)*

CNAM undertakes monitoring of the safety of medicines on the market and control of clinical trials (CTs) by jointly with DPM. The legislation for pharmacovigilance (PV) is in place. However, there is a need to develop and implement guidelines on safety monitoring by marketing authorization holders (MAHs); for stronger and closer collaboration and communication between DPM and CNAM; and to clearly specify the role of Clinical Trials (CT) Ethical Committees to avoid misunderstanding roles and responsibilities.

In addition, regulations should be put in place to ensure that the pharmaceutical industry complies with good clinical practices (GCP) and that DPM has enforcement powers to halt CTs that do not comply with specified regulations. Without clear guidance for applicants on the requirements for CTs, requirements are bound to be misinterpreted and time will be wasted, hence the need to develop and implement guidelines for applications for control of CTs

### **6.5.3. Cape Verde**

Cape Verde has on ISO 17025 Certified quality control laboratory called Inlab Laboratoria de control de qualidade Inpharma (Cape Verde) engaged in market surveillance to verify that products comply with the specifications of marketing authorization (MA) and testing of post-marketing samples serves as a deterrent against negligent or fraudulent manufacturing and trading practice. Achieving either WHO Prequalification or ISO 17,025 accreditation status ensures that a laboratory has demonstrated technical competence to produce precise and accurate data, and that it meets internationally accepted standards of quality and reliability

### **6.5.4. Guinea Conakry**

The Ministry of Health (MOH) is the regulatory authority responsible for clinical trial approvals and drug import licensing in the Republic of Guinea. The two branches within the MOH directly involved with the clinical trial approval process are:

1. The National Ethics Committee for Research in Health (Comité National d'Ethique pour la Recherche en Santé) (CNERS) is in charge of the clinical trial application review and

approval process. However, applications for all Ebola-related research must first obtain protocol approval from the Ebola Research Commission in Guinea (ERCG) prior to obtaining CNERs' approval.

2. The National Directorate of Pharmacy and Medicine (Direction Nationale de la Pharmacie et du Médicament) (DNPM) which handles the licensing of imports of pharmaceutical products. The MOH assigned the roles of laboratory and drug oversight to DNPM in April 2016.

## **6.6. Academic/University – Industry Linkage**

Pharmaceutical manufacturing requires a pool of skilled professional personnel trained in product identification, formulation, clinical trials and production.

### **6.6.1. Benin**

Several institutions are involved in training health personnel in Benin. The Faculty of Health Sciences at the University of Abomey-Calavi and the Parakou Medical School train physicians. Medical specialists are trained in the Faculty of Health Sciences in Abomey-Calavi for specialties like general surgery, gynecology and obstetrics, internal medicine, pediatrics and psychiatry. The Regional Public Health Institute, whose construction was financed by the World Bank, is an integral part of the University of Abomey-Calavi and it trains physicians and other health officials in public health and epidemiology.

The Government of the Republic of Benin established a Regional Public Health Institute with support from the World Health Organization to address the shortage of health research and personnel, particularly in rural areas. The Institute offers tertiary training in public health, health care management, health economics and sanitary engineering; organizes seminars and conferences on health care management for administrators and technical staff; promotes better preventive health care and treatment for researchers; and avails a documentation center for community health practitioners.

There are other vocational training schools such as the National Health Institute (INMES) and the Benin National School of Nurses and Nursing Assistants (ENIAB). INMES is a government technical and vocational training establishment that covers four schools: the Benin National School of Nurses and State-Registered Nurses (ENIIEB), the Benin National School of State-Registered Midwives (ENSFEB), the National School of Social Welfare Assistants (ENAS), the National School of Clinical Laboratory Technicians (ETLAM) and the National School of Sanitary Technicians (ENTS).

The National Medico-Social Institute (INMES) is composed of five schools that train the different categories of medical professionals: nurses, midwives, social workers, laboratory and other health technicians. The institute trained 3,063 nurses from 1992 to 2004. In 2002, a specialized school was created to train nurses and midwives in anesthesiology and cardiopulmonary resuscitation (CPR).

The National Nursing School of Benin (ENIAB) and the National School of Sanitation and Hygiene (ENAAH) are three-year professional and technical institutes based in Parakou that train, respectively, assistant nurses and hygiene and sanitation health workers. More than 2,355 assistant nurses have been trained at ENIAB since its creation in 1973, and 29 hygiene workers



have completed their training in 2004 at ENAAH, which was created in 2001 (SNIGS-Annuaire des Statistiques Sanitaires 2004).

### **6.6.2. Cape Verde**

Until very recently, Cape Verde has been relying on outside countries to train its health personnel. Its doctors were trained abroad, especially in Cuba, Portugal and the Union of Soviet Socialist Republic (USSR). The first in-country undergraduate medical education began in October 2015, with major support from the Faculty of Medicine of Coimbra (FMUC), Portugal, which seeks to replicate the model of medical education developed by the University of the Azores, Portugal, in the University of Cape Verde (Uni-CV).

### **6.6.3. Guinea Conakry**

There is a mal-distribution of health training institutions across the country, specifically universities and professional schools which train state nurses, midwives, laboratory and public health technicians, and social assistants. Most are located in Lower Guinea, particularly in Conakry. Much of Middle and Upper Guinea lacks health training institutions. There are four universities in Guinea: three in Conakry (two are private) and one in N'zérékoré.

There has been an upward trend in the number of health workers graduates (total 15 000) trained in Guinea between 2010 and 2015. ATS, state nurses, and midwives were the largest professional groups trained. Almost all professional categories, except ATS, were trained in lower Guinea, amounting to nearly 44% of the HWF trained over the last 5 years.

Private institutions have played a prominent role in the training of midwives, nurses, and public health technicians between 2010 and 2015. Doctors, pharmacists, dentists, social assistants, and ATS were exclusively trained in public institutions.

#### *Observations:*

It is noted that few health science training institutions in the countries in the study have not been able to offer training on knowledge and skills relevant to the pharmaceutical manufacturing industry. Their curriculums have been hospital-centered (for doctors, nurses, community health workers), and not aligned to the needs of the pharmaceutical manufacturing industry. The manufacturing industry requires knowledge and skills in areas such as pharmaceutical regulatory affairs, pharmaceutical technology, drug formulation and development and clinical studies.

As such, there is a need to strengthen the linkages between academia, research institutions and the manufacturing industry. Health sciences training programmes and institutions need to be re-evaluated and oriented towards the industry requirements. Universities should realign their training curricula to produce the right caliber of personnel needed by the industry. Policies, legislations and structures that promote the linkages between Universities and the pharmaceutical industry are needed to develop the local pharmaceutical manufacturing sector

Given the HWF crisis in the overall health systems, investment in HRH should be made in areas that bring maximum returns to the health system and alleviate the HWF shortage and imbalances. The training programs should build on the functional job/task analysis that seeks to define and describe the knowledge, skills and abilities (KSA) involved in a job. On the assumption that some proportion of health workers will go overseas, additional efforts should be made to strengthen the capacity of national training institution to scale up education and training of health workers in terms of numbers and range of skills relevant to the needs of countries'

health systems. Efforts should be made to train a critical mass of mid-level cadres such as nurses, technicians, clinical officers.

## **6.7. Intellectual Property Rights and Technology Transfer**

Intellectual Properties refers to the innovations in the form of creative ideas and expressions of the human mind that have commercial value and are entitled to legal protections using legal mechanisms such as copyrights, patents, and trademarks. Intellectual property rights enable owners to select who may access and use their intellectual property and to protect it from unauthorized use. Technology transfer is defined by the United Nations (DFID 2004) as the process of sharing knowledge, skills, expertise and know-how.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an international legal agreement between all the member nations of the World Trade Organization (WTO). TRIPS was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) between 1989 and 1990 and is administered by the WTO. It sets down minimum standards for the regulation by national governments of many forms of intellectual property (IP) as applied to nationals of other WTO member nations. TRIPS also contain provisions that allow a degree of flexibility and sufficient room for countries to accommodate their own patent and intellectual property systems and developmental needs. Patents on medicines have been one of the most hotly debated topics since the adoption of the TRIPS Agreement because patents grant exclusivity for the duration of the patent term and result in patent holders having control over the production, supply, distribution and, by virtue of exclusivity, price.

### **6.7.1. Benin**

Benin is a member of many international/regional intellectual property agreements: Bangui Agreement (OAPI) (since 1983); Berne Convention (since 1961); Hague Agreement on Designs (since 1986); Nairobi Treaty on Olympic Symbol (since 2006); Nice Agreement on Classification of Marks (since 1979); Paris Convention (since 1967); Patent Cooperation Treaty (since 1987); WIPO Convention (since 1975); WIPO Copyright Treaty (since 2006); WIPO Performances and Phonograms Treaty (since 2006); and WTO/TRIPS (since 1996) IP legislation.

Benin also joined the union of 16 predominantly Francophone countries constituting the Organisation Africaine de la Propriété Intellectuelle (OAPI). The principles governing OAPI include:

1. the adoption of uniform legislation to create a uniform system of intellectual property rights protection with a common administrative procedure
2. the creation of a common authority to serve as a national intellectual property rights protection office for each of the member states
3. the centralization of procedures so that a single title would issue creating national intellectual property rights in the individual member countries

OAPI member countries are required to ‘renounce’ their national sovereignty in the area of intellectual property, to afford the right holder a single regional title of protection valid in each country, obtained via an OAPI application and registration procedure. Thus, in order to join

OAPI, Benin had to renounce its national IP legislation. Benin is also a member of the Bangui Agreement, which provides for copyright protection. It is not clear which of the legal dispensations will apply in practice.

### **6.7.2. Mali**

Mali is a member of the following international agreements: Bangui Agreement (OAPI) (since 1984); Berne Convention (since 1962); Hague Agreement on Designs (2006); Paris Convention (since 1983); Patent Cooperation Treaty (since 1984); WIPO Convention (since 1982); WIPO Copyright Treaty (since 2002); WIPO Performances and Phonograms Treaty (since 2002); and WTO/TRIPS (since 1995). It is also a member state of the union of 16 predominantly Francophone countries constituting the Organisation Africaine de la Propriété Intellectuelle (OAPI), which requires members to 'renounce' their national sovereignty in the area of intellectual property. It is not clear how this legal dispensation will apply in practice.

It is observed that while the countries in question have the right to exercise the flexibilities under the TRIPS Agreement, in reality it is very difficult to make effective use of these flexibilities as a public health policy tool. Although the Doha Declaration on TRIPS and public health allows developing countries to issue compulsory licenses, they lack sufficient manufacturing capacity.

Additional challenges include:

1. lack of technical expertise to effectively implement the TRIPS flexibilities
2. lack of technical and infrastructural capacities for medicines regulations
3. bilateral and other pressures not to use the TRIPS flexibilities for public health purposes and/or to adopt TRIPS-plus standards
4. difficulties in regulating anti-competitive practices and abuse of intellectual property rights; and
5. difficulties in accessing pricing and patent status information

A regional approach to the use of TRIPS flexibilities will enable similarly situated countries to address their constraints jointly by drawing on each other's expertise and experience and by pooling and sharing resources and information. It will also enhance the efforts to pursue common negotiating positions at the WTO and in other multilateral negotiations such as those on a substantive patent law at the World Intellectual Property Organization (WIPO). In addition, a regional approach coincides with the objective of enhancing South-South cooperation on health and development.

### **6.7.3. Cape Verde**

Joined the World Intellectual property Organization in 1997 and has developed the national intellectual property laws and regulations. Cape Verde is a member of the following international agreements: Berne Convention (since 1997); Rome Convention (since 1997); WIPO Convention (since 1997); WTO/TRIPS (since 2008). It has developed IP legislation on trademarks, Industrial Property Code, Patents, Industrial Property Code, Designs, Copyright and Related Rights.

The Institute for Quality Management and Intellectual Property (IGQPI) is the coordinating body of the National System of Intellectual Property Protection and the National Standards Organization. Its mission is to promote the defense and protection of intellectual property at both

national and international level, fully integrated by industrial property, copyright and related rights with the support of the World Intellectual Property Organization (WIPO). IGQPI is in the process of developing the National Intellectual Property Policy and Strategy (PENPI), in order to provide the Country with adequate Intellectual Property public policies, with positive impacts on the competitiveness of the national economy, innovation and dissemination of new technologies.

The National Intellectual Property Policy and Strategy (PENPI), to be developed, should take into account national priorities, especially those identified in national innovation and development plans, as well as the multifaceted challenges facing the country in promoting an environment conducive to the creation of a social awareness about intellectual property (IP). On the other hand, they should emphasize the integration of IP system dimensions into national development planning.

## CHAPTER SEVEN

### 7.0. PHARMACEUTICAL SECTOR IN TOGO

#### 7.1. Promotion of local pharmaceutical industries and social inclusion through procurement policies and strategies

##### 7.1.1. Practices in Togo that promote local pharmaceutical industries

There is a national committee composed of members from academia, public and private sector, dedicated to the help of local manufacturers. Their missions are among others:

1. Helping them in launching their activities through technical support about procedures ;
2. Helping them in preparing their Market Authorization according to CTD template ;
3. Holding extraordinary session to assess their Market Authorization dossiers in order to help them gain time in new drugs release.

The committee was appointed by a note of the Ministry of Health for one particular manufacturer. Its mission is assumed to be extended to all the manufacturers.

There are also customs and economic facilities in raw material procurement, since they are considered pharmaceutical products.

Fourteen (14) out of the 15 products of one of the manufacturers cost less than 33.33 % percent (1/3) of the minimum wage while the 1 remaining costs 37.93 % of the minimum wage.

Forty-one (41) out of the 42 products of one of another manufacturer cost less than 33.33 % percent (1/3) of the minimum wage while the 1 remaining costs 44.07 % of the minimum wage.

All the prices of the third manufacturer are below one third of the minimum wage and the prices of the last one were not available, since he does no Market Authorization in Togo.

##### 7.1.2. Regional programmes promoting local industries through procurement policy

The four main agencies, promoting local pharmaceutical industries are:

1. United Nations Industrial Development Organization (UNIDO) ;
2. West African Economic and Monetary Union (WAEMU) ;
3. The World Health Organization (WHO) ;
4. African Medicine Agency (AMA).

UNIDO has gone these 2 years, through an assessment process of local manufacturers and classified their risks. It has also helped them editing their Corrective Actions and Preventive Actions (CAPA). It's now helping them, moving from the WAEMU good practices recommendations to those of World Health Organization.

The AMA business plan position is the following: « *Harmonization and collaboration among NMRAs should streamline drug registration procedures, merge fragmented national markets into regional markets to reduce the regulatory burden on the pharmaceutical industry and allow faster access to a drug market wider drug. It was noted that the introduction of the Common Technical Document (CTD) by the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) has reduced the resources and time required for the approval of a product by industry and regulators in the ICH regions. While the interventions will reduce the substandard drugs and increase the volume of*

*activities of the regulatory industry investing in quality systems, they will result in the bankruptcy of some companies that are unable to comply with the regulations standards and to keep the increased competition arising from the merger of the markets*

This global approach, taking into account time and resource saving one hand and the viability of the manufacturers on the other, seems to be the way to promote regional integration of manufacturers.

### **7.1.3. Donors policies impact**

The full list of subsidized products is annexed to this report. It is noteworthy that besides Artemether + Lumefantrine and Tenofovir, none of them are produced locally.

## **7.2. Human resource development for the Pharmaceutical manufacturing sector**

### **7.2.1. Human resource situation**

The table shows the situation of human resources in manufacturers in Togo.

**Table:** Human resource situation

<b>Manufacturer</b>	<b>Shareholder</b>	<b>Strategic Technical Positions</b>	<b>Strategy</b>
GGIA	Togolese exclusively	Togolese	Local production
DO PHARMA	Togolese exclusively	Indians	Local production
SPRUKFIELD	Indians	Indians	Local production
TONGMEI	Chinese	Chinese	Reconditioning

### **7.2.2. Role of university and training programmes in addressing HR issues**

National universities provide human resources for administrative and financial positions. Pharmacists trained in Lomé are also hired, but since there are not yet postgraduate studies in pharmaceutical industry, production and control activities are managed by technicians from abroad.

### **7.2.3. Possible role of diaspora**

Togo in the diaspora is full of skilled people that should be convinced to come back and hold the strategic positions in local manufacturers. There was a foreign affairs minister's program which invited Togolese in the diaspora to an important meeting herein, some years back ago. Many of them are now taking part in projects but I have not found yet any such collaboration in the pharmaceutical industry.

### **7.2.4. Possible role of collaboration with Asia**

Asian technicians are already working in manufacturers in Togo, as said in the lines above. What needs to be done is to carry that cooperation to institutional level. That will enable the training of

many national technicians and make the cooperation more fruitful and foster technology transfer. Furthermore, most of the local manufacturers get their APIs from Asia.

### **7.3. Research and Development**

#### **7.3.1. R & D existing funding programmes**

According to both the Dean of the Faculty and the Director of the Pharmacy Board, there is no specific funding for R&D in Togo. At the regional level, WAHO provides funding for registration process mastery and equipment upgrading to meet requirements. This is done through the UNIDO GMP initiative with an ECOWAS funding.

#### **7.3.2. Bottlenecks of local API production**

According to the supplier of 3 of the 4 local manufacturers that lives in France, Asia prices hard extremely difficult to beat. Then producing APIs locally will not be competitive. Moreover there is lack of local skilled persons to produce their own APIs.

#### **7.3.3. Universities activities striving to develop local API production**

The pharmacy faculty has equipment for teaching students how to produce tablets, pills and infusion products. All the APIs are supplied from France. There is no particular known activity to foster our young colleagues to engage in this route.

#### **7.3.4. Existing activities targeting malaria and HIV with indigenous therapies**

There are local repulsive products used against *Anopheles* (mosquito) biting. There are also different brands of Artemisia annual powders or herbs available in our market. Those are produced locally and used by the population to prevent and/or heal malaria conditions that may occur. HIV known local treatments aim the opportunistic infections of patients that are already at AIDS stage. The issue with those is that those patients have stopped their conventional therapy to head to local treatments, leading to a 2 risks: drug resistance and health condition rapid decrease.

### **7.4. Intellectual Property Rights and Technology Transfer**

#### **7.4.1. Case study of ARVs or generic medicines producers**

Sales statistics provided by wholesalers throughout the country show that local products are widely consumed locally and some of them like: paracetamol, chloramphenicol, ibuprofen, norfloxacin are even the top sold products of their International Nonproprietary Name (INN).

All the 4 manufacturers export to foreign countries.

No agreement was needed since all the generics produced are those of products that are no longer under patent then there are no local big pharmaceutical industry complaints. Furthermore ARVs are provided to Togo by the Global Fund which is in charge of arrangements to get the products to the country. There is no record of TRIPS flexibilities policy and guidelines developed in Togo.

### **7.5. WHO certification**

#### **7.5.1. Status of WHO certification and effort provided by the government**

None of the 4 local manufacturers has obtained the WHO certification. Government effort consists of 2 points: 1) the appointment of an expert committee to assist them, 2) the adhesion to UNIDO and ECOWAS GMP initiative. The roles of WAHO, UNIDO and ECOWAS were

described previously. The GMP initiative consists of 3 phases, and the first 2 are already completed. The phases are the following:

Phase 1: introduction of key actors to the project and national technical groups' creation;

Phase 2: technical assessment of local manufacturers leading to a roadmap;

Phase 3: (upcoming): manufacturers and regulators trainings.

## **7.6. Academia – University - Industry linkages**

### **7.6.1. Successes and challenges relating to university industry partnership in Togo**

The only university-industry linkage recorded is the assistance provided by the national committee appointed by the Ministry of Health. There are no particular policy incentives for such linkage. Nonetheless, there is cooperation between university and traditional practitioners even if the latter don't disclose their ingredients easily.

### **7.6.2. Best practices and lessons learned from such partnerships in developing countries and in developed countries**

There are manufacturers in many African countries, held mostly by the public sector such as Soidal in Algeria, and Sahpad in Tunisia. Mozambique even has a 100 % public company that produces ARVs with the cooperation of Brazil. There is another example in South Africa where the government has an agreement with Lonza, a great API manufacturer to produce ARVs' API.

## **7.7. Conclusion**

A descriptive cross sectional study conducted among direct and indirect stakeholders of pharmaceutical industries has helped us to describe 6 components of medicines access in Togo. The local products are quite accessible to the population, while compared to the minimum wages and the sales statistics are coherent with that assumption. Two manufacturers out of 4 are ruled by Togolese shareholders while the other 2 belong to foreign citizens. Almost all the technical production and control positions are held by foreign technicians, due mainly to the unavailability of post graduate studies in the field, locally. There is none R&D funding for industry but a coalition of ECOWAS, UNIDO and WAHO is in place to help local pharmaceutical industries to increase their processes. All the generic produced locally are those of no more patented products so there is no recorded issue with a big pharmaceutical company about a patent violation. None of the 4 local manufacturers has the WHO certification. There is no formal cooperation between university and industry, besides a technical assistance of a committee of 4, appointed by the Ministry of Health.

We think that all the stakeholders should make an effort to develop local pharmaceutical industry.



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