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ORGANISATION OUEST AFRICAINE DE LA SANTE
ORGANIZAÇÃO OESTE AFRICANA DA SAÚDE**



**THE ECONOMIC COMMUNITY OF WEST AFRICAN STATES (ECOWAS)
REGIONAL PHARMACEUTICAL PLAN (ERPP)**

APRIL 2014



**ECOWAS Regional Pharmaceutical Plan (ERPP)
Developed by West African Health Organization, Bobo- Dioulasso, Burkina Faso**

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175, Avenue Ouezzin COULIBALY, 01 BP 153 Bobo-Dioulasso 01, Burkina Faso.
Tel: [+22620970100](tel:+22620970100)/[20975775](tel:+22620975775), Fax: [+22620975772](tel:+22620975772);
email: wahooas@wahooas.org , wahooas@fasonet.bf.

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From ECOWAS of Member States to ECOWAS of the People

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It is our expectation that the population of the ECOWAS region and the Pharmaceutical sector will benefit greatly from this ECOWAS Regional Pharmaceutical Plan

FORWARD

The Economic Community of West African States (ECOWAS) was established via the Treaty of Lagos in May 1975. ECOWAS is a regional organization for West Africa headquartered in Abuja, Nigeria, with 15 member countries including: Benin, Burkina Faso, Cape Verde, Cote D'Ivoire, Gambia, Ghana, Guinea, Guinea-Bissau, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone and Togo. The 15 countries that constitute ECOWAS have different political heritage. There are eight (8) Francophone countries, five (5) Anglophone countries and two (2) Lusophone countries. This political reality significantly influences policies, practices as well as business activities. Coincidentally, the linguistic differences are also reflected in the systems of medicines regulation, contributing to the challenges facing medicines registration harmonization as a public health tool for improving accessibility, affordability and availability of safe, efficacious and quality medicines in the region.

The region, with a population of about 365 million, has similarities of disease burden. In general, all the countries have a huge burden of malaria, HIV/AIDS, Tuberculosis, neglected tropical diseases and other newly emerging diseases. Combined with these communicable and non-communicable diseases are poverty and malnutrition, which also impact on the types of medicines required.

Existing disparity among health standards, expertise and policies in West Africa is a significant but not an insurmountable barrier to better overall health. The lack of reciprocal recognition of regulatory processes between Anglophone, Francophone and Lusophone countries is a constraint to human resource mobility that, once removed, will allow quality and affordable medicines to circulate throughout the region as needed. Additionally, enhanced communication and information exchange between member countries will make integration easier and more beneficial to all Member States.

Equally the low availability of essential medicines to support, sustain and manage public health interventions of the disease burdens is aggravated by non commitment of Governments of ECOWAS Member States and stakeholders to strengthen the pharmaceutical industries to step up medicines production and improve on other pharmaceutical sectors. When local pharmaceutical production of medicines particularly for priority essential medicines are promoted, encouraged and financed by ECOWAS Agencies and Stakeholders, increase in the capacity of available quality, safe and affordable medicines in the region would be achieved.

The West African Health Organization (WAHO) formed in 1987 by the Heads of State and Government from all fifteen (15) countries in the Economic Community of West African States (ECOWAS) through an adopted Protocol created the organization. By The Protocol, WAHO was granted the status as a Specialized Agency of ECOWAS and describes the organization's mission as follows: "*The objective of the West African Health Organization shall be the attainment of the highest possible standard and protection of health of the peoples in the region through the harmonization of the policies of the Member States, pooling of resources, and cooperation with one another and with others for a collective and strategic combat against the health problems of the region.*"

From this mandate the objective of the West African Health Organization (WAHO) under its Essential Medicines and Vaccines Programme is to facilitate access to essential and quality medicines, vaccines and essential health products and reduce the use of illicit medicines and counterfeiting in the ECOWAS region.

Among the various activities done under the programme, it sets its goal to have a harmonized and functioning pharmaceutical sector within ECOWAS in accordance with national and international recognized policies and standards. Such initiatives will enable the industry and the various relevant institutions make their contribution to improved public health in the region of which it is capable and will contribute to West Africa truly becoming self sufficient in the provision of healthcare. This then calls for a strong strategic plan which would inform the future; a region that is capable of taking care of its people. It also recognizes the human resource limitations in access to medicines and seeks to help address this situation through the development of the pharmaceutical industry, strengthening of regulatory institutions and quality control laboratories, improvement in information sharing system and issues on TRIPS flexibilities as well as the fight against counterfeit and illicit trade in medicines.

Our commitment is clear: quality, safe, efficacious medicines for the ECOWAS region cannot be compromised, all efforts to support and strengthen the Pharmaceutical Sector to achieve WAHO's mandate is our utmost concern. We would ensure the establishment and implementation of the ECOWAS Regional Pharmaceutical Plan, WAHO therefore calls on all stakeholders to support the implementation of the Plan to make it effective and beneficial to the population of the region.

Dr Xavier CRESPI
Director General
West African Health Organization

PREAMBLE

Continuous availability of favourably priced pharmaceuticals is an important aspect of any national health system. Providing quality and low priced pharmaceuticals to the population is a complicated undertaking, ranging from the identification and selection of medicines to the procurement and quality assurance of medicines circulating on the market.

National registration of medicines is one way to assure the quality, safety and efficacy of medicines being provided to the population. However, registration of medicines can be cumbersome requiring a lot of information from applicants. As a result it is sometimes difficult to get pharmaceutical companies to cooperate fully in the registration process as the cost may outweigh the benefits.

A regional pharmaceutical sector, incorporating a vibrant manufacturing industry, and a robust regulatory system, that is enduring, sustainable, competitive and managed in an integrated manner to be able to provide quality affordable, safe and efficacious essential medicines to meet the needs of the region and for exports.

The ECOWAS Regional Pharmaceutical Plan, is an overarching regional sectoral strategic document and roadmap that would achieve its vision for the pharmaceutical sector through the promulgation of medicines policies, provision of support to pharmaceutical manufacturing, effective and robust medicines regulatory systems, research and development, information sharing, competent and motivated human resource.

It is a plan that would oversee the entry of West Africa into new medicines discovery and the development and commercialization of West African developed, researched blockbuster medicines, reference centers of excellence for quality control laboratories and centers of excellence for local production of medicines, as well as strengthen the medicines regulation harmonization processes. It also recognizes the critical need for good governance of pharmaceutical systems by governments to play a catalytic role in order to strengthen the growth of the industry and to put a brake on overreliance on imports and pharmaceutical Education and Research to achieve excellence in pharmaceutical sciences and technologies, education and training.

The impact would in the medium to long term enable the pharmaceutical industry to meet almost entirely the region's demand for formulations and substantially for bulk medicines and in the long round the pharmaceutical industry would achieve global recognition as a low cost producer and supplier of quality bulk drugs and formulations to the world. Creation of centers of reference excellence for quality control laboratories, bioequivalence, bioavailability and clinical trials of medical products, foreign, regional and national investments and access to affordable finance and provision of time-limited, easily understood accessible incentives and foreign Technology.

The package of solutions proposed is in line with the strategic approach of the African Union Commission (AUC) and the Pharmaceutical Manufacturing Plan for Africa (PMPA). Similarly, it is recognized that there are a host of development partners, Non Governmental Organizations (NGOs), African centers of excellence and others already engaged in various activities including regulatory harmonization, skills development, technology transfer and so forth. WAHO believes that in

implementing this **ECOWAS Regional Pharmaceutical Plan**, the coordination and integration of these various initiatives will be critical.

EXECUTIVE SUMMARY

The Essential Medicines and Vaccines program of the West African Health Organisation (WAHO) covers seven strategic areas that ensure the earlier accessibility of safe, efficacious and quality essential medicines and other medical products for the population in the region. These areas are carefully aligned to handle the challenges facing the region taking into consideration the disease burden and cross border issues, the high incidence of priority diseases such as HIV/AIDS, Malaria, Tuberculosis, infectious diseases, neglected tropical diseases and non-communicable and communicable diseases. The fight against counterfeit and illicit trade in medicines, the utilization of the WTO TRIPS flexibilities provisions on pharmaceutical products, pharmacovigilance, medicines regulation, quality control of medicines and the strengthening of the pharmaceutical production of medicines. Africa is hugely dependent on imported pharmaceutical and medical products.

The case of HIV is a clear example: Africans home to nearly 70% of the 34 million people living with HIV globally, and yet it imports more than 80% of its antiretroviral drugs. The HIV/AIDS response can act as a pathfinder to catalyse progress in Africa across health and can be leveraged to support Africa to enhance pharmaceutical security for TB, malaria and other health challenges. Today, there is a real opportunity for Africa to develop its pharmaceuticals sector, both to enhance supply security and to advance industrial development. Interventions made by way of policy and guidelines development, building capacities, support to ECOWAS Member States in the provision of Anti-retroviral Therapies to treat people leaving with HIV/AIDS, establishment of pharmacovigilance centers and centers of excellence of quality control laboratories. Equally numerous supports have been given to some pharmaceutical manufacturing companies in the region by means of enhancing their facilities to increase the production of essential medicines which is one of the key objectives of this program to strategically intervene for easier and early access to essential medicines.

The ECOWAS Regional Pharmaceutical Plan gives a clear vision and mission to achieving self-sufficiency and a fair collaboration with the global players in the production, distribution and safe use of quality, efficacious, safe and affordable essential medicines throughout the region. Clear goals and objectives have been set and activities mapped out to meet them between now and the year 2025. In doing so, cognizance was taken of the efforts that have been made by WAHO so far, certain inherent risks and assumptions that are likely to affect implementations and a broad stakeholder outlook that brings all players in the pharmaceutical sector on board. The plan is supported by a clear implementation plan for the activities, timelines and expected outcomes.

Abbreviations

AfDB	African Development Bank
AIT	Accra Institute of Technology
AHM	Assembly of Health Ministers
AMRH	African Medicines Regulatory Harmonisation
API	Active Pharmaceutical Ingredient
ARIPO	African Regional Intellectual Property Organization
AU	African Union
AUC	African Union Commission
BA/BE	Bio-availability/Bio-equivalence
CBBR	Center for Bioequivalence and Bio-Pharmaceutical Research
CePAT	Centre for Pharmaceutical Advancement and Training
CS	Communication Strategy
CTDs	Common Technical Documents
EAC	East African Community
EBID	ECOWAS Bank for Investment and Development
ECSA-HC	East, Central and Southern African Health Community
ECOWAS	Economic Community of West African States
EMACCOM	ECOWAS Medical Product Anti-Counterfeit Committee
ERPP	ECOWAS Regional Pharmaceutical Plan
FPP	Finished Pharmaceutical Products
GDP	Gross Domestic Product
GLP	Good Laboratory Practice
GIZ	Deutsche Gessellschaft fur Internationale Zusammenarbeit
GMP	Good Manufacturing Practice
IFC	International Finance Corporation
IFPMA	International Federation of Pharmaceutical Manufacturers Association

IMF	International Monetary Fund
ISO	International Standard Organization
JURTA	Joint United Nations Regional Team on AIDS
MOH	Ministry of Health
MRH	Medicines Registration Harmonization
NEPAD	New Partnership for African Development
NMRAs	National Medicines Regulatory Authority
NQCL	National Quality Control Laboratory
OAPI	Organisation Africaine de la Propriété Intellectuelle (African Intellectual Property Organization)
ORD	Oral Dosage Form
PLWHAs	People Living With HIV/AIDS
PMAG	Pharmaceutical Manufacturers Association of Ghana
PMGMAN	Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria
PMPA	Pharmaceutical Manufacturing Plan for Africa
PPP	Public Private Partnership
QA	Quality Assurance
QC	Quality Control
QCL	Quality Control Laboratory
R & D	Research and Development
SIAPS	Systems of Improved Access to Pharmaceuticals and Services
SSFFC	Substandard, Spurious, Falsified and Falsely Labeled Counterfeit
TRIPs	Trade Related Aspects of Intellectual Property Rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNIDO	United Nations Industrial Development Organization
WAEMU	West Africa Economic Monetary Union

WAHO/XVI.AHM/2015/Res-04/d

WAHO	West African Health Organization
WAPCP	West Africa Post-graduate College of Pharmacy
WAPMA	West African Pharmaceutical Manufacturers Association
WHO	World Health Organization
WHO-UMC-PV	World Health Organization-Uppsala Monitoring Centre - on Pharmacovigilance
WTO	World Trade Organization

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1.0 INTRODUCTION

The Economic Community of West African States (ECOWAS) was established via the Treaty of Lagos in May 1975. ECOWAS is a regional organization for West Africa headquartered in Abuja, Nigeria, with 15 member countries including: Benin, Burkina Faso, Cape Verde, Cote D'Ivoire, Gambia, Ghana, Guinea, Guinea-Bissau, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone and Togo. The 15 countries that constitute ECOWAS have different political heritage. There are eight (8) Francophone countries, five (5) Anglophone countries and two (2) Lusophone countries. This political reality significantly influences policies, practices as well as business activities. Coincidentally, the linguistic differences are also reflected in the systems of medicines regulation, contributing to the challenges facing medicines registration harmonization as a public health tool for improving accessibility, affordability and availability of safe, efficacious and quality medicines in the region.

The region, with a population of about 365 million, has similarities of disease burden. In general, all the countries have a huge burden of malaria, HIV/AIDS, Tuberculosis, neglected tropical diseases and other newly emerging diseases such as Ebola. Combined with these communicable and non-communicable diseases are poverty and malnutrition, which also impact on the types of medicines required.

Figure 1. Map of West Africa Member States



Most of the 15 countries in the ECOWAS region source most of their medicines from south East Asia especially India and China. For instance, although 70% of people living with HIV/AIDS are in Africa, 34m globally, 80% of their medicines are imported.

To create more value for their shareholders, research and development (R&D) multinational pharmaceutical companies in developed countries are forming partnerships with pharmaceutical manufacturers in Asia. This has made Asian pharmaceutical manufacturers to focus on exporting to the developed markets for better value creation instead of Africa. If this trend continues, the security of pharmaceutical supplies to Africa cannot be guaranteed and this would equally affect the West Africa region thereby leading to the collapse of our health systems, exacerbate public health challenges and stifle industrial and economic developments in ECOWAS.

Health Systems rely on the continuous availability of safe, affordable pharmaceuticals of assured quality. Results from surveys done between 2001 and 2007 by UN (2008) indicate that availability of essential

medicines in developing countries averages 35% in the public sector and 63% in the private sector. WHO (2004) estimates that almost two billion people lack regular access to essential medicines, and addressing this gap could save up to 10 million lives every year. Poor access and irrational use of pharmaceuticals influence the performance of health systems and ultimately affect health outcomes.

In recognition of the enormous challenges facing healthcare systems, including lack of access to essential medicines, and the reliance on others for solutions, Heads of State of Africa directed the African Union Commission to develop a pharmaceutical manufacturing plan (PMPA) for the continent. The PMPA was duly developed and adopted by the Conference of African Ministers of Health held in Johannesburg, South Africa in April 2007 and endorsed by the Heads of State and Government in Accra, Ghana in July 2007. The PMPA is premised on the inalienable principle that access to quality healthcare, including access to all essential medicines that are affordable, safe, efficacious, and of good quality, is a fundamental human right. The PMPA proposes that the promotion of industrial development and the safeguarding and protection of public health are not mutually exclusive priorities and that the production of quality medicines and the development of an international GMP compliant industry in Africa are possible, desirable and eminently doable.

The Joint Multi-stakeholders Consultation meeting for the implementation of the *ECOWAS Charter on Public Private Partnership Initiative for Local Pharmaceutical Production of Priority Essential Medicines signed by all ECOWAS Health Ministers in Praia, Cape Verde on the 5th of April, 2013, during the 14th Ordinary Meeting of the Assembly of Health Ministers (AHM)*, was jointly organized with UNAIDS in Bobo-Dioulasso from 6-7 November, 2013. Participants including pharmaceutical manufacturers, ECOWAS Member States representatives, the PLWHAs, Civil Society, bilateral partners and the AU/PMPA consortium affirmed the need to have a regional pharmaceutical plan which would identify and strengthen all areas that are relevant to ensuring quality, safe and efficacious essential medicines as well as embrace all relevant stakeholders and institutions.

The 15 countries of ECOWAS have similar health and economic challenges. The disease patterns are similar and so are the peoples and their cultures. Although formal trade between ECOWAS countries is low, movement of peoples and informal trading are very active indeed.

Pharmaceutical regulation is at different levels in the 15 ECOWAS countries; some regulators are strong, others are not. As a result, medicine distribution in the ECOWAS region is very chaotic and very undesirable, with poor prospects for the achievement of the expected healthcare outcomes.

These challenges impede pharmaceutical and economic development of the ECOWAS region. The ECOWAS Regional Pharmaceutical Plan should provide a framework that will capture all the challenges and provide strategies to address them in a systematic and cost effective way.

2.0 SITUATION ANALYSIS OF THE ECOWAS PHARMACEUTICAL SECTOR

2.1 The Scope

Within the concept of the ECOWAS Regional Pharmaceutical Plan, the pharmaceutical sector and system comprises manufacturers, distributors, wholesalers, retail pharmacies, hospitals and clinics, as well as the

policies and the legislative frameworks that underpin the regulation and control of the manufacture, distribution, sale and use of pharmaceutical products. The manufacturers are either local or multinational firms. Some multinational firms have local manufacturing units, but most have only scientific and marketing offices. The multinational firms appoint distributors of their products, who in turn sell these products to wholesalers and retailers countrywide. The multinationals manufacture or distribute for sale branded products and compete in the market through innovation, research and development. The local manufacturers may or may not have appointed distributors, but they rather sell their products directly to wholesalers, retailers, hospitals and clinics and compete by selling low-priced generics. As in other regions of Sub-Saharan Africa, the ECOWAS pharmaceutical sector is characterized by net imports of pharmaceuticals, largely from India and China.

2.2 Pharmaceutical Production in ECOWAS

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. However, the local pharmaceutical production within the ECOWAS region is still characterized by dependence on imported medicines and other health-related products. The Table 1 below indicates the distribution of pharmaceutical manufacturing units across the 15-member state ECOWAS region:

Table 1–Distribution of Pharmaceutical Manufacturers in ECOWAS

Country	Number of Manufacturers	Remarks
Benin	1	Francophone
Burkina Faso	-	Francophone
Cape Verde	1	Lusophone
Cote d'Ivoire	2	Francophone
Gambia	-	Anglophone
Ghana	36	Anglophone
Guinée Conakry	1	Francophone
Guinea Bissau	-	Lusophone
Liberia	-	Anglophone
Mali	1	Francophone
Niger	-	Francophone
Nigeria	120	Anglophone

Senegal	2	Anglophone
Sierra Leone	-	Anglophone
Togo	2	Francophone
Total	166	Anglophone = 156 +Francophone = 9+ Lusophone = 1

As can be seen from the Table, the manufacturing industry is concentrated in Nigeria and Ghana: Nigeria alone has up to 120 active registered manufacturers while Ghana has 36 active manufacturers. Capacity utilization in Nigeria however is about 40 per cent, meaning that there is a large volume of underutilized manufacturing capacity which could be applied to produce new products upon demand, for example for export. The vast majority of manufacturing activity focuses on formulation of imported raw materials, with only small scale active pharmaceutical ingredients(API) manufacturing in Ghana by Lagray Chemicals Ltd for the production of azithromycin API.

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, there are many challenges such a slow patronage, high cost of production, high dependence on imported inputs, lack of capital and high commercial interest rate from banks, low level of export and lack of a policy framework for pharmaceutical business in ECOWAS. These factors militate against the policies of government of the ECOWAS, which largely seek to promote local production of pharmaceuticals. In summary, the industry today is nascent, with a few countries that can serve as a base on which to build. Although it is theoretically possible to start pharmaceutical manufacturing from scratch, ECOWAS would be better served by focusing its energy and resources on existing players as they have a better chance of succeeding.

2.2.1 ARVs demand and supply within ECOWAS

Africa represents the vast majority of the world's demand for antiretroviral medicines by volume. In 2010, antiretroviral therapy coverage stood at 30% in the ECOWAS countries, with 618 000 people on treatment in the region. On the supply side, however, ECOWAS countries have very little production capacity, and hence almost all of the region's antiretroviral medicines are imported from India. 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.

On antiretroviral medicine manufacturing, ECOWAS countries are not starting from zero. Several companies in Nigeria are locally manufacturing anti-retrovirals – though they represent only 6% of the country's market share. DANADAMS Pharmaceuticals Industry in Ghana, Evans Medicals Ltd, May and Baker PLC both in Nigeria produce anti-retrovirals, but only produce 20 per cent of its capacity because of low demand. Apart from periodically supplying the Ministry of Health and partners with anti-retroviral

medicines, the company also exports to Burkina Faso, Cote d'Ivoire, the Gambia, Benin and Togo under the support of WAHO.

African anti-retroviral medicine manufacturers-in general focus-predominantly on downstream parts of the value chain – that is, packaging and formulation of pills. No company in Africa, and for that matter, ECOWAS, currently produces APIs for antiretroviral medicines. The lack of antiretroviral API capacity is a significant gap in supply security. It is also a key component of cost competitiveness, as API accounts for 60–80% of the price of antiretroviral medicines. On quality, a core group of manufacturers in Africa have achieved international-level certification. However no company in an ECOWAS country has yet managed to secure prequalification or good manufacturing practice certification for antiretroviral drugs. This is a critical requirement for success, as antiretroviral drugs are currently purchased primarily by donors who require international certification for procurement. Currently, WHO has selected and endorsed five pharmaceutical manufacturing units in Nigeria to be given the WHO prequalification certification within the next two years, the process is ongoing. The Pharmaceutical manufacturing companies in Ghana are seriously working towards that.

2.2.2 Challenges to Local Manufacture of ARVs

Estimates value the global antiretroviral medicine market at about US\$18billion. Generic-accessible emerging economies, including Africa, make up less than 5% of the market, totalling about US\$850million in 2010. 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: On average, in 2010, first-line therapy cost only US\$109 per person per year and second-line therapy cost US\$673 per person per year in African countries. By contrast, a year of antiretroviral therapy in developed countries costs in the order of US\$10,000 per person.

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.

Although West Africa has a small pharmaceutical manufacturing base today, truly addressing supply security will require upgrading capacity and capabilities to move to world-class levels of quality and cost. To better understand the cost challenges faced by ECOWAS, it is useful to get a general sense of oral solid dosage (OSD) manufacturing economics.

Costs of a typical multi-product facility break down roughly as 60–80% API and 20–40% conversion cost. Conversion cost is composed of approximately 50% labour and 50% other components. For APIs, an at-scale plant can be reasonably assumed to have similar costs to plants in India and elsewhere, although some Indian plants are vertically integrating to produce their own APIs, thereby saving a 10–20% margin on that cost. On the labour side, ECOWAS generally lags behind on both cost and productivity. In addition, there are hidden costs, including the tariffs associated with importing raw materials and exporting finished goods, taxes paid on profits, and interest paid on loans.

Across all these areas, stories abound of how small differences add up to a significant advantage for foreign manufacturers. A similar situation exists on capital to set up the plants; building in ECOWAS is generally more expensive than in India, making capital investments harder to pay off. Altogether, the status quo makes it difficult for African manufacturers to compete with established foreign manufacturers. If West Africa is to build a competitive pharmaceutical manufacturing industry, the time to start is now.

First, pharmaceutical usage in the region may be at a low base, but it is beginning to take off. With West Africa's projected economic growth rates (Table 1), more money will be available for healthcare through government investment and private spending. This presents an opportunity for the region to capture its fair share of market growth rather than having to displace existing competitors. The antiretroviral drugs market is expected to grow substantially. West African treatment coverage is currently only 30%, and growth will be driven by the continued scale-up of programmes to close that gap. If West Africa were to reach the African Union's adopted target of 80% coverage by 2015, the market today would more than triple, to 2.4 million people. Further growth potential exists with the introduction of treatment as prevention.

Table 1: Real GDP growth in West Africa: Average 1993-2002 and 2011

	Average 1993-2002	2011
West Africa	3.4	4.9
Benin	4.9	3.8
Burkina Faso	5.5	4.9
Cape Verde	7.5	5.6
Cote d'Ivoire	3.2	-5.8
Gambia	3.8	5.5
Ghana	4.5	13.5
Guinea	4.4	4.0
Guinea-Bissau	0.4	4.8
Liberia	-	6.9
Mali	4.5	5.3
Niger	2.8	5.5
Nigeria	4.7	6.9
Senegal	3.2	4.0
Sierra Leone	1.9	5.1
Togo	1.0	3.8

Source: IMF, World Economic and Financial Surveys, October 2011.

Secondly, as India and China continue to emerge, their labour costs will rise and manufacturing will need to look for its next low-cost location. Already some manufacturing is moving out of China as minimum wage rises. West Africa can capture some of that business if it can improve its competitiveness.

Thirdly, developing a pharmaceutical manufacturing industry is a long-term project, and so West Africa must start sowing seeds now for that future. China has been building for 15 years and is only now starting to reap rewards, while India's strong global business is the result of more than 30 years of sustained investment.

Fourthly, the shift in development cooperation towards an emphasis on country ownership and leadership and fostering a more balanced relationship with international partners in terms of power and investments, has been accelerated by the financial crisis. The political window is open to garner support from development partners for more sustainable solutions, in the AIDS response and beyond, including to investing in local manufacturing and simplifying market access to medicines through regulatory harmonization as a means to cultivate a knowledge-based economy, strengthen industry, reduce costs and ultimately save lives and money.

Developing pharmaceutical manufacturing along regional lines has several advantages. Manufacturing hubs that serve the region could achieve scale faster than manufacturers that only serve a national market. Scale is critical to achieving cost competitiveness and the viability of this industry. Greater scale allows fixed costs to be spread more effectively, allows for lower price API procurement due to the higher volumes and over the longer term could even permit the development of API production.

At the institutional level, much of the technical know-how required will need to be obtained through technology transfer arrangements with existing skilled players from outside West Africa. Finding sufficient partners for long-term skills transfer may be facilitated through a regional approach, and could be focused on several selected facilities that serve the regional market.

2.2.3 Interventions in Support of Local Pharmaceutical Manufacture

Over the past 5 years, a number of interventions have been initiated by the West Africa Health Organization (WAHO) in partnership with development partners and ECOWAS to strengthen the manufacturing capacity of selected pharmaceutical firms and the supply within the region of anti-malarials and ARVs. Between 2009 and 2010, consultants were engaged to develop business plans, feasibility studies and facility structural drawings for 4 pilot pharmaceutical manufacturing units, Danadams -Ghana, Evans Medicals PLC-Nigeria, May and Baker -Nigeria and Inpharma Pharmaceuticals in Cape Verde. Equipment support to Danadams Pharmaceuticals Ltd, Ghana, received support from WAHO to purchase equipment (3 Humidity Chambers and 1 Infra-red Spectrophotometer) worth US\$ 80,000 in March, 2011. Between March 2010 and March 2011, sixty local pharmaceutical manufacturers were trained in Good Manufacturing Practice (GMP) based on WHO Modules 1, 2, 3 in Nigeria, Cape Verde and Benin.

In March 2011, representatives of local pharmaceutical manufacturers in the region validated and adopted the Common Technical Document (CTD) on Medicines in Bobo-Dioulasso. In February 2011 a consultant was engaged to develop Financial Proposal to support Local Pharmaceutical Manufacturers to produce essential medicines within ECOWAS Member States followed by a visit to the ECOWAS Investment and Development Banks (EBID) by Management and Professional Officer for Medicines and Vaccines to negotiate WAHO support to facilitate funds Local Pharmaceutical Manufacturers. A Workshop on the development of a Business plan for the operationalization of the Pharmaceutical Manufacturing Plan for Africa (PMPA) was held in Chad, between 6th and 10th June, 2011. WAHO supported the development of Bioavailability/Bioequivalence (BA/BE) studies guidelines, from 27-29 June, 2012 in Lomé, 30 regulatory affairs personnel in the pharmaceutical manufacturing sector were respectively trained on the application of Bioavailability and Bioequivalence studies guidelines and the WAHO Certification Schemes in pharmaceutical finished products, Active pharmaceutical ingredients and prequalification of medicines to enhance the work of the BA/BE Centre which is to be established in the region. To improve the safety and efficacy of medicines imported and produced in the region, in 2011, WAHO supported the development of guidelines for ECOWAS/WAHO Certification Scheme for finished products, raw pharmaceutical materials and pre-qualification requirements documents for evaluation of pharmaceutical manufacturers for market authorization.

Six pilot Pharmaceutical Manufacturers in the region, received US \$25,000 each, to support their WHO prequalification processes, from WAHO in June, 2012. To ensure ECOWAS commitment to improving the local pharmaceutical production of medicines, the 14th Assembly of Health Ministers endorsed the “ECOWAS Charter on Public Private Partnership Initiative for Local Pharmaceutical Production of Priority Essential Medicines” in Praia, Cape Verde from 4-5 April, 2013. A Joint Multi-stakeholder Consultation for the Implementation of the ECOWAS Charter on Public Private Partnership Initiative for Local Pharmaceutical Production of Priority Essential Medicines was held in Bobo-Dioulasso from 6-7 November, 2013. Contracts were signed between WAHO and two Pharmaceutical Industries for the supply ARVs for the ECOWAS Buffer Stock in Cote d’Ivoire.

2.2.4 Challenges to building local manufacturing

Regards of the efforts done in the ECOWAS the region the pharmaceutical industry is faced with challenges. Estimates value the global antiretroviral drug market at about US\$ 18 billion. Generic-accessible emerging economies, including Africa, make up less than 5% of the market, totalling about US\$ 850 million in 2010. Given the low health budgets of African governments and the dire need for antiretroviral drugs, African countries pay far lower prices for their antiretroviral drugs than do developed markets: On average, in 2010, first-line therapy cost only US\$ 109 per person per year and second-line therapy cost US\$ 673 per person per year in African countries. By contrast, a year of antiretroviral therapy in developed countries costs in the order of US\$ 10 000 per person.

The implication is that generic antiretroviral drug 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.

Although West Africa has a small pharmaceutical manufacturing base today, truly addressing supply security will require upgrading capacity and capabilities to move to world-class levels of quality and cost. To better understand the cost challenges faced by Africa, it is useful to get a general sense of oral solid dosage (OSD) manufacturing economics.

Costs of a typical multi-product facility break down roughly as 60–80% API and 20–40% conversion cost. Conversion cost is composed of approximately 50% labour and 50% other components. For APIs, an at-scale plant can be reasonably assumed to have similar costs to plants in India and elsewhere, although some Indian plants are vertically integrating to produce their own APIs, thereby saving a 10–20% margin on that cost. On the labour side, Africa generally lags behind on both cost and productivity. In addition, there are hidden costs, including the tariffs associated with importing raw materials and exporting finished goods, taxes paid on profits, and interest paid on loans.

Across all these areas, stories abound of how small differences add up to a significant advantage for foreign manufacturers. A similar situation exists on capital to set up the plants; building in Africa is generally more expensive than in India, making capital investments harder to pay off. Altogether, the status quo makes it difficult for African manufacturers to compete with established foreign manufacturers.

2.3 Distribution of Pharmaceuticals in the region

In general, there exists pharmaceutical distribution system across the ECOWAS region. In the private sector, the distribution system is largely poorly organized and disjointed. There are several unauthorized intermediaries involved in pharmaceutical distribution. This poses a great challenge in conducting audit trail of imported or locally manufactured products from the point of supply to the ultimate consumer. The environmental and climatic conditions under which pharmaceutical products are stored in, this negatively impacts on product availability, security and the final price and in turn accessibility. Across the region, the distribution through the public sector as in the Central Medical Stores (CMS) and the C entral  d'Achat des M edicaments Essenti els et G en eriqu es (CAMEG), however, are much better organized and managed through the national procurement agencies. Global initiatives support these national procurement agencies to ensure access to essential medicines such as ARVs, ACTs and anti-TB medicines.

2.4 Medicines Regulation

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. Situational analysis shows the existence of two different systems that serve to regulate health-related products within the region. The English-speaking countries have a system in which the regulatory functions are centralized in a semi-autonomous/autonomous body; the French and Portuguese-speaking system has regulatory functions shared between several bodies under the authority of the Ministry of Health. Assessment of NMRAs in 2008 by WHO and in 2011, by AU/NEPAD-WAHO, both showed major deficiencies in the regulatory capacities of the NMRAs. Medicine regulation in the sub-region is still problematic, a

situation precipitated by weak infrastructure, weak enforcement power and lack of cooperation from other law enforcement agencies, inadequate human resource capacity, over-reliance on imported pharmaceuticals, lack of bio-analysis facilities for pre-qualification, and lack of an avenue for information exchange between agencies. 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 were also differences in the requirements for medicines registration in member countries. There is need to improve, and some of the actions required include the restructuring or establishment of NMRAs to enable them to undertake their regulatory activities more effectively, developing and implementing comprehensive guidelines and procedures for drug registration and strengthening human capacity at NMRAs in Partner States.

It is a general consensus among NMRAs that the various institutional authorities agree on a common system on which all the pharmaceutical policy harmonization and regulation issues would depend. Given the diversity and severity of health issues afflicting West Africans, there was a compelling need to harmonize health policies, practices and standards among ECOWAS Member States. The fast-spreading illicit medicines markets and the sophistication in counterfeit medicines meant that in the absence of a unified and collaborative approach to combating these problems at the regional level, gains made by local- and national-level campaigns would be lost. Acknowledging this reality, ECOWAS committed itself to bringing about true regional integration in the health sector to ensure the highest possible standard of health for all West Africans.

Subsequently, the NMRAs have agreed to work towards a region-wide approach to reviewing the institutional and legal framework for medicines regulation, dossier evaluation, inspections, local production of essential medicines including traditional medicines, illegal markets and counterfeiting, quality control and pharmacovigilance. In this regard, and in support of harmonization of medicines registration across the ECOWAS region, WAHO has funded the development of the Common Technical Document (CTD) and training manual for medicines registration harmonization, which was validated and adopted by NMRAs in March 2011, in Bobo-Dioulasso, Burkina Faso. WAHO trained 45 NMRAs regulators from seven (7) Member States of ECOWAS on the medicines registration harmonization common technical document in April 17 - 19, 2013. A further 15 regulators were also trained on Good Manufacturing Practice (GMP) based on WHO Modules 1, 2, 3, conducted in three sessions in Nigeria, Cape Verde and Benin from March 2010 –March 2011. To strengthen the MRH process in the ECOWAS region a project proposal was sent to AU/NEPAD Consortium in March, 2011 for financial and technical support.

In May 2012, in Cote D'Ivoire, 30 regulatory inspectors and registrars of medicines were trained on the application of bioavailability and bioequivalence studies guidelines and the WAHO Certification Schemes for Pharmaceutical Finished Products (FPP), Active Pharmaceutical Ingredients (APIs) and prequalification of medicines. The medicines registration harmonization (MRH) Governing Board and six Technical Working Groups (TWGs) were constituted for the implementation of the MRH process in the region and their terms of references (TORs) were also developed in Accra, Ghana from 22-23 May, 2013.

2.5 Pharmacovigilance

The situation of pharmacovigilance in the region was assessed from 11-14 May, 2010 for the 15 ECOWAS member states. From this analysis only five (5) countries were full members of WHO-UMC-PV, four (4) were associate members and six (6) countries did not have a pharmacovigilance system in place. As such WAHO, trained two persons from each of these six (6) countries to equip them with basic skills and research tools to enhance pharmacovigilance system, and technically provide laptops and financially supported their linkage via Vigiflow to WHO-UMC from 13-15 April, 2011. A total of 15 pharmacovigilance contact persons from the national medicines regulatory authorities were empowered in the skill of communication and crisis management in pharmacovigilance 22-24 February, 2012 in Accra to understand the data/signals of adverse reports and interpret to health workers and patients.

2.6 TRIPS and access to medicines

Lack of access to medicines remains a major impediment to public health in many African countries. This has a negative impact on the achievement of the health related Millennium Development Goals. The desire to improve on the accessibility of essential medicines on the African continent motivated the AU Assembly Decision 55, at the Abuja Summit in January 2005 to mandate the African Union Commission (AUC) to develop a Pharmaceutical Manufacturing Plan for Africa (PMPA) within the NEPAD framework, the 2nd Session of the AU Conference of Ministers of Health undertook “to pursue, with the support of our partners, the local production of generic medicines on the continent and to making full use of the flexibilities within the Trade and Related Aspects of Intellectual Property Rights (TRIPS) and DOHA Declaration on TRIPS and Public Health” as an important element of improving access to medicines.

It is evident that ECOWAS, as a region, needs to strengthen its health systems by enhancing access to essential medicines. The region is fast losing opportunities for improving her people’s development and health due to the poor response to the challenges of lack of access to medicines. ECOWAS needs to follow the example of other regional organizations that have made great advances towards harmonization of regulations on access to medicines using TRIPs flexibilities. There is therefore an urgent need to take appropriate actions to ensure effective improvement of access to medicines in the region, using TRIPs Flexibilities. In recent times, several important interpretations have been tested in bilateral negotiations, in national courts and, most importantly, at the WTO Council on TRIPs. The examination of those specific TRIPs flexibilities and safeguards would ensure that the current development at the global level in respect with TRIPs flexibilities and its impact on access to essential medicines inures to the benefit of Member States of the region. So far WAHO has developed the TRIPs flexibilities policy and guidelines for the ECOWAS which was validated and adopted from 28-29 October, 2012 in Accra by Intellectual Property officers from all 15 Member States and key partners such as ARIPO, OAPI, UNDP and WHO. From 15-16 July, 2013, in Bobo-Dioulasso, WAHO also sensitized directors of the ministries of health, trade, judiciary and industry in the 15 ECOWAS member states to create awareness on the existence of the ECOWAS TRIPs policy and guidelines, the need for its incorporation into national laws and the benefits of implementing the provisions of the WTO TRIPs flexibilities to improve access to essential medicines for public health interventions. An Advocacy TRIPs flexibilities document to enhance the

implementation of the TRIPS flexibilities has been developed and was validated by TRIPs experts' from 19-22 November, 2013 in Bobo-Dioulasso.

2.7 Counterfeit Medicines

The fight against counterfeit and illicit medicines trade in the ECOWAS region cannot be over emphasized. Counterfeit and illicit medicines trade is a menace that has negatively affected public health globally, threatening patient safety, jeopardizing the health of its victims and often leading to deaths.

Between January 1999 and October 2000 alone, the WHO received from 20 countries, 46 confidential reports on fake medicines, notably counterfeit medicines, with 60% of the reports coming from developing nations and 40%, developed nations, notably countries south of the Sahara. Even though the reports received were not validated, and therefore, could not be used for the purposes of quantification, the information clearly confirms the existence of the phenomenon. Many stakeholders globally, such as the World Health Organization (WHO), International Federation of Pharmaceutical Manufacturers Association (IFPMA), Chirac Foundation, have tried to find solutions to combat this menace but with no much success.

In West Africa, the incidence of counterfeit medicines has been studied with reports varying from about 17% in Nigeria to over 50% in other countries and further compounded by illicit medicine markets. Prevalence of counterfeit medicinal products in the region has led to reported therapeutic failures, drug resistance and in some cases, death on a rather alarming scale. The West African Health Organization, deem it her responsibility to solicit the collaboration of all stakeholders in the fight against counterfeit and illicit medicines trade to arrest the situation in West Africa. In the bid to find solutions to such a problem, the fight against Counterfeiting and Medicines trafficking in ECOWAS Member States constitutes a major priority in WAHO's Strategic Plan 2009-2013. WAHO has tried to achieve its goal by having series of consultative meetings with the various key stakeholders, developed and validated an operational strategic plan to be used as a tool in the fight against counterfeit and illicit medicines trade and has put in place a legal framework to enforce the fight. To ensure the smooth and effective operation of the strategic plan, a regional ECOWAS Medicines Anti-counterfeit Committee (EMACCOM) was constituted with members drawn from the National Medicines Regulatory Authorities (NMRAs) of all the 15 ECOWAS Member States to control counterfeit medicines in the region.

2.8 Quality Control of Medicines

The sale of medicines on the open unregulated market makes the ECOWAS region particularly susceptible to the circulation of substandard and counterfeit medicines. The situation is further compounded by poor QC infrastructure for testing suspected products. QC laboratories are expensive to set up, run and maintained because of equipment costs, cost of chemicals, reagents and reference standards, retention of qualified human resource personnel, provision of constant supply of electricity,

running water, etc. A survey conducted under the auspices of WAHO in 2011, showed that 17 national QC laboratories for the testing of medicines were in existence in the ECOWAS region providing support to the NMRAs in regulatory assurance of the quality of medicines. A needs assessment of these laboratories conducted by WAHO between 2010 and 2011 showed that none had been accredited to ISO 17025; five of the laboratories located in Ghana, Nigeria, Senegal, Burkina Faso and the Cape Verde were well equipped, adequately resourced with qualified personnel and had quality management system in place. These laboratories had reasonable capacity to conduct both chemical and microbiological analyses of pharmaceutical products. The remaining 12 laboratories were not adequately resourced and therefore could not carry out sufficient pharmacopeial tests to assess the quality of pharmaceutical products.

Besides efforts by national governments to upgrade national laboratories, WAHO, the regional health agency had since 2010, initiated programmes to strengthen the capacity of medicines testing laboratories in selected countries. These include development of guidelines and training manuals for laboratory quality management systems, training of laboratory managers and staff in the utilization of the developed manuals and guidelines, selection of five QC laboratories for upgrade and support towards attainment of ISO 17025 certification and subsequent elevation to the status of centers of excellence for testing of medicines.

2.9 Innovation, Research and Training in support of local pharmaceutical production

ECOWAS states governments recognize the critical role of research and development in the promotion of quality health care. Some ECOWAS countries have in place policies related to support for research into industrial development in general and the pharmaceutical or health sector in particular. 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.

Additionally, most research funding targets basic and operational research which does not necessarily lead to product development. The linkages between academia, research institutes and industry are so weak that they rarely collaborate in research and development. There is a lot of interest in traditional medicines as potential sources of lead molecules for new treatment of diseases, but there is also a lack of capacity in this respect. While most of the Research & Development (R&D) institutions in the region are able to screen plant extracts for activity they are however unable to move beyond screening to structure elucidation and optimization because of lack of equipment and expertise in drug discovery. There is a need to provide equipment and develop expertise in order to create a platform for medicine discovery in the region.

Training curriculum in the region's universities should be tailored to suit both traditional and modern trends of pharmaceutical developments. Areas such as regulatory affairs, pharmaceutical technology, drug formulation and development and clinical studies have to be strengthened. Paying attention to regional harmonization of

educational curriculums at the undergraduate, post graduate and at the pharmacy technician levels would lead to the production of qualified manpower and improve the quality of pharmacy practice. The West Africa Post-graduate College of Pharmacists (WAPCP) and any other similar institutions within the region can play leading roles in ensuring the training of Pharmacists and Pharmaceutical Scientists to meet the expertise and demand of the pharmaceutical market within the ECOWAS region.

2.10 SWOT Analysis

This section presents a summary analysis of the strengths, weaknesses, opportunities and threats (SWOT) of the ECOWAS pharmaceutical sector with respect to capacity for production of essential medicines, supply of medicines and operating regulatory environment.

2.10.1 Strengths

- Leadership and governance (Political will to support pharmaceutical sector)
- Availability of Manufacturing Capacity
- Developing Regulatory Capacity
- Harmonization (Medicines Regulation, education)
- Rapidly expanding Market (Population greater than 300 million)
- Increased collaborations and improved information sharing amongst stakeholders
- Human Resources and Training
- Financial incentives
- ECOWAS public-private-partnership (PPP) initiatives
- Most ECOWAS countries have Medicines policies

2.10.2 Weaknesses

- Leadership and governance at the enterprise level
- Lack of a regional strategic approach
- Inability of Manufacturers to attain WHO pre-qualification
- High cost of locally manufactured medicines compared to imports as a result of: -
 - a. High Tariffs
 - b. Human Resources
 - c. Cost of funds
 - d. Inadequate infrastructures
 - e. Dependence on imported raw materials
 - f. Inadequate implementation of existing policies
 - g. Inadequate incentives
- Inadequate regulatory capacity
- Poor distribution & supply chain system
- Inadequate investments in Research and Development

- Over reliance on imported medicines
- Inadequate Human Resource and Poor remunerations
- Inadequate Market Information and data
- Low level of Pharmaceutical research, development and technology
- Weak capacity of QC Laboratories
- Porous borders

2.10.3 Opportunities

- Proposed Common External Tariff
- ECOWAS Trade Liberalization Scheme
- Existence of Generic Manufacturers
- Existence of the AUC-PMPA
- WHO Pre-qualification of Medicines program
- TRIPS Flexibilities and safeguards
- Proposed Regional Certification Schemes
- Proposed Regional Centres of Excellence
- Existence of reasonable regulatory capacity
- Charter of AHM on PPP for local production of medicines
- Propose Centre for Bioequivalence & Biopharmaceutical Research (CBBR)
- ECOWAS initiative for private sector development

2.10.4 Threats

- Political Instability in the region
- Weak Governance and Procurement Systems
- Inadequate Healthcare budgets
- Dependence on Donated Medicines
- TRIPS Flexibilities and safeguards
- Substandard, Spurious, Falsified, Falsely labeled and counterfeit medical products
- Lack of transparency in the Procurement Systems
- Smuggling of Medical products
- Low Patronage by Governments and Donors for locally produced medicines

3.0 VISION OF THE ECOWAS PHARMACEUTICAL PLAN

A regional pharmaceutical sector, incorporating a vibrant manufacturing industry and a robust regulatory system that is enduring, sustainable, competitive and managed in an integrated manner to be able to provide quality, affordable, safe and efficacious essential medicines that meet the needs of the region and for exports by 2025.

4.0 MISSION OF THE ECOWAS PHARMACEUTICAL PLAN

The ECOWAS Regional Pharmaceutical Plan seeks to lay down a strategic approach for member states to develop an efficient and effective pharmaceutical sector that would manufacture and supply safe and good quality medicines for national, regional and international markets. This shall be accomplished through the promulgation of policies and legislation that support pharmaceutical manufacturing, robust and harmonized medicines regulatory systems, establishment of centers of excellence and best practices in pharmaceutical services, research and development, information sharing and the development and maintenance of competent and motivated human resources.

5.0 GOAL OF THE ECOWAS PHARMACEUTICAL PLAN

The goal of the ECOWAS Regional Pharmaceutical Plan is to provide a strategic framework within which the pharmaceutical sector in the region will be managed and regulated to provide self-sufficiency in the production, access to and rational use of affordable essential medicines and other medical products of proven quality safety and efficacy.

6.0 OBJECTIVES WITH JUSTIFICATION

6.1 To improve and strengthen the governance of the pharmaceutical systems to ensure transparency, accountability as well as patronage of medicines produced in the ECOWAS region by the year 2020

Governance systems for pharmaceuticals and other medical products differ widely in member states. Whereas in some countries matters that have to do with medicines policies, regulation, procurement, quality control and other such activities are handled directly by departments in the Ministries of Health, in other countries these activities are shared between different Agencies which may or may not be part of the MOH establishment. These different governance systems result in overlap of functions which tend to create gaps that threaten the efficiency and effectiveness of medicines management. This objective tends to evaluate these systems to facilitate exchanges, build confidence in pharmaceutical manufacturing, distribution and use within ECOWAS.

The activities to be undertaken as part of this plan to achieve this objective include:

Activities:

- a. Conduct a survey of existing governance structures and policies pertinent to the pharmaceutical sector in each ECOWAS member states
- b. Review the existing governance structures and their functions in the ECOWAS member states and make recommendations
- c. Provide technical and logistics support to strengthen the governance structures in the ECOWAS member states

- d. Harmonize all the policies and develop a regional medicines policy
- e. Develop an implementation plan and budget ECOWAS Regional Pharmaceutical Plan
- f. Support countries to develop and review their medicine policies to be in line with the regional Pharmaceutical Plan
- g. Develop, adopt and promote an ECOWAS regional strategy for procurement of pharmaceutical products
- h. Promote regional pooled procurement for medicines, vaccines and API's
- i. Provide buffer stock of medicines and vaccines for priority endemic diseases and for seasonal outbreaks of epidemics within the region
- j. Develop and implement a communication strategy for the major changes proposed in this plan

6.2 To promote and support competitive and efficient regional pharmaceutical manufacturing to ensure the supply of essential medicines produced in the region from 30% to 60% by the year 2020

It is recognized that local production of essential medicines has many advantages for the region including but not limited to; saving foreign exchange, creation of jobs thus alleviating poverty and promoting social development, technology transfer, stimulation of exports, and enhanced self-sufficiency in drug supply. A viable pharmaceutical Industry in West Africa will, therefore, positively impact on the Health system and its capacity to respond to the health needs of the people as well as contribute to overall socio-economic development of the ECOWAS region. A pharmaceutical manufacturing hub that would move the region to achieve faster scale up of the national markets, critical cost competitiveness and the viability of the manufacturing industry. Greater scale up allows fixed costs to spread more effectively, lowers price of API procurement due to the higher volumes and over the longer term could encourage the development and production of APIs within the ECOWAS region.

At the institutional level, much of the technical know-how required will need to be obtained through technology transfer arrangements with existing skilled players from outside West Africa. Finding sufficient partners for long-term skills transfer may be facilitated through a regional approach, and should focus on selected facilities that serve the regional market. The following activities are therefore to be implemented as part of the ERPP to achieve this objective:

Activities

- a. Advocate for zero tariff on pharmaceutical raw materials within the ECOWAS Common External Tariff (CET)
- b. Advocate for Exemption of Finished Pharmaceutical Products and inputs from VAT
- c. Identify manufacturers of API's and support them to build capacity to supply the pharmaceutical manufacturing sector
- d. Identify manufacturers of EXCIPIENTS and support them to build capacity to supply the pharmaceutical manufacturing sector

- e. Develop credit worthiness and capacity of industry to access funds
- f. Advocate for establishment of special fund to support the industry
- g. Develop capacity in pharmaceutical technology and good manufacturing practices (GMP)
- h. Promote medicines produced within the region through education and exhibitions

6.3 To support pharmaceutical manufacturing in order to achieve international certification for 10 pharmaceutical manufacturers by the year 2020

Although pharmaceutical manufacturing has been going on in some member countries for several years, none of them has so far had any of their products prequalified under the WHO prequalification scheme or other Good Manufacturing Practice (GMP) certification. This is a critical requirement for success, as medicines for Malaria, Tuberculosis and antiretroviral drugs are currently purchased primarily by donors who only patronise those companies with International Certification. Currently, WHO has selected and endorsed five pharmaceutical manufacturing facilities in Nigeria and two in Ghana which have expressed interest in the WHO prequalification scheme and are being supported for certification within the next two to three years. In response to this and as a strategy to facilitate regional trade in quality assured pharmaceuticals, an ECOWAS/WAHO Certification Scheme for finished pharmaceutical products, raw materials for pharmaceutical production and pre-qualification requirements documents for evaluation of pharmaceutical manufacturers for market authorization was developed in 2011. This is an opportunity for countries and manufacturing establishments to participate in the process in order to provide assurance of procurement of medicines from certified sources in the region and to have access to the regional market. The following activities are therefore planned.

Activities

- a. Circulate an expression of interest document for interested industries to indicate their willingness to participate in the ECOWAS Certification and Prequalification Scheme
- b. Conduct audit of selected companies and identify GAPS
- c. Establish an incentive scheme for progress in compliance requirements of the certification and prequalification schemes
- d. Develop a cGMP roadmap for manufacturers in the region
- e. Provide Technical assistance and capacity building for companies that have expressed interest in attaining international certification
- f. Secure technical and financial support for the actualization of the regional Centre for Bio-equivalence and Bio-pharmaceutical Research (CBBR) in Ghana

6.4 To strengthen the National Medicines Regulatory Authorities (NMRAs) regulatory capacity and quality infrastructure in the ECOWAS region to achieve International Certification and designation as Regional Centers of Excellence by the year 2018.

Pharmaceutical manufacturing in the ECOWAS region faces a number of challenges and to make them competitive and ready for international certification, there will be need for capacity building in

areas such as Regulatory affairs, Pharmaceutical business management, Pharmaceutical manufacturing and Plant operations and maintenance among others. At the country level, building the industry also requires enhanced regulatory capacity. Creating markets with consistent, sufficient demand will require streamlined and enhanced registration processes and good-quality regulation. Although 17 National Medicines Quality Control Laboratories exist in most member states, a recent WAHO study has indicated that only one of them is ISO 17025 certified for certain tests while others are in the process of achieving international certification. It is therefore of utmost importance that the 5 laboratories classified under Category A by WAHO be supported to achieve international certification. NMRAs and NQCLs that achieve international standards will then be designated Centres of Excellence to provide training and capacity building for the others.

Activities

- a. Conduct needs assessment of medicines regulatory authorities.
- b. Review National Medicines laws.
- c. Develop/improve the infrastructure of NMRAs including Quality Control Laboratories and CBBR.
- d. Develop the HR capacity of NMRAs.
- e. Develop criteria for certification of Medicines Regulatory Professionals.
- f. Harmonize requirements for registration of medicines and licensing of manufacturing facilities across the region.
- g. Implement the WAHO Certification and Pre-qualification Schemes.
- h. Develop a harmonized regional Pharmacovigilance policy to ensure the safety of medicine and vaccines,
- i. Support NMRAs to obtain International Standard Organization Certifications (ISO)
- j. Design a website for MRH to link with existing WAHO website, and train NMRAs on its application
- k. Provide technical and logistics support to five identified laboratories to achieve International Certification and be designated as Regional Centers of Excellence in the ECOWAS region
- l. Monitor and evaluate performance of the quality control laboratories every two years

6.5 To reduce by 75% the incidence of Substandard, Spurious Falsified and Falsely labeled Counterfeit - (SSFFC) medical products in the ECOWAS region

The fight against counterfeit and illicit medicines trade in the ECOWAS region cannot be over emphasis. Counterfeit and illicit medicines trade is a menace that has negatively affected public health globally, threatening patient safety, jeopardizing the health of its victims and often leading to deaths. Although details of studies are uncoordinated and sketchy, it is estimated that the incidence varies from about 10% to over 50% across the region and is further compounded by illicit medicines markets. Prevalence of counterfeit medicinal products in the region has led to reported therapeutic failures, drug resistance and in some cases, death on a rather alarming scale. In the bid to find solutions to the problem, WAHO has developed and validated an operational strategic plan to be used as a tool in the fight against counterfeit and illicit medicines trade and has put in place a legal framework to enforce the fight. To ensure the effective operation of the strategic plan, a regional committee called the ECOWAS Medicines Anti-

counterfeit Committee (EMACCOM) has been established. It is believed that with collaboration from all the key stakeholders the fight against counterfeit and illicit medicines trade in West Africa can be successfully achieved.

Activities

- a. Create, support and build capacity of EMACCOM National steering committees in the 15 countries
- b. Conduct a situation analysis of SSFFC medical products and illicit trade in Medicines in the region
- c. Develop, validate, adapt and adopt common tools for the evaluation of the counterfeit medicines phenomenon and pre-test tools in 3 countries
- d. Conduct surveys in ECOWAS member countries to establish level and extent of counterfeit medicines in the region
- e. Support intensified Post Marketing Surveillance activities by NMRAs/EMACCOM
- f. Provide resources to stakeholders for effective monitoring and evaluation.

6.6 To establish a regional body for medicines regulation in line with the African Union's medicines harmonization program by the year 2020

Realizing the importance of regional medicines harmonization as a tool to access quality and safe medicines, a Consortium consisting of partners to facilitate African Medicines Regulatory Harmonization initiative under the AU/NEPAD was constituted. The Consortium has received six project proposals for harmonization of medicines registration in the East African Community (EAC), Southern Africa Development Community (SADC), Central African region, Economic Community of West African States (ECOWAS), West African Monetary Union (UEMOA) and the East, Central and Southern African Health Community (ECSA-HC). The ECOWAS MRH project proposal and budget was sent to NEPAD and the Consortium for approval in March 2011. Already various portions of this proposal including the development and validation of the terms of reference for the Governing Board and Technical Working Groups have been accomplished. A common technical document (CTD) for medicines registration has been developed and approved which has been followed with training sessions for member states. The ultimate goal of the medicines registration harmonization is to create a platform for the establishment of a regional medicines agency in line with the AU-WHO project for the establishment of the African Medicines Agency in the long run. The following activities will be implemented as part of this plan to achieve the objective:

Activities

- a. Implement the ECOWAS Medicines Harmonization project proposals submitted to the AU and the Consortium
- b. Formulate Regional Medicines Regulatory Harmonization Policy.
- c. Review and adapt the African Union's Medicines Regulation Harmonization program as appropriate
- d. Conduct sensitization workshops for decision makers and key stakeholders on the adapted Harmonization program

- e. Constitute a Governing Board and Technical Working Groups for Medicines Regulation Harmonization in ECOWAS region
- f. Monitor and evaluate performance of the Medicines Regulatory Authorities every two years

6.7 To facilitate the incorporation of ECOWAS policies on TRIPs flexibilities into national laws of a minimum of ten member states within the region by the year 2020.

Over the years ECOWAS has recognized the urgent need for appropriate actions to ensure effective improvement of access to medicines in the region, using TRIPs Flexibilities. In recent times, several important interpretations have been tested in bilateral negotiations, in national courts and, most importantly, at the WTO Council on TRIPs. The examination of those specific TRIPs flexibilities and safeguards would ensure that the current development at the global level in respect with TRIPs flexibilities and its impact on access to essential medicines inures to the benefit of Member States of the region if a regional approach is used. These benefits include: Development and strengthening of regional pharmaceutical production; Strengthening of research capabilities and the establishment of networks for research and development; Higher effective demand for the same medicines due to climatic conditions and other geographical reasons; Lower consumer drug prices due to increased economies of scale in production, procurement and distribution; Stronger local technological capacities and technology transfers; Domestic innovation resulting from the pooling of resources including financing; Capacity building in terms of human resource and infrastructure; and improvement of cross-border disease control. So far WAHO has developed the TRIPs flexibilities policy and guidelines for the ECOWAS region which has been validated and adopted by Intellectual Property officers in all 15 Member States. WAHO is planning a sensitization program for the ministries of health, trade, judiciary and industry as part of its overall advocacy strategy, to create awareness on the existence of the ECOWAS TRIPs policy and guidelines, the need for its incorporation into national laws and the benefits of applying the WTO TRIPs flexibilities provisions for improved access of essential medicines for public health interventions. Other activities considered in this plan to achieve this objective are:

Activities

- a. Implement the WAHO TRIPs flexibilities strategies as contained in the harmonized ECOWAS TRIPs Policy and Guidelines with reference to the WAHO TRIPs Strategic Advocacy Document 2013.
- b. Monitor and evaluate the implementation of the WAHO TRIPs flexibilities strategies every year
- c. Create awareness in OAPI and ARIPO member states on the TRIPs flexibilities in the region

6.8 To formulate and implement policies that will promote innovation, research and development into pharmaceuticals and medicinal products within the ECOWAS region as well as establish a competitive grant in the ECOWAS region by the year 2020

Through a multi stakeholder approach, this objective seeks to institute regional scientific conferences with varying themes based on current issues in the pharmaceutical sector. These will afford a platform for manufacturers, scientists, researchers, academia and regulators to exchange scientific papers from which new policies and actions will evolve. It also seeks to encourage drug development research activities and eventually the manufacture of traditional medical products of proven quality and safety under current good manufacturing practices (cGMP) conditions. The activities to achieve this objective are:

Activities

- a. Organize an annual/ biennial scientific and technology exchange meetings for the Pharmaceutical sector players and other stakeholders in the ECOWAS region
- b. Establish ECOWAS research grants for collaborative development of traditional medicinal products and excipients
- c. Build drug development capacity (pharmaceutics, toxicology, clinical trials etc.) backed by an incentive scheme within the industry
- d. Manufacture standardized traditional medicinal products under GMP
- e. Establish working relations with the Drug Advisory Council of the WAPCP on Pharmaceutical research and practice in the region.

7.0 RISKS, ASSUMPTIONS AND MITIGATION PLANS

	RISKS/ ASSUMPTIONS	MITIGATION PLANS
1	Resistance of MRAs to the harmonization of medicine regulatory systems	An ECOWAS medicines harmonization network should be developed within the AMRH to push the regional process forward and in all these the economic and developmental prices the region is paying must be brought to the fore in real terms. Develop and implement a communication strategy (CS) for all stakeholders.
2	Non-cooperation of procurement agents and variation in procurement laws/regulation in member countries	WAHO champions must be identified in all the structures of ECOWAS as well as in-countries to be used for advocacy and implementation of the CS.
3	Unavailable development financing to support the plans	Relevant DFIs and DPs must be identified and brought on board to help with financing the plan. Implement the CS.
4	Unavailability of human capital to support the plans	An HR plan should be developed as part of this plan but that implementation should be 5 years ahead of all other strategies of this plan
5	Non-cooperation of stakeholders to actualize the plans in all its forms	Use the ECOWAS structures and champions in-country to advocate for cooperation from stakeholders and implement the CS.
6	Is the political will available to support the implementation of the plans?	The opportunity costs of inaction in financial and developmental terms should always be included in WAHO reports to the Assembly of Health Ministers. Implement the CS.
7	Human resource for pharmaceutical sector requires other scientists aside pharmacists	Recognize other disciplines in the human resource development plans

8.0IMPLEMENTATION FRAMEWORK FOR ACTIVITIES

OBJECTIVE6.1	To improve and strengthen the governance of the pharmaceutical systems to ensure transparency, accountability as well as patronage of medicines produced in the ECOWAS region by the year 2020						
ACTIVITIES	TIME LINE	BY WHO	EXPECTED OUTCOMES	INDICATORS	PARTNERS	RISK	ASSUMPTIONS
Conduct a survey of existing governance structures and policies pertinent to the pharmaceutical sector in each ECOWAS member states	June – Sept 2014	WAHO, WAHO Experts, Member Countries and Partners	Survey of existing governance structures and policies conducted and gaps identified	Report of Survey on governance structures and policies pertaining to the pharmaceutical sector in each ECOWAS member states available	WHO, UNDP, UNAIDS, ONUSIDA MSH/SIAPS, AU/NEPAD WAPMA	<p>Non-cooperation of member countries and other stakeholders</p> <p>Poor governance and non-adherence to existing policies</p> <p>Non-availability of resources (human and financial) for the conduct of survey</p> <p>Poor design of survey</p> <p>Inappropriate/ inadequate survey tools.</p>	<p>Support by WAHO and Member States to conduct survey</p> <p>Availability of resources</p> <p>Availability of appropriate survey tool</p>
Review the existing governance structures and their functions in the ECOWAS member states and make recommendations including	June - Aug 2014	WAHO, WAHO Experts, Member Countries and Partners	Review of the existing governance structures and their functions in the ECOWAS member states conducted and	Report and recommendations of review exercise available	WHO, UNDP, UNAIDS, ONUSIDA MSH/SIAPS, AU/NEPAD WAPMA	<p>Non-cooperation of member countries and other stakeholders</p> <p>Poor quality of recommendations</p>	<p>Consensus on the recommendations</p> <p>Willingness to change</p>

appropriate models			recommendations made				
Provide technical and logistics support to strengthen the governance structures in the ECOWAS member states	June 2014	WAHO, WAHO Experts, Member Countries and Partners	Technical and logistics support to strengthen the governance structures in the ECOWAS member states provided	Number of countries provided with technical and logistics support	WHO, UNDP, UNAIDS, ONUSIDA MSH/SIAPS, AU/NEPAD WAPMA	Non-availability of resources (human and financial)	Availability of resources to provide technical and logistics support to strengthen governance structures (for both WAHO and Member States)
i. Develop a regional medicines and vaccines policy and get political backing of Heads of States ii. Harmonize all the National medicines and vaccines policies	As from July 2014	WAHO, WAHO Experts, Member Countries and Partners	Harmonised Regional Drug Policy for ECOWAS towards improved healthcare outcomes developed	Availability of a Harmonised Regional Drug Policy for ECOWAS member states	WHO, UNDP, UNAIDS, ONUSIDA MSH/SIAPS AU/NEPAD WAPMA	Non-availability of resources Poor cooperation from member states	Availability of resources Political will
Implement Regional Pharmaceutical Plan	As from July 2014	WAHO, WAHO Experts, Member Countries and Partners	An ECOWAS Pharmaceutical Plan developed and implementation started	Number of ECOWAS member states implementing the Regional Pharmaceutical Plan	WHO UNDP UNAIDS ONUSIDA MSH SIAPS, AU NEPAD WAPMA	Non-availability of resources Poor cooperation from member states and other critical Stakeholders.	Availability of resources (human and financial) in WAHO and Member Countries
Develop, adopt and promote an ECOWAS regional strategy for	Jan – March 2015	WAHO	Regional strategy for procurement of pharmaceutical	Number of ECOWAS member states that have	WHO UNDP UNAIDS ONUSIDA	Resistance by member states Non-patronage of	Availability of adequate human and financial resources in

procurement of pharmaceutical products			products developed and adopted by ECOWAS member states	adopted and are implementing the ECOWAS regional strategy for procurement of pharmaceutical products	MSH/SIAPS AU/NEPAD WAPMA	locally produced pharmaceutical products.	WAHO
Initiate regional pooled procurement for medicines, vaccines and API's	Q3 2015	WAHO and partners	Implementation of Pooled procurement for medicines and vaccines and APIs initiated in ECOWAS member states	Drastic reduction in the Prices of medicines, vaccines and APIs as a result of pooled procurement	WHO, UNDP, UNAIDS, ONUSIDA MSH/SIAPS, AU/NEPAD WAPMA	Resistance by member states Non-patronage of locally produced pharmaceutical products Change management issues Resistance from Manufacturers (pricing, quality and specifications of APIs) Different API specifications for FPP Differences in National Procurement cycles Non availability	Political will for patronage of locally produced pharmaceutical products Pooling manufacturers (with similar capacities) Availability of resources

						of financial resources	
Adopt the WHO codification system for all medicines and APIs in ECOWAS	Q2 2015	WAHO and Partners	Adoption of WHO codification system for all medicines and APIs in ECOWAS member states	Systematic availability of Market data on medicines and APIs. Number of ECOWAS member states that have adopted the WHO codification system for all medicines and APIs	WHO, UNDP, UNAIDS, ONUSIDA, MSH/SIAPS, AU/NEPAD WAPMA	Non-cooperation from member states and stakeholders	Support from member states and stakeholders
Provide buffer stock of medicines and vaccines for priority endemic diseases and for seasonal outbreaks epidemics within the region	Ongoing activity	WAHO and Partners	Buffer stock of medicines and vaccines for priority endemic diseases and for seasonal outbreaks of epidemics within the ECOWAS region provided	Availability of Buffer Stocks for effective management of public health interventions of priority diseases and outbreaks across ECOWAS	WHO, UNDP, UNAIDS, ONUSIDA MSH/SIAPS, AU/NEPAD WAPMA	Lack of financial resources Change management issues	Availability of resources
Develop and implement a communication strategy for the major changes proposed in this plan	Q2 2015 This activity needs to start early to	WAHO, Member States and Partners	Communication Strategy (CS) for the major changes proposed in the ECOWAS	Number of ECOWAS member states that have commenced the implementation	WHO, UNDP, UNAIDS, ONUSIDA MSH/SIAPS, AU/NEPAD	Lack of financial resources Change management issues.	Availability of resources

	effectively engage and get commitment from Member States		Pharmaceutical Plan developed and implemented	of the WAHO initiatives on procurement, codification, governance, etc.	WAPMA		
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OBJECTIVE 6.2 To promote and support competitive and efficient regional pharmaceutical manufacturing to ensure supply of essential medicines produced in the region from 30% to 60% by the year 2020							
ACTIVITIES	TIME LINE	BY WHO	EXPECTED OUTCOME	INDICATORS	PARTNERS	RISK	ASSUMPTIONS
Advocate for zero tariff on pharmaceutical raw materials within the ECOWAS CET	By 2015	WAHO/ECOWAS	Zero tariff on pharmaceutical raw materials within the ECOWAS CET approved by ECOWAS	Reduction in cost of Locally manufactured pharmaceutical products within the ECOWAS member states leading to improved access	MINISTRIES OF FINANCE, TRADE & CUSTOMS UNION, ECOWAS PARLIAMENT	Delay in the conduct of advocacy Poor implementation in member states	Political will Implementation in member states
Exemption of finished pharmaceutical products and inputs from VAT	BY 2015	WAHO Member States	VAT exemption in Members States	Reduction in cost of Locally manufactured pharmaceutical products within the ECOWAS member states leading to improved access	MINISTRIES OF FINANCE, TRADE & CUSTOMS UNION, ECOWAS PARLIAMENT	Poor implementation by revenue agencies	Cooperation from revenue agencies
Identify manufacturers of APIs and support	BY 2018	WAHO WAPMA	Manufacturers of APIs in ECOWAS	APIs produced in commercial quantities within	AfDB, UNIDO IFC	Poor response by manufacturers	Commercial viability

them to build capacity to supply the pharmaceutical manufacturing sector			member states identified and supported to build capacity to supply the pharmaceutical manufacturing sector	the ECOWAS region especially for antibiotics, anti-malarials and anti-retrovirals			
Identify manufacturers of EXCIPIENTS and support them to build capacity to supply the pharmaceutical manufacturing sector	BY 2016	WAHO WAPMA	Manufacturers of EXCIPIENTS identified and supported to build capacity to supply the pharmaceutical manufacturing sector	EXCIPIENTS such as pharmaceutical grade starch, kaolin, Shea butter, etc. produced in commercial quantities within the region	AfDB, UNIDO IFC	Shortage of manufacturers of Excipients	Ability to develop pharmaceutical grade products
Conduct sensitization workshops on credit worthiness and capacity of industry to access funds	BY 2015	UNIDO WAHO WAPMA	Pharmaceutical industry sensitized on credit worthiness and able to access funds for improved local production of pharmaceutical products	Improved capacity utilization by pharmaceutical industry leading to availability of pharmaceutical products	EBID AfDB IFC UNIDO	Lack of financial resources	Availability of funds
Advocate for establishment of special fund to support the industry	BY 2015	ECOWAS WAHO EBID AFDB	Low cost, long term funding available to develop the industry	Improved capacity utilization by pharmaceutical industry leading to availability of pharmaceutical	EBID AfDB IFC UNIDO	Lack of interest of development banks to provide such support	Willingness to provide funding support to industry Availability of funds

				products			
Participation in the development of capacity in pharmaceutical technology and GMP by the pharmaceutical industry	By 2015	WAPMA WAHO	Pharmaceutical industry participates in the development of capacity in pharmaceutical technology and GMP	Establishment of certificate and diploma programs in pharmaceutical technology and GMP	AfDB, WAPCP CEPAT UNIDO GIZ AIT	Poor response by industry	Availability of expertise and facilities
Actively promote medicines produced within the region through education and exhibition	By 2016	WAPMA WAHO	Regularly scheduled ECOWAS pharmaceutical expo.	Increase in the level of patronage and sales of locally produced pharmaceutical products	AfDB, ECOWAS UNIDO MINISTRIE S OF TRADE AND INDUSTRY	Sustainability of quality of medicines to meet expectations	Increased acceptance of locally produced medicines

OBJECTIVE 6.3	To support pharmaceutical manufacturing in order to achieve international certifications for TEN pharmaceutical manufacturers by the year 2020						
ACTIVITIES	TIME LINE	RESPONSI BILITY	EXPECTED OUTCOME	INDICATORS	PARTNERS	RISK	ASSUMPTIONS
Circulate and expression of interest document for interested pharmaceutical companies to indicate their willingness to participate to achieve international certification	2014	WAHO WAPMA	Expression of interest document for interested industries to indicate their willingness to participate to achieve international certification	Number of companies expressing interest (At least 20 companies express interest and at least 10 companies achieve certification by 2020)	AfDB, WHO UNIDO WAHO WAPMA	Poor response by companies in expressing interest	Increased response by companies in expressing interest

circulated			circulated				
Conduct audit of companies that have expressed interest to achieve international certification and identify GAPS	2015	WAHO	Audit of companies that have expressed interest conducted and GAPS identified	Number of interested companies audited and aware of their gaps	AfDB, WHO UNIDO	Gaps too large or too many companies with large gaps.	Cooperation by companies towards success of audit
Provision of technical assistance and capacity building for companies that have expressed interest	2014	WAHO WAPMA	Technical assistance and capacity building for companies that have expressed interest provided	Number of companies that have achieved international certification	AfDB WHO UNAID	Lack of funds	Availability of funds
Develop a cGMP roadmap for manufacturers in the region	2016	WAHO WAPMA	A cGMP roadmap for pharmaceutical manufacturers in the ECOWAS region developed and guidance provided for implementation	Availability and implementation of developed roadmap by Pharmaceutical manufacturers in the ECOWAS region for improved quality of locally manufactured pharmaceutical products	AfDB, WHO, WAPMA, UNIDO, ERPP/ PMPA CONSORTIUM AMRH Consortium	Conflict and confusion with other roadmaps e.g. national, PMPA Resistance to implementation and enforcement	Support for the roadmap by manufacturers
Establish an incentive scheme for progress in compliance with GMP	2015	MINISTRIES OF HEALTH/ WAHO	An incentive scheme for progress in compliance with GMP established	Increase in the number of GMP compliant companies	AfDB WHO GIZ ERPP Consortium AMRH Consortium	Lack of funds	Availability of funds Political will
Contribute to the	2014	WAHO/	CBBR	Availability of	AfDB	Poor response	Patronage and

funding for the actualization of Centre for Bio-equivalence and Bio-pharmaceutical Research (CBBR)		WAPMA	operational	capacity to conduct affordable bioequivalence and bioavailability studies in the ECOWAS region	WHO GIZ ERPP Consortium AMRH Consortium	Lack of funds	sustainability
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OBJECTIVE 6.4	To strengthen National Medicines Regulatory Authorities (NMRAs) regulatory capacity, and quality infrastructure in the ECOWAS region to achieve international standards by the year 2018.						
ACTIVITIES	TIME LINE	RESPONSI BILITY	EXPECTED OUTCOMES	INDICATORS	PARTNERS	RISKS	ASSUMPTIONS
Conduct assessment of medicines regulatory capacities (e.g. functions, structures, standards etc.) by external assessors.	2015	WAHO, NEPAD, WHO, NMRAs.	Need assessment conducted.	Assessment report submitted.	AfDB, WHO, AU/NEPAD World Bank and Development Partners	Lack of appropriate survey tools Poor conduct of survey Lack of funds	The assessment will reveal the actual situation in member states. Selection of appropriate assessment tools NMRAs will cooperate.
Formulate Regional Medicines Regulatory framework (N.B: Medicines Policy should include Medicines Regulation)	July 2015	WAHO, MOH in Member States, NMRAs, AMRH.	Regional Framework formulated	Framework document circulated to stakeholders.	AfDB, WHO, AU/NEPAD World Bank and Development Partners	Lack of cooperation and support from member states	Member States will cooperate, adopt and operationalize the Framework and reviewed law.
Review National	From	WAHO,	Medicines laws	Reviewed laws	AfDB, WHO,	Lack of	Member States

Medicines laws.	2014 to 2018	NMRAs.	in all member states reviewed	adopted by member states.	Development Partners, AMRH, relevant MDAs	cooperation and support from member states	will cooperate, adopt and operationalize the policy and reviewed law.
Develop/improve the infrastructure and QMS of i) NMRAs ii) QC Labs and iii) CBBR.	From 2014 - 2018 2014-2016 2014-2015	WAHO, MOH in member states	QC Labs upgraded. NMRAs strengthened QMS in place CBBR established.	Demonstrate Five (5) QC labs are in conformance with internationally accepted standards Regulatory functions conforming to international best practices including QMS. CBBR operational.	AfDB, WHO, GIZ USP/CePAT and other Partners. World Bank and Development Partners	Lack of funds Poor patronage and viability of the facilities Poor regulatory enforcement of required standards	Availability of funds for improvement of infrastructure and maintenance to achieve intended purpose. Patronage of Services will be guaranteed. Commercial viability of centres. Availability of adequate financial and technical resources. Manufacturers have resources to utilize the services. Regulators to enforce BE requirements
Develop the i) Human Resource	From 2014-2020	WAHO, NMRAs ,	NMRAs personnel	Fifty (50) NMRAs staff	AfDB, WHO,	Dependence on other bodies for	The training will result in the

Capacity of NMRAs. ii) Framework for sustainable development and retention of human resources		WHO,	trained in good regulatory Practices.	trained and certified per year.	AU/NEPAD USP/CEPAT World Bank and Development Partners	training and certification High turnover of qualified personnel	improvement of regulatory functions. Retention of trained staff
Develop criteria for certification of Medicines Regulatory Professionals.	From 2015-2020	WAHO, NMRAs.	Criteria for certification developed Criteria for recognizing capacity building institutions developed.	Accreditation entity operational.	AfDB, WHO, AU/NEPAD World Bank and Development Partners	Poor accreditation processes	Support for the development of the criteria for certification by NEPAD, ECOWAS, etc. Availability of qualified and certified staff.
Harmonize requirements for registration of medicines and licensing of manufacturing facilities across the region.	2015	WAHO, NMRAs	Requirements for medicines registration and licensing of manufacturer harmonized.	Harmonized requirements operational.	AfDB, WHO, AU/NEPAD World Bank and Development Partners	Resistance from member states and other stakeholders Lack of political will	Widespread support for the harmonisation processes Political will to drive processes
Implement the WAHO Certification and Pre-qualification Schemes.	2016	WAHO, ECOWAS Medicines Regulation Governing Board.	WAHO certification and pre-qualification scheme implemented.	Five manufacturing sites certified. At least five (5) products in each of these Therapeutic Categories: Antimalarial, Antibiotics, ARVs and	AfDB, WHO, AU/NEPAD World Bank and Development Partners	Lack of resources (human and financial) for the implementation Poor cooperation	Availability of resources Manufacturers will have the will to pursue the certification.

				Pediatric Anti-diarrhea, Anti-TB Pre-qualified			
Develop a harmonized regional Pharmacovigilance strategy	June – Dec 2014	WAHO, NMRAs	A harmonized regional Pharmacovigilance strategy developed	Availability of Harmonised Pharmacovigilance strategy document	AfDB, WHO, AMRH AU/NEPAD, WAPMA and World Bank and Development Partners	Likelihood of poor response by stakeholders	Political will to drive process
Development of the regional MRH Program	Ongoing	WAHO, NMRAs	A regional MRH Program developed	Availability of developed Regional MRH document	AfDB, WHO, AMRH NEPAD UNIDO. MSH World Bank and Development Partners	Resistance from countries Delay from WAHO	Political will to drive process
Design and develop a website for MRH link to existing WAHO website, and train NMRAs on its application	From March 2014 – March 2016	WAHO	A web portal for enhanced information sharing mechanism for medicines, vaccines and other pharmaceutical data designed and developed	Availability of launched web portal for enhanced information mechanism for medicines, vaccines and pharmaceuticals and the conduct of training of NMRAs on application	AfDB, MSH, WHO, AU/NEPAD, WAPMA World Bank and Development Partners	Lack of resources (human and financial) to drive processes	Support by Partners envisaged
Provide technical and logistics support to Five identified	Ongoing	WAHO	Technical and logistics support to Five	Achievement of Centre of Excellence	AfDB, MSH, WHO. AU/NEPAD,	Lack of resources (technical and financial)	Availability of resources by WAHO and

Laboratories to achieve International Certification and be designated as Regional Centers of Excellence in the ECOWAS region			identified Laboratories to achieve International Certification and be designated as Regional Centers of Excellence in the ECOWAS region provided	status by at least Five Regional Quality Control Laboratories	WAPMA and Partners World Bank and Development Partners	Lack of Interest by the Laboratories considering the increased workloads expected	partners (technical and financial)
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OBJECTIVE 6.5							
75% reduction in the incidence of Substandard, Spurious Falsified and Falsely Labeled Counterfeit -(SSFFC) medical products in the ECOWAS region							
ACTIVITIES	TIME LINE	RESPONSIBILITY	EXPECTED OUTCOME	INDICATORS	PARTNERS	RISKS	ASSUMPTIONS
Create, support and build capacity of EMACCOM National Steering Committees in the 15 countries	2014	WAHO, EMACCOM NMRAs	EMACCOM National Steering Committees in the 15 countries created and capacity built for members of the committees	Number of functional EMACCOM National Steering Committees	AfDB, WHO, INTERPOL, UNODC, Civil Society and other partners	Poor response by member states Lack of resources to drive processes	Commitment by member states Availability of resources
Develop, validate, adapt and adopt common tools for the evaluation of the counterfeit medicines phenomenon in	As from March 2014	WAHO, EMACCOM, NMRAs	Tools developed and tested	Availability of developed tools for the evaluation of counterfeit medicines in ECOWAS	AfDB, WHO, INTERPOL, UNODC, Civil Society and other partners	Inappropriate survey tools	Availability of developed, validated and adopted common survey tools

ECOWAS member states				member states			
Conduct a situation analysis of SSFFC medical products and illicit trade in Medicines in the region	June –Sept 2015	WAHO, EMACCO M, NMRAs	Situational analysis of SSFFC medical products and illicit trade in Medicines in the region conducted	Number of countries evaluated for counterfeit medicines in ECOWAS member states	AfDB, WHO, INTERPOL, UNODC, Civil Society and other partners	Lack of political will Lack of funds to conduct survey in all member states	Political will by Member States to combat SSFFC Availability of funds
Intensify Post Marketing Surveillance activities	Ongoing	NMRAs & other Agencies.	Regular conduct of post marketing activities.	Reports of Post marketing surveillance activities.	AfDB, WHO, INTERPOL, UNODC, Civil Society and other partners	Lack of funds Lack of commitment by NMRAs and other stakeholders	Availability of funds Commitment by NMRAs, manufacturers and distributors of pharmaceutical products
Provide resources to Stakeholders for effective monitoring/post marketing surveillance activities.	2015	WAHO, NMRAs, WAPMA, Development Partners.	Adequate resources provided to stakeholders for post marketing surveillance activities.	Number of post marketing surveillance activities conducted	AfDB, WHO, INTERPOL, UNODC, Civil Society and other partners	Lack of resources (financial and human) for effective conduct of activities	Availability of resources Commitment by NMRAs and other stakeholders to effectively combat SSFFC on a sustained basis.

OBJECTIVE 6.6	To establish a regional body for medicines regulation harmonization in line with the African Union’s medicines harmonization program by the year 2020						
ACTIVITIES	TIME LINE	RESPONSIBILITY	EXPECTED OUTCOME	INDICATORS	PARTNERS	RISKS	ASSUMPTIONS

Implement the ECOWAS Medicines Harmonization project proposals submitted to the AU and the Consortium	As from April 2014	WAHO, Member States	ECOWAS MRH operational	Number of common documents adopted and used in member countries	AfDB AU/NEPAD, Consortium, WHO, UNIDO, MSH and other partners	Lack of funds Resistance from member states	Release of funds by Consortium Political will for the harmonisation process
Review and adapt the African Union's Medicines Regulation Harmonization program as appropriate	As from June 2014	WAHO, Member States, Partners	African Union's Medicines Regulation Harmonisation reviewed and adopted by ECOWAS	The number of firms doing cross country registration. Reduction in the cost of multi country registration for firms	AfDB AU/NEPAD, Consortium, WHO, UNIDO, MSH and other partners	Distrust amongst NMRA (medicines registration an important source of revenue for NMRAs)	Political will for the harmonisation process
Conduct sensitization workshops for decision makers and key stakeholders on the adapted Harmonization programme	As from January 2014	WAHO, Member States, Partners	Sensitization workshops for stakeholders conducted on regional harmonisation plan	Number of countries adopting & implementing the harmonised plan	AfDB AU/NEPAD, Consortium, WHO, UNIDO, MSH and other partners	Resistance and lack of support for the harmonisation process Lack of resources	Widespread support for the harmonisation process premised on political will Availability of resources to conduct planned activities
Constitute a Governing Body on Medicines Regulation Harmonization in ECOWAS region	As from June 2014	WAHO, NMRAs	Governing Board or Medicines Regulation Harmonisation constituted and launched	Functioning regional harmonization governing body in place	AfDB, AU NEPAD, Consortium, WHO, UNIDO, MSH and other partners	Lack of support from stakeholders within the countries	Political will

OBJECTIVE 6.7	To facilitate the incorporation of ECOWAS policies on TRIPs flexibilities into national laws of a minimum of ten member states within the region by the year 2020.						
ACTIVITIES	TIME LINE	RESPONSIBILITY	EXPECTED OUTCOME	INDICATORS	PARTNERS	RISKS	ASSUMPTIONS
Implement the WAHO TRIPs flexibilities advocacy strategies (see WAHO TRIPs Strategic Advocacy Document 2013)	As from April 2014	WAHO Advocacy Team, IP Experts	Incorporation of TRIPs flexibilities in National Laws of ECOWAS member countries	Number of countries within ECOWAS that have incorporated TRIPs flexibilities in national laws	AfDB ,WHO, WTO, WAPMA, Civil Society Groups, Media, etc.	Delay due to legislative procedures Lack of resources (human and financial) to drive processes	Prompt actions by countries towards legislation and implementation of TRIPs flexibilities Availability of resources from WHO and partners
Monitor and evaluate the implementation of the WAHO TRIPs flexibilities advocacy strategies every year	Once every year	WAHO Advocacy Team, IP Experts	Yearly monitoring and evaluation of TRIPs flexibilities implementation by ECOWAS member countries conducted	Availability of reports of monitoring and evaluation that have been conducted	AfDB, WHO, WTO, WAPMA, Civil Society Groups, Media, etc.	Non availability of resources	Availability of resources
Create awareness in OAPI/ARIPO member states on the TRIPs flexibilities in the region	As from April 2014	WAHO Advocacy Team and IP Experts	Awareness created in OAPI member states on TRIPs flexibilities in the ECOWAS region	TRIPs flexibilities incorporated in at least ten countries in the ECOWAS region by 2016	WHO, WTO, WAPMA, Civil Society Groups, Media, etc.	Resistance and lack of support from OAPI member states Non availability of resources	Commitment to derive benefits of implementation of provisions of TRIPs flexibilities Availability of resources

OBJECTIVE 6.8	To formulate and implement policies that will promote innovation, research and development into pharmaceuticals & traditional medicinal products as well as establish a Competitive Grant in ECOWAS by the year 2020						
ACTIVITIES	TIME LINE	RESPONSIBILITY	EXPECTED OUTCOME	INDICATORS	PARTNERS	RISK	ASSUMPTIONS
Organize an annual scientific and technology exchange meetings between the industry and research institutions in ECOWAS region	Every year starting from 2015	WAHO, ECOWAS WAPMA/ WAPCP- Drug Advisory Council	Collaborative MOUs between Industry and Research Institutions.	Number of MOUs signed between Industry and Research Institutions	ECOWAS, AfDB, ANDI/ FAPMA, African Diaspora, Research Institutions	Lack of interest and commitment	Participation and interest
Establish ECOWAS competitive research grants for collaborative development of pharmaceuticals and medicinal products including traditional medicines.	2016	WAHO/ ECOWAS	ECOWAS Competitive Research Grant established for collaborative development of pharmaceuticals and medicinal products including traditional medicines.	Increased R&D activities in traditional medicines in ECOWAS member states Number of grantees benefitting from the grant.	AfDB, PATH, USAID, AUC- NEPAD, EBID, WHO, Research Institutions	Lack of funds and sponsorships	Availability of funds Political will
Establish incentive scheme for involvement of industry in R&D e.g. tax credit	2015	ECOWAS Commission and Member States	Incentive scheme for involvement of industry in R&D established through revision of tax laws to promote R&D	Increased R&D activity in the industry and development of new molecules	AfDB, PATH, USAID, AUC- NEPAD, Pharmaceutical Industries and Laboratories, Research Institutions	Lack of funds	Availability of funds Political will

<p>Build drug development capacity (pharmaceutics, toxicology, clinical trials etc.) within the industry</p>	<p>2020</p>	<p>WAHO/ WAPMA, IFPMA</p>	<p>Expertise in R&D developed in the industry</p>	<p>MOUs signed with institutions Number of linkages established</p>	<p>AfDB, NIPRD, CBBR, NMIMR, Pharmaceutic al Industries and Laboratories, and other Research Institutions</p>	<p>Lack of funds Lack of interest and commitment</p>	<p>Availability of funds Interest within the industry</p>
<p>Manufacture of standardized traditional medicines products under GMP</p>	<p>2020</p>	<p>WAPMA</p>	<p>Availability of high quality, efficacious and safe traditional medicinal products</p>	<p>Number of high quality efficacious and safe traditional medicinal products available for use by the public. Number of traditional medicinal products listed among products of companies</p>	<p>NIPRD, CSRPM and other Research Institutions Selected Associations of Traditional medicines Practitioners</p>	<p>The absence of sui generis methods for the protection of traditional medicines knowledge</p>	<p>Economic viability</p>

9.0 CONCLUSION

The ECOWAS Pharmaceutical Plan is expected to serve as a technical document or reference material for the wholesome development of the pharmaceutical sector within the West African Region. It is to be operated within the overall structure of the African Union Pharmaceutical Manufacturing Plan although its coverage extends beyond manufacturing to cover all the determinants of growth in the entire pharmaceutical sector. The aspects to be covered are all well spelt out in the regional plan and should provide a platform for the systematic implementation of the activities that should lead to the expected outcomes in the plan.

The potentials of the ECOWAS region are enormous. The success of the implementation of the ECOWAS Pharmaceutical Plan will define the roadmap for the total attainment of health within the region because of the critical nature of medicines and pharmaceutical products in the fight against diseases. It therefore behooves on WAHO and Stakeholders to provide the needed resources and support that will see to the achievement of the Plan in the interest of the region and the African Continent.

10.0 RECOMMENDATIONS

1. Need for a Pharmacovigilance Policy and Drug Distribution Guidelines
2. Need to strengthen resource capacities other than pharmacy
3. Plan should cover issues on pharmaceutical marketing and career development/pathways
4. Need to expedite action on Harmonization in line with global trend, particularly in regulatory affairs.
5. Need to increase patronage of locally produced pharmaceutical products by member states to encourage and promote the growth of the pharmaceutical industry
6. Pharmaceutical/health issues are multi-sectorial and this calls for advocacy and communication strategies in order to strengthen the Regional Pharmaceutical Plan
7. Structure of drug advisory Council of WAPCP should be re-engineered (WAHO should establish structures or forum that would stimulate the WAPCP, WAPMA, meeting of Academia, and academic research, policy makers and regulators)
8. Plan should make room for a firm commitment of intra-adherence or collaboration between institutions
9. There should be a Forum specifically for ECOWAS multi-professional group on clinical trials
10. Need to control the chaotic Pharmaceutical distribution in West Africa.
11. Manufacturing of medicines in West Africa should be technologically strengthened to meet regional needs and for exports
12. The process of Transfer of Technology should be well exploited with reference to the provisions of relevant sections of TRIPs flexibilities

11.0 APPENDIXES

1. ECOWAS MRH Project Proposal and budget
2. ECOWAS Regional Action Plan on Counterfeit and illicit trade in Medicines
3. WAHO TRIPs Policy and guidelines
4. Plan for Harmonization of Pharmacy Training Curriculum