SITUATION ANALYSIS STUDY ON

MEDICINES REGISTRATION HARMONISATION IN AFRICA

FINAL REPORT FOR THE ECONOMIC COMMUNITY OF WEST AFRICAN STATES (ECOWAS)

JUNE 2011

NEPAD
TRANSFORMING AFRICA

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ACRONYMS

ACAME	Association africaine des Centrale d'Achats de Médicaments Essentiels
AI	Assessment Instrument
AIDS	Acquired immune deficiency syndrome
AMRH	African Medicines Regulatory Harmonisation
ARVs	Antiretroviral drugs
AU	African Union
BMGF	Bill and Melinda Gates Foundation
CPP	Certificate of Pharmaceutical Products
CSM	Committee on Safety of Medicine
CTD	Common Technical Document
DFID	UK's Department for International Development
DPL	Directorate of Pharmacies and Laboratories
DPML	Department of Pharmacy, Medicines and Laboratories
DRF	Drug Revolving Fund
EAC	East African Community
ECOWAS	Economic Community of West African States
FGD	Focus Group Discussion
GDP	Gross Domestic Product
GMF	(for generics)
GMP	Good Manufacturing Practice
GNP	Gross National Product
GTZ	Deutsche Gesellschaft fur Technische Zusammenarbeit
HIV	Human Immune Deficiency Virus
HRD	Human Resource Development
HRM	Human Resource Management
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

ICM	Integrated Council of Ministers
INCB	International Narcotics Control Board
MOH	Ministry of Health
NCEs	New Chemical Entities
NDA	National Drug Authority
NEPAD	New Partnership for Africa's Development
NMRA	National Medicine Regulatory Authority
NMP	National Medicine Policy
NPCA	NEPAD Planning and Coordinating Agency
OCCGE	Organisation de Coordination et de Coopération pour la Lutte Contre les Grandes Endémies
PAP	Pan African Parliament
PIC	Prior Informed Consent
PMAG	Pharmaceutical Manufacturers Association of Ghana
PMGMAN	Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria
PQ	Pre-qualification or Pre-qualified
Pre-MA	Pre-Market Authorization
PRSAO	Programme Régional Santé en Afrique de l'Ouest (PRSAO)
REC	Regional Economic Community
SADC	Southern African Development Community
SRA	Stringent Regulatory Authority
TB	Tuberculosis
UEMOA	West African Economic and Monetary Union (Union Economique et Monétaire Ouest-Africaine)
UK	United Kingdom
US$	United States Dollar
WAHC	West African Health Community
WAHO	West African Health Organization
WAPMA	West African Pharmaceutical Manufacturers Association
WHO	World Health Organization
WHO-PQ	World Health Organization Prequalification

FOREWORD

This Situation Analysis Report on Medicines Registration Harmonisation for the Economic Community of West African States (ECOWAS) has been prepared following rigorous scientific methods and participatory methods. Assessment instruments (AI) consisting of three separate structured questionnaires were administered at REC, Regional/National Association of Pharmaceutical manufacturers and NMRA levels to gather information from a representative cross section of stakeholders, and analyzed to give a reflection of the situation of medicine registration harmonisation. In addition focus group discussions (FGD) and key informant interviews were conducted in order to collect both qualitative and quantitative data.

The purpose of the Situation Analysis serves to establish the status of medicines regulation capacity, harmonisation efforts and challenges in ECOWAS and Member States with a view to enhancing a better understanding of the situation in the region, learn from past experiences and develop appropriate interventions to facilitate AMRH. The report has been prepared by the consultant with invaluable support received from the West African Health Organization (WAHO), Heads of National Medicines Regulatory Authorities and Pharmaceutical Manufacturers and their Associations. This great support catalysed the collection of data and validation of this report. The report serves among other things as a baseline on the status of medicines regulatory harmonisation in the region, and focuses efforts towards responding to identified gaps, while capitalizing on existing strengths.

This Situation Analysis Report and the important data it provides is timely for the ECOWAS sub-region, in order to expedite efforts to increase the availability of quality and affordable medicines and to counter the huge burden of Malaria, HIV/AIDS, Tuberculosis, neglected tropical diseases and other newly emerging diseases that are generally faced by the countries of this region.

Further the lack of reciprocal recognition of regulatory processes between Anglophone and Francophone countries presents a constraint to human resource mobility that, once removed, will facilitate accomplishments of the objectives of the AMRH Initiative, for quality and affordable medicines to circulate throughout the sub-region as needed. It is therefore our expectation that the report will serve as a key source to inform strategies that will be developed in furtherance of the African Medicines Regulatory Harmonisation Initiative in this region.

ACKNOWLEDGEMENTS

The team would like to acknowledge with gratitude the invaluable support received from the West African Health Organization (WAHO), Heads of National Medicines Regulatory Authorities and Pharmaceutical Manufacturers and their Associations. This great support catalysed the collection of data and verification of this report. Further, we thank Professor Aggrey Ambali, Mrs Mercy Fomundam and several other staff members of the NEPAD Office of Science and Technology in Pretoria, South Africa for providing extensive logistical and technical advice on this work. Finally, we thank Mrs Jane Makhambera for data entry and secretarial services.

EXECUTIVE SUMMARY

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 drugs to the procurement and quality assurance of medicine circulating on the market. Regional and national registration of medicines is one way to ensure the quality, safety and efficacy of medicines being provided to the population. However, registration of medicines is cumbersome requiring a lot of information from applicants. As a result, it is sometimes difficult to get companies to comply fully with the registration process as the cost may outweigh the benefits. Over the years, international organisations have been supporting African countries to establish and strengthen medicine regulatory authorities by providing technical and financial resources needed to progress the African Medicines Regulatory Harmonisation (AMRH) initiative.

Cognisant of the importance of the AMRH initiative, NEPAD commissioned a consultancy to conduct a situation analysis of medicines regulation harmonisation in the Economic Community of West African States (ECOWAS). The study was aimed at establishing the status of medicines regulation capacity, harmonisation efforts and challenge in ECOWAS and Member States with a view to enhancing a better understanding of the situation in Africa, learn from past experiences and develop appropriate interventions to facilitate the AMRH initiative. The collection of data involved (a) administration of three (3) separate structured questionnaires to the ECOWAS, pharmaceutical manufacturers and NMRAs (b) a review of documents from ECOWAS and NMRAs including WHO reports on Medicine Regulatory Harmonisation in Africa and (c) discussions with key people from ECOWAS and NMRAs. The data was then analysed to realise the objectives stated above.

The data being presented currently covers thirteen of the 15 NMRAs and two pharmaceutical industries in the Economic Community of the West African States (ECOWAS). The NMRAs that did not respond are from Benin and Sierra Leone. It must be pointed out that not all countries responded to all questions. The section entitled “Registration of Medicine” was poorly responded to and in particular questions relating to application of prioritization, receipt of application and factory inspection. Cote d ‘Ivoire did not respond to most questions. These shortfalls notwithstanding the results show that in the last 10 years ECOWAS as well as other sub-regional organizations have made an enormous strides with a view to harmonising medicine registration within the sub-region.

Currently the region has a treaty, a health protocol through which WAHO was formed, whose mission is “the attainment of the highest possible standard and protection of health of the peoples in the sub-region through the harmonisation 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 sub-region.” At this stage however most countries are registering medicines independently and with independent technical and administrative procedures. Six countries (Burkina Faso, Gambia, Niger, Republic of Guinea, Senegal and Togo) have policies or legislations that provide a mandate for recognition of regulatory decisions made by other regulatory agencies. The corporate profile of NMRAs in the region does vary. Some are established by law as body corporate while others operate as departments of Ministries responsible for health. In either case the law provides for the establishment of a body responsible for medicines regulation in Burkina Faso, Cape Verde, Gambia, Ghana, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal and Togo. The study has also established that Burkina Faso, Cape Verde, Gambia, Ghana, Liberia, Niger, Nigeria and Republic of Guinea have National Medicines Policies, however their implementation plans are either not in place or still being developed.

The survey revealed that in 11 countries which responded (Burkina Faso, Cape Verde, Gambia, Ghana, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal and Togo) there is explicit provision in the legislation which provides legal mandate for the NMRAs to register medicine. All the 11 countries were actively

registering medicines. In 10 of the countries with the exception of Gambia, the registration requirements covered products for both public and private sector procurement and distribution. In Gambia the registration requirement covers only the private sector. Provisions also exist in some countries for assessment of applications, factory inspections and testing samples before registration.

ECOWAS however faces several challenges in moving forward the medicines regulation harmonisation agenda. The most important ones are:

a) The need to harmonise regional initiatives such as those spearheaded by WAHO and UEMOA.

b) The human capital resources (both skills and numbers) at the Secretariats and in respective Member States are limited.

c) Physical facilities vary in Member States and require expansion to cater for the full functions of medicines regulation.

d) There is a shortage of quality control laboratories in most NMRAs. In addition few are pre-qualified by the World Health Organization (WHO).

e) Information Communication Systems also vary among the Member States and are inadequate.

f) Inadequate financial support especially for small medicines regulatory authorities.

g) Regional decisions remain undomesticated by Member States and therefore decisions made by individual members are rarely recognized by others.

In view of the above the following recommendations are being made:

Legal framework

ECOWAS member states need to fast track change of national laws for regulating medicines so as to have a harmonised regional platform for accessing safe, quality and efficacious medicines. According to Article 9 of the Treaty, a decision may be passed by the Heads of State that compels Member States to change their domestic legislations within specific time in favor of harmonisation of medicine regulation. After the decision has passed, each member state will be bound to publish this in the gazette to facilitate it becoming a domestic law. This may shorten the parliamentary process of making laws. The other option would be for the region to have another protocol to complement the protocol that established WAHO. Both the recommended decision and a protocol, (which ever perceived to suit the region) on harmonisation of regulation of medicines is recommended to be developed taking into account among things, the following:

a) Application of approximate medicine regulation laws which leads to the uniform application of medicine registration and documentation in the region;

b) Use of common procedures for decision on approval of medicines registration which sets a precedent to the subsequent applications for medicine registration in any other member state NMRAs;

c) Elimination of internal registration barriers that impede access to affordable medicines by all member states;

d) Harmonise registration charges of equivalent cost and remove discriminatory treatment to medicines registered among other member states;

e) Encourage export promotion and competitiveness through various incentive schemes on medicines within the region;

f) Medicine laws be made with provisions that recognize decisions of each Member State and taking

precedence over the subsequent laws; provided that the safety, quality and efficacy of medicine is not compromised;

g) The NMRAs of Member Countries that do not have in place mission statements drawn out from the existing legislation and policies that regulate medicines should be encouraged to have their missions in place so as to set the overall goal of government commitment to safe and quality medicines; and

h) To allow better and conducive environment for harmonisation of regulatory functions, it is recommended that WAHO in its capacity as an already existing platform for the region on matters of health, maintains oversight of the implementation status of these recommendations

Registration of medicines

Certain problems were identified in the responses given by NMRAs in the questionnaire. In the first instance only 10 NMRAs responded to this section on medicine registration systems. Amongst the NMRAs, responses to questions on application for prioritization, receipt of applications and factory inspection were given by only a few countries. In some sections responses were about 40%, thus making it difficult to make conclusions. This may be due to lack of capacity. It was observed that only 5 countries responded to the section on applications for all the medicines for HIV/AIDS, TB, Malaria, NCEs and generic products. Only 2 countries answered the question on the percentage of application reviewed within target. Although the number backlogs recorded was small, it has to be borne in mind that limited statistics were provided by the 4 countries that responded. It is therefore recommended that:

a) Capacities of the NMRAs need to be improved to enable them to fulfill their statutory legal and regulatory functions;

b) Registration of medicines needs to be vigorously embarked on by the NMRAs. Factors responsible for the small number of registered medicines need to be determined so that remedial action can be taken;

c) In countries with resource constraints, sharing of information and facilities to register medicines in the sub-region must be encouraged;

d) The NMRAs that did not respond or provide statistics must be encouraged to do so. It might be necessary for a follow-up exercise to be carried out in future where all the NMRAs participate, so that a correct picture can emerge and,

e) A regional programme for harmonising medicine registration is developed.

Sharing of information and stakeholder consultation

ECOWAS and its Member Countries' NMRAs need the full participation of all stakeholders to support a growing industry and gain greater profits from this sector. Therefore:

a) ECOWAS and NMRAs should engage the industry and associations on the developments of medicine harmonisation registration, sharing clearly the benefits of medicine registration harmonisation;

b) Each NMRA should promote the establishment of national associations, where this is absent;

c) ECOWAS and NMRAs should dialogue with Governments and other stakeholders to provide a conducive environment for business ventures;

d) Industries should be encouraged to form associations wherever this is possible;

e) ECOWAS and NMRAs need to strengthen effective information access and sharing amongst themselves and with various stakeholders; and

f) ECOWAS and NMRAs should regularly update websites giving recent information and resource materials.

Capacity building

a) To ensure greater value for harmonisation and benefits, ECOWAS and associated NMRAs should build capacity for better sharing of resources;

b) To strengthen NMRA programmes, adequate funding is required to support operations and regional activities. Consequently, Government should provide adequate subvention to support programmes implementation and NMRAs should access and use most of the industry fees;

c) In order to address human resource constraints countries with medical personnel should support others, the following is recommended: NMRAs without HRM plan should develop and implement their own; utilization of the human capital across ECOWAS should be harnessed; investment in the training of the human capital for efficient implementation of various functions of regulation should be mandatory; and

d) ECOWAS should add value to the statistics of medical and ancillary personnel by improving record keeping.

There is enthusiasm and commitment of ECOWAS, NMRAs and the pharmaceutical industry towards implementation of a harmonised medicine regulatory system. The key stakeholders and partners are aware of and recognize the benefits of medicine harmonisation.

1. BACKGROUND

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 in 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 companies to comply fully with the registration process as the cost may outweigh the benefits. In recognition of medicine registration challenges, the New Partnership for Africa's Development (NEPAD), World Health Organization (WHO), Pan-African Parliament (PAP), the Bill and Melinda Gates Foundation (BMGF), the UK's Department for International Development (DFID) and the Clinton Foundation have formed a Consortium and together they have developed a strategic approach to mobilizing technical and financial resources to progress the African Medicines Regulatory Harmonisation (AMRH) initiative. The overall objective of the AMRH initiative is to improve the health of the people in the region by improving the availability of safe, efficacious and good quality essential medicines for the treatment of neglected and priority diseases. This is expected to be achieved through harmonisation of medicines regulations and standards, starting with medicines registration, within and across African Regional Economic Communities (RECs) and organizations.

As a means of building upon and strengthening plans that already exist in sub-regional groupings, the Consortium has invited RECs to submit project proposals for medicines registration harmonisation. NEPAD and the members of the Consortium are working with RECs to ensure complementarities of their efforts, enable continent- wide communication, coordination and technical consistency and mobilize donor support.

Having a better understanding of ongoing efforts and related barriers to the harmonisation process is an essential ingredient for succeeding in the harmonisation process. In order for NEPAD, PAP and WHO to effectively execute their strategic roles in supporting RECs to harmonise their medicine regulations, it is important that the existing information regarding the capacity of medicines regulation in RECs and their specific National Medicines Regulatory Authorities (NMRAs) is updated to reflect the realities on the ground. For instance, according to the report presented by WHO at the 1st African Medicines Regulatory Authorities Conference held from 31st October to 3rd November, 2005 in Addis Ababa, Ethiopia, only about 7% of the 46 sub-Saharan African countries had a moderately developed medicine regulatory capacity. Of the remaining, about 63% had minimal capacities whereas 30% did not have NMRAs in place.

Over the years, the WHO and other international organizations and donor countries have been supporting African countries to establish and strengthen their NMRAs. Various assessments of medicines regulatory systems have been undertaken over the years using the 'WHO Data Collection Tool for the Review of Drug Regulatory Systems.' However, information collected by these assessments needs to be updated taking into account various developments that have taken place over the years and to collect legislative and institutional information that will support the advocacy role of AMRH needs to be collected. This information is also essential for establishing benchmarks that would be used for assessing the efficiency and effectiveness of the harmonisation process.

The need for a situation analysis was further reiterated during the 2nd African Conference for Medicines Regulatory Authorities held in Maputo, Mozambique from 24th – 26th November, 2009. The conference recommended among other things that NEPAD should develop a specific tool to obtain information on legislative and institutional frameworks that will assist in its advocacy and coordination of the medicines regulation harmonisation on the continent.

Based on this background, NEPAD commissioned a consultancy to conduct a situation analysis of medicines regulation harmonisation on the African continent. The assessment was aimed at providing useful information for developing a strategy to support RECs in their ongoing medicines regulation harmonisation initiatives.

1.1 OBJECTIVES

The study was aimed at establishing the status of medicines regulation capacity, harmonisation efforts and challenges in RECs and Member States with a view to enhancing a better understanding of the situation in Africa, learn from past experiences and develop appropriate interventions to facilitate AMRH.

The specific objectives were:

a) Critical analysis of legislative and legal framework governing harmonisation of medicines policies and regulations at national, sub-regional and regional levels with a focus on medicines registration harmonisation.

b) Evaluation of the status of human capital and infrastructure needs and challenges.

c) Evaluation of structures, systems, and institutional framework as they relate to harmonisation of medicines regulation at national, sub-regional and regional levels.

d) Assessment of funding and financing mechanisms for national medicines agencies and their operations.

e) Identification of challenges, barriers and constraints regarding harmonisation of medicines policies and regulations and exploring opportunities for effective harmonisation.

f) Delineation of views, perceptions and needs for regulatory harmonisation.

g) Establishment of logical steps towards medicines regulation harmonisation in Africa.

1.2 METHODOLOGY

Assessment instruments (AI) consisting of three separate structured questionnaires were administered at REC, Regional/National Association of Pharmaceutical Manufacturers and NMRA levels to gather information, that was then analyzed to give a reflection of the situation of medicine registration harmonisation. In addition, checklists were used during focus group discussions (FGD) and key informant interviews were conducted in order to collect both qualitative and quantitative data.

The AI was piloted in the East African Community (EAC) taking into account a recent assessment of medicines regulatory capacities in the five Partner States which was conducted using the WHO Assessment Tool. During the second week of May 2010 the assessment team conducted discussions with the EAC Secretariat, Industry and Heads of NMRAs with a view of identifying gaps in the AI and gather inputs from stakeholders. Input from the EAC pre-testing was used to review the AI with a view to replicate the exercise in the remaining RECs. The assessment team reviewed various documents including the latest WHO reports on medicines regulatory harmonisation in Africa and other relevant papers as an input in the assessment exercise.

Data was collected and analyzed to realize the above stated objectives. Where no assessment has been done using WHO Assessment Tool, the assessment team did the following: conducted a thorough review of all laws, regulations, forms and instructions pertaining to drug regulatory systems in all Partner States/Member States, collected new data; analyzed processes and systems; evaluated institutional capacity and provided a qualitative and quantitative assessment using the data collected. The team has made recommendations and proposed strategies for addressing needs and gaps identified both at national and regional levels.

2. ECONOMIC COMMUNITY OF WEST AFRICAN STATES

2.1 BACKGROUND

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-Bisau, 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 harmonisation as a public health tool for improving accessibility, affordability and availability of safe, efficacious and quality medicines in the sub-region.

The sub-region, with a population of about 300 million, has similarities in terms of burden of disease. 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 impacts on the types of medicines required.

Existing disparities 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 and Francophone countries is a constraint to human resource mobility that, once removed, will allow quality and affordable medicines to circulate throughout the sub-region as needed. Additionally, enhanced communication and information exchange between member countries will make integration easier and more beneficial to all Member States.

2.1.1 The West African Health Organisation (WAHO)

The West African Health Organisation (WAHO) was formed in 1987 when the Heads of State and Government from all fifteen countries in the Economic Community of West African States (ECOWAS) adopted the Protocol creating the organisation. The Protocol, which was subsequently ratified by each government in the sub-region, grants WAHO status as a Specialised Agency of ECOWAS and describes the organisation's mission as follows: "The objective of the West African Health Organisation shall be the attainment of the highest possible standard and protection of health of the peoples in the sub-region through the harmonisation 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 sub-region."

The driving force behind WAHO's creation was the incongruence of the agendas that were being pursued by the two existing inter-governmental health organisations in the sub-region, the Francophone Organisation de Coordination et de Cooperation pour la Lutte Contre les Grandes Endemies (OCCGE) and the Anglophone West African Health Community (WAHC). It was determined that, as matters of health are not bound by linguistic difference, it would benefit the organisations to synchronise their efforts and combine resources to enhance the impact of their programmes in West Africa. Thus, the OCCGE and WAHC merged to form WAHO, an organisation committed to transcending linguistic borders in the sub-region to serve all fifteen ECOWAS Member States. In October of 1998, the ECOWAS Heads of State and Government established Bobo-Dioulasso,

Burkina Faso as the site of WAHO Headquarters and appointed the Organisation's Director and Deputy Director. In March of 2000, WAHO began active operations as a leading health authority in the sub-region, serving ECOWAS Member States. It is a proactive instrument of regional health integration that enables high-impact and cost-effective interventions and programmes by:

a) Maintaining sustainable partnerships

b) Strengthening capacity building

c) Collecting, interpreting and disseminating information

d) Promoting cooperation and ensuring coordination and advocacy

e) Exploiting information communication technologies

The Authority of Heads of State and Government of Member States is the supreme institution of the Community and is composed of Heads of State and/or Government of Member States. The Authority is responsible for the general direction and control of the Community and takes all measures to ensure its progressive development and the realisation of its objectives. As such, it is also the supreme decision-making body of WAHO.

The Council of Ministers is a rotating panel of Ministers from ECOWAS Member States that can include Ministers of Integration, Economic Planning and Finance, and Foreign Affairs. The Council is responsible for the functioning and development of the Community and makes recommendations to the Authority of ECOWAS on any action related to the objectives of the Community.

The jurisdiction of the Assembly of Health Ministers is principally limited to matters of health, and more particularly to the technical aspects therein. The Assembly determines the general policies of WAHO and makes other appropriate decisions to promote or advance the objectives of the Organisation.

Although it is a Specialised Agency of ECOWAS, WAHO enjoys administrative and financial autonomy. The General Directorate of WAHO, which is responsible for the execution of the organisation's programmes and activities, is headed by a Director General, assisted by a Deputy Director General. The activities of WAHO are distributed among five divisions that comprise the General Directorate:

a) Human Resources Development.

b) Planning and Technical Assistance.

c) Primary Health Care and Disease Control.

d) Research and Health Management Information System.

e) Administration and Finance.

2.1.2 Union Economic et Monetaire Ouest-Africaine (UEMOA)

UEMOA or The West African Economic and Monetary Union was established to promote economic integration among countries that share a common currency, the CFA franc. It was created by a treaty signed in Dakar, Senegal on January 10, 1994 by the Heads of State and Government of Benin, Burkina Faso, Cote d'Ivore, Mali, Niger, Senegal and Togo. On May 2, 1997, Guinea-Bissau became its eighth member state. Since its inception, UEMOA member states have implemented macroeconomic convergence criteria and an effective surveillance mechanism; adopted a customs union and common external tariff (2000); harmonised indirect taxation regulations; and initiated regional structural and sectoral policies.

ECOWAS and UEMOA have developed a common programme of action on trade liberalization and macroeconomic policy convergence. They have also agreed on common rules of origin to enhance trade, and ECOWAS has agreed to adopt UEMOA's customs declaration forms and compensation mechanisms.

2.1.3 Programme Regional Sante en Afrique de l'Ouest (PRSAO)- West African Regional Programme for Health

The West African Regional Programme for Health (PRSAO) was an initiative of the European Commission and ECOWAS. It operated between 2006 and 2008 with funding from the European Union covering the fifteen (15) ECOWAS countries and Mauritania.

The main activities of PRSAO related to the present initiative are summarized as follows:

a) Develop a regional approach for the implementation of public health safety measures in conformity with the TRIPS agreements;

b) Support the organization and harmonisation of regional marketing of essential generic medicines;

c) Strengthen member countries medicines regulatory authorities;

d) Promote the harmonisation of medicine marketing authorizations within the 16 countries ;

e) Organize a ministerial meeting on the coordination, harmonisation and integration of pharmaceutical policies and the fight against epidemics;

f) Reinforce countries' capacities in epidemics surveillance and pharmaceutical inspection;

g) Develop and set training modules online in epidemiology as well as a programme of training for pharmacy inspectors

2.1.4 The WAHO/PRSAO roadmap for medicines regulation harmonisation

Given the diversity and severity of health issues afflicting West Africans, there was a compelling need to harmonise 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 sub-regional level, gains made by local- and national-level campaigns would be lost. Acknowledging this reality, ECOWAS committed itself to bringing about true sub-regional integration in the health sector to ensure the highest possible standard of health for all West Africans. The PRSAO project was therefore embarked upon with funding for the EU to achieve this objective.

The Pharmaceutical component of this project had a major component of strengthening and building the capacities of NMRAs in the region and working towards harmonisation of regulatory systems to combat the myriad of common regulatory problems identified. Consequently, a situational analysis was carried out by experts and the results were confirmed by the study visits to the NMRA in Ghana, Senegal and Nigeria. It was established that two different systems that serve to regulate health-related products existed within the sub-region. It became clear that the English-speaking countries have a system in which the regulatory functions are centralized in a semi-autonomous/autonomous body; while the French and Portuguese-speaking system has regulatory functions shared between several bodies under the authority of the Ministry of Health. Subsequently, a harmonisation workshop took place in Abuja where the NMRAs expressed their wish that the various institutional authorities agree on a common system on which all the pharmaceutical policy harmonisation and regulation issues would depend. Subsequently, the NMRAs 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.

A road-map to Medicines Regulatory Harmonisation was proposed by WAHO/PRSAO in July 2008

and adopted by all member states in Abidjan. Its implementation has been left with WAHO and subsequently included in the WAHO medicines and vaccines programme.

Besides the differences in the system of administration of medicines regulation in the sub-region, several other factors are known to contribute to the difficulties encountered by the sector. These include 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 harmonisation of medicines regulation.

In order to improve the processes for approving pharmaceutical products within the sub-region therefore, ECOWAS and the other sub-regional institutions recognize the need to develop a harmonised common technical document that will reflect all the harmonisation initiatives previously undertaken within the sub-region.

To facilitate the availability and affordability of safe, quality and efficacious medicines in ECOWAS, the West African Health Organization (WAHO), a specialized agency of ECOWAS, has as part of its priority programmes, a Medicines and Vaccines programme, which aims to improve access to quality, affordable essential medicines for the treatment of malaria, HIV/AIDS, tuberculosis and other priority diseases. WAHO is also developing a Regional Drug Revolving Fund (DRF) for pooled procurement of essential medicines in ECOWAS.

2.1.5 Steps taken towards medicines regulation harmonisation

In the last 10 years, ECOWAS as well as other the sub-regional organizations have made enormous strides with a view to harmonising medicines regulation within the sub-region. Among the steps that have been taken so far are:

a) Commencement of a medicines harmonisation process by Nigeria and Ghana in 1999, which was not conclusive;

b) Existence of a network of Medicine Regulatory Authorities in ECOWAS albeit without structures and a permanent secretariat;

c) UEMOA's harmonisation of certain medicines regulation procedures, processes and requirements in the eight Francophone member countries;

d) Experience of the "Association Africaine des Centrale d'Achats de Medicaments Essentieles" (ACAME) in harmonisation of procurements of medicines in member countries;

e) Establishment of pharmaceutical manufacturers networks, e.g. the Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria (PMGMAN); the Pharmaceutical Manufacturers Association of Ghana (PMAG); the West African Pharmaceutical Manufacturers Association (WAPMA);

f) ECOWAS , WAHO & UEMOA's participation in the DFID/Bill & Melinda Gates Foundation Workshop in Johannesburg in February 2009;

g) The ECOWAS Medicine Regulatory Authorities meeting in Ouagadougou, March 12-13 2009, hosted by WAHO/ and

h) The Road map to Drug Regulatory Harmonisation in ECOWAS developed by PRSAO/WAHO in 2007 and adopted in 2008.

2.2 OVERVIEW OF LEGAL ISSUES AFFECTING MEDICINES REGULATION

2.2.1 National Medicine Policy (NMP)

This section provides key explanations of countries that have Medicine Policies of the type recommended by WHO. It also highlights those countries that have implementation plans for their policies and as to whether they reflect in their context that the Government has the obligation to regulate medicines. The study has established that some countries within the region have National Medicines Policies of the type recommended by WHO. These include Burkina Faso, Cape Verde, Gambia, Ghana, Liberia, Niger, Nigeria and the Republic of Guinea. Out of these countries, Cape Verde, Ghana, Republic of Guinea, Senegal and Togo do not have in place policy implementation plans while Liberia and Burkina Faso are still developing their plans (see Table 1).

Both policies in place and those under development do mention in their context that the responsibility to regulate medicines and ensure the safety, quality and efficacy of those medicines is solely vested in the government. Thus it can be observed that Governments through their National Medicine Policies have committed themselves to the regulation of medicines in their countries. These policies could therefore be easily used as a platform to push ahead the medicine regulation harmonisation agenda.

Table 1: List of countries with National Medicines Policies and status of their implementation plans

Countries with written National Medicine Policy (NMP) of the type recommended by WHO		
Country	**Existence of policy**	**Description**
Burkina Faso	Yes	Dated 1996 and updated in 2010 and is awaiting adoption).
Cape Verde	Yes	-
Gambia	Yes	
	Updated in July 2007	
Ghana	Yes	-
Liberia	Yes	The Ministry of Health and Social Welfare produced a draft that is being reviewed by a technical working group of which the LMHRA is a part
Niger	Yes	-
Nigeria	Yes	National Drug Policy Published by Federal Ministry of Health
Republic of Guinea	Yes	-

Countries with Policy implementation plans	
Burkina Faso	No -(the blue print is in development)
Gambia	Yes -(developed and validated in Dec 2007)
Cape Verde, Ghana, Republic of Guinea, Senegal, Togo	-
Liberia	Yes - (Implementation plan is being developed).
Niger	Yes

2.2.2 Legislation, regulations and mission

One of the most significant determinants of safe, quality and efficacious medicines within the regulatory legal framework is the existence of legislation, regulations and policies that aim to ensure comprehensive control of medicines. This section intends to identify the status quo of the current medicine regulatory framework in each country within the ECOWAS region. The ultimate goal is to link the country legal framework to the regional harmonisation initiatives on the control of medicines to facilitate access to safe, quality and efficacious medicines in the region.

Currently, the region has got the Treaty of the Economic Community of West African States (ECOWAS) that was signed in Lagos on 28 May, 1975 as revised from time to time. This is the first legal base at the regional level as it provides for existence of the Community. The second legal base focusing on health matters is the Protocol adopted and ratified by the 15 countries in 1987. This Protocol formed the West African Health Organisation (WAHO) which operates as a Specialised Agency of ECOWAS in relation to health issues. Its mission is stated as follows : "The objective of WAHO shall be the attainment of the highest possible standard and protection of health of the peoples in the sub-region through the harmonisation 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 sub-region."

Heads of State and Government agreed that, matters of health are not bound by linguistic differences. Thus, WAHO is an organisation committed to transcending linguistic borders in the sub-region to serve all fifteen ECOWAS Member States. The vision also implies that WAHO is a proactive instrument of regional health integration that enables high-impact and cost-effective interventions and programmes. It may therefore be concluded that, through this organisation and its Protocol, the Community has an enabling environment for regional health interventions.

This paragraph analyses the domestic legal framework of Member States. Each of the 15 ECOWAS Member States controls medicines independently. Their legislations are neither uniformly applicable nor take precedence over any decision made regarding regulation of medicines within other Member States. Subsequently, these domestic laws limit the implementation of regulatory decisions made by other Member States. Most countries are registering medicines independently and with independent technical and administrative procedures for registration of medicines without clear indications as to how long it would take to register such medicines. The various pieces of legislation that are used to regulate medicines in the ECOWAS Member States are listed in Table 2.

Table 2: List of legislations for regulating medicines in ECOWAS Member States

Title of enactment of the different medicine legislation/regulations currently used to regulate medicine in the country	
Country	**Description/Title**
Burkina Faso	1. Document Reference: Law No. 23/94/ADP of 19 May 1994 Code of Public Health
Gambia	2. Medicines Act (1984) 3. Medicines Regulations (1986) 4. INCB 5. Trips agreement
Ghana	6. Food and Drugs Law 1992 PNDCL 305B (1992) 7. Food and Drugs amendment Act 523 (1996) 8. Pharmacy Act (Act 489) (1994)
Guinea Bissau	9. Legal Regime of the pharmaceutical business (2010) 10. National Pharmaceutical Policy (2010) 11. Registration (ongoing) 12. Pharmacovigilance (ongoing) 13. Laboratory (ongoing)
Liberia	14. Pharmacy Board Act of 1967 (April 20, 1967) 15. Public Health Law (1956) 16. An Act to Establish the Liberia Medicines and Health Products Regulatory Authority (LMHRA) of 2010 (September 29, 2010)
Niger	17. Ordinance No. 97-002 of 10 January 1997 (1997) 18. Decree No. 97-301/PRN/MSP of 6 August 1997 (1997) 19. 24 regulatory applications of April 1998 (1998) 20. 04 regulatory applications of 1999 (1999) 21. 02 regulatory applications of 2000 (2000) 22. 02 regulatory applications of 2002 (2002)
Nigeria	23. NAFDAC ACT N1 Laws of the Federation of Nigeria (LFN) 2004
Republic of Guinea	24. Single Convention on Narcotic drugs, 1961 1991 (1991) 25. Single Convention on Narcotic Drugs of 1961 as amended by the Protocol of 1972 1991 (1991) 26. Convention on Psychotropic Substances 1991 (1991) 27. Law no. L94/012/CTRN on Pharmaceutical Legislation
Senegal	28. 28. Law No. 63-33 of 19th May 1965 29. 29. Circular in relation to procedures of Registration of pharmaceutical products for human usage in Senegal according to the laws of UEMOA (7 Feb. 2011) 30. Circular in relation to advertising (12 January 2011) 31. Circular in relation to flyers (12 January 2011) 32. Circular in relation to free units (12 January 2011)

Title of enactment of the different medicine legislation/regulations currently used to regulate medicine in the country	
Country	**Description/Title**
Togo	33. Framework on drug and pharmacy and the text of application (2001) 34. Public Health Code of the Republic of Togo (15 May 2009) 35. Elaborated provisions of the code of Public Health (2010) 36. Regulation No. 6/2010/CM/UEMOA procedures relating to registration of pharmaceuticals for human use in the Member States of the UEMOA (2010)

2.2.3 Comprehensiveness of legislation

Having established the existence of country legislation for regulating medicines, this section determines to what extent these laws provide for key regulatory functions in each Member State. Some of these functions include the establishment of specific regulatory bodies responsible for medicines regulation, and licensing of various medicines dealers like manufacturers, importers, wholesalers, distributors and retailers through various dispensing outlets. Other functions are registration, market authorization, inspection, quality control laboratory, and control of clinical trials, control of counterfeit, import and export as well as monitoring of safety of medicines. Some of the laws also provide for control of medicine promotion and other regulated products, medicines distribution schedules, narcotics and psychotropic substances, provision of sanctions and regulations. Table 3 provides the status of countries regarding provision of laws for some key regulatory functions.

Table 3: Comprehensiveness of Legislation for key regulatory functions.

Key regulatory function/ provision	Yes/ No	Country	Comments
1. Establishment of a body responsible for medicines regulation	Yes	Burkina Faso, Cape Verde, Gambia, Ghana, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal, Togo	
Licensing of: 2. Manufacturers	Yes	Burkina Faso, Cape Verde, Gambia, Ghana, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal, Togo	
	No	Guinea Bissau	
3. Importers	Yes	Burkina Faso, Cape Verde, Gambia, Ghana, Guinea Bissau, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal, Togo	Directorate of Pharmacy (Guinea Bissau)
4. Wholesalers	Yes	Burkina Faso, Cape Verde, Gambia, Ghana, Guinea Bissau, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal, Togo	Directorate of Pharmacy (Guinea Bissau)
5. Distributors	Yes	Burkina Faso, Cape Verde, Gambia, Ghana, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal	
6. Retailers/dispensing outlets	Yes	Burkina Faso, Cape Verde, Gambia, Ghana, Guinea Bissau, Mali, Niger, Nigeria, Republic of Guinea, Senegal, Togo	
	No	Liberia	Responsibility of the pharmacy Board of Liberia

Key regulatory function/ provision	Yes/ No	Country	Comments
7. Other	Yes	Burkina Faso, Cape Verde, Mali, Niger, Nigeria, Republic of Guinea, Senegal	1. Medical representatives, practicing medicine and traditional pharmacopoeia (Burkina Faso) 2. NGO, Clinics, Private Hospitals (Niger) 3. NGO/Hospitals, International Organizations, Religious Institutions (Republic of Guinea)
	No		
8. Market Authorization/ Registration of medicines	Yes	Burkina Faso, Cape Verde, Gambia, Ghana, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal, Togo	
	No		
	-	Guinea Bissau	
9. Inspection of premises and manufacturing sites	Yes	Burkina Faso, Cape Verde, Gambia, Ghana , Liberia, Mali, Nigeria, Republic of Guinea, Senegal, Togo	If requested by the Board of Registration of Medicines (Burkina Faso)
	No	Guinea Bissau, Niger	
10. Establishment of Quality Control Laboratory	Yes	Burkina Faso, Cape Verde, Ghana, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal, Togo	1. But independent from the DGPML (Burkina Faso) 2. But controls substandard etc (Liberia) 3. Upgrading of the laboratory in progress (Liberia) 4. LANSPEX (Niger)
	No	Gambia	Updating Act to include it (Gambia)
		Guinea Bissau	Lab records and installation in progress
11. Control of clinical trials	Yes	Burkina Faso, Cape Verde, Ghana, Liberia, Mali, Niger, Nigeria, Senegal, Togo	1. Early implementation of the regulations recently (Burkina Faso 2. Bioethics Commission (Togo)
	No	Gambia, Guinea Bissau, Republic of Guinea	Updating Act to include it (Gambia)
12. Control of counterfeit medicines	Yes	Burkina Faso, Cape Verde, Liberia, Niger, Mali, Republic of Guinea, Senegal	1. From 2011 through quality control testing using a basic Minilab (Burkina Faso) 2. Not systematic (Niger)
	No	Gambia, Ghana, Nigeria, Guinea Bissau, Togo	Updating Act to include it (Gambia)
	N/A		
13. Control of imports and exports	Yes	Burkina Faso, Cape Verde, Ghana, Guinea Bissau, Mali, Niger, Nigeria, Republic of Guinea, Senegal, Togo	By granting visas to import (Burkina Faso)No Exceptions (Republic of Guinea)By CAMEG Togo

Key regulatory function/ provision	Yes/ No	Country	Comments
14. Safety monitoring of products	Yes	Burkina Faso, Cape Verde, Gambia, Ghana, Mali, Niger, Nigeria, Republic of Guinea, Togo	By the implementation of a national quality control program since 2010 (Burkina Faso)
	No	Gambia, Ghana, Guinea Bissau	Updating Act to include it (Gambia)
15. Control of product promotion and advertisement	Yes	Burkina Faso, Cape Verde, Ghana, Guinea Bissau, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal, Togo	1. Recent adoption of legislation on advertising and creation of an inspectorate (Burkina Faso) 2. Directorate of Pharmacy and inspection pharmaceutique (Guinea Bissau) 3. Regulations on publicity and medical representatives (Niger)
	No	Gambia	Updating Act to include it (Gambia)
16. Control of other products	Yes	Burkina Faso, Cape Verde, Gambia, Ghana, Mali, Niger, Nigeria, Togo	
	No	Republic of Guinea	
	N/A		
17. Provision for medicines distribution schedules/ categories	Yes	Burkina Faso, Cape Verde, Gambia, Ghana, Guinea Bissau, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal, Togo	1. LNEME revisited every 2 years, regular updating of the national classification (Burkina Faso) 2. List of essential medicines (Guinea Bissau) 3. List of essential medicines (Niger)
18. Laboratory reagents	Yes	Burkina Faso	
19. Control of narcotics and psychotropic substances	Yes	Burkina Faso, Cape Verde, Gambia, Ghana, Guinea Bissau, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal, Togo	Narcotics are a state monopoly and are mainly imported by the Ministry of Health (Burkina Faso)DPM (Guinea Bissau)System of official certificates of conformity to apply the Vienna Conventions (Niger)
20. Mineral Water	Yes	Togo	
21. Administrative and legal sanctions e.g. suspension or revocation of licenses or fines/imprisonment	Yes	Burkina Faso, Cape Verde, Gambia, Ghana, Guinea Bissau, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal, Togo	DPM/IP (Guinea Bissau)
22. Authority to make regulations	Yes	Burkina Faso, Cape Verde, Gambia, Ghana, Guinea Bissau, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal, Togo	1. DGPML and other structures involved (Burkina Faso) 2. National Commission of Medicines 3. Ministry of Public Health (Niger)
	No		

2.2.4 Member states legislation and regulations

Six countries (Burkina Faso, Gambia, Niger, Republic of Guinea, Senegal and Togo) have policy or legislation that provides a mandate for the NMRA to recognize regulatory decisions made by

other regulatory agencies. Cape Verde, Ghana, Guinea Bissau, Liberia and Mali do not have such instruments. The relevant frameworks that provide such mandates in the Gambia are (a) National Health Policy, (b) National Medicines Policy and (c) ECOWAS Convention. In Niger these are (a) Directives of UEMOA, (b) Regulations of UEMOA and (c) Decisions of UEMOA. In the Republic of Guinea these are are (a) Title of instrument and (b) Manual Harmonisation of registration procedures while in Senegal there is a Circular on the procedures for registration of pharmaceuticals for Human Use which is under the rules of UEMOA.

Nine countries (Burkina Faso, Gambia, Guinea Bissau, Liberia, Mali, Niger, Nigeria, Senegal and Togo) are currently involved in some regional or continental efforts towards harmonisation of medicines regulation while the Republic of Guinea is not involved in any efforts. The specific regional or continental efforts that various countries are involved in are shown in Table 4 provided below.

Table 4: Regional/ Continental Efforts towards Harmonisation of Medicines Regulation

Initiative	Country
1. UEMOA	Burkina Faso, Mali, Niger, Senegal, Togo
2. ECOWAS	Cape Verde, Senegal
3. WAHO	Burkina Faso, Gambia, Ghana, Liberia, Mali, Niger, Senegal, Togo
4. WHO	Gambia
5. African Medicine Forum	Ghana
6. VIGIMED database	Guinea Bissau
7. Exchange of information	Guinea Bissau
8. Recognition of information	Guinea Bissau
9. Collective information	Guinea Bissau
10. Group training common technical requirements	Ghana
11. WHO-Technical Regulatory package	Nigeria

Most of the NMRAs are actively involved in the NATURE programmes which promote information sharing, information recognition, joint training, common guidelines and joint assessments/inspection.

2.2.5 Mission statements of regulatory authorities

This section provides information on whether the region and its respective NMRAs have developed mission statements that support the implementation of medicine regulations. WAHO's mission is "to attain the highest possible standard and protection of health of the peoples in the sub-region through the harmonisation 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 sub-region." Some countries like Burkina Faso, Liberia and Mali have their mission statements in place which require that these respective NMRAs ensure that medicines are of good quality and efficacious. For example the mission statement for Burkina Faso is "to ensure that medicines of good quality, effectiveness and without risk are available and accurate information is provided about them". In Liberia it is "to ensure safety, efficacy and quality of medicines and health products" while Mali stands for "ensuring equitable access to quality essential medicines to people and promote their rational use".

Gambia, Ghana, Cape Verde, Niger, Nigeria, Republic of Guinea, Senegal and Togo do not have in place mission statements in favour of national medicine regulation. The countries that do not have in place the mission statements drawn from the existing legislation and policies that regulate medicines should be encouraged to do so. Such an undertaking will emphasize the serious intent and commitment of governments to fulfill their obligations to protect the public. The absence of mission statements for national regulation should neither compromise the role of government to regulate medicines nor underestimate the need to have it drawn as soon as possible.

2.2.6 Decision making process

The decision making process for matters affecting the region depends upon the arrangement derived from the Treaty of the respective region. In the case of ECOWAS the binding force of the decisions made under the Treaty including the Protocol are under Article 9 of the Treaty. The Heads of State and Government of Member States (Authority) is the supreme institution of the Community. Unless stated otherwise by the Protocol, the decisions made by the Heads of State are binding to all Member States. In order to operationalize these decisions, they are supposed to be published in the gazettes of each Member State 60 days after being made.1

The Heads of Government of Member States are responsible for the general direction and control of the Community and take all measures to ensure its progressive development and the realisation of its objectives. As such, it is also the supreme decision-making body of WAHO2 which is responsible for health matters in the region.

The Council of Ministers is a rotating panel of Ministers from Member States. It includes Ministers of Integration, Economic Planning and Finance, and Foreign Affairs. The Council is responsible for the functioning and development of the Community and makes recommendations to the Heads of Government of Member States on any action related to the objectives of the Community.

The jurisdiction of the Assembly of Health Ministers is principally limited to matters of health, and more particularly to the technical aspects as they arise from time to time. The Assembly determines the general policies of WAHO and makes other appropriate decisions to promote or advance the objectives of the Organisation. In addition to it being a Specialised Agency of ECOWAS, WAHO enjoys administrative and financial autonomy. The Directorate of WAHO, which is responsible for the execution of the organisation's programmes and activities, is headed by a Director General, assisted by a Deputy Director General.

Like many other international Treaties, the Treaty for Establishment of ECOWAS is non-self-executing and requires 'implementing legislation' that is a change in the domestic law of a Member State that will direct or enable it to fulfill treaty obligations. Following the contents of the Treaty and legitimacy of state jurisdiction, this can be done in two ways: one is to change the domestic law whereby a Member State incorporates through the parliamentary processes of law making the decision made hence making it part of the domestic law or secondly for each Member State to simply publish in its domestic government gazette such decision passed by the Heads of State in order for it to form part of the domestic law as stated in Article 9 of the Treaty.

The challenge that is perceived in the domestication of laws is the variation in the determination and commitment of the Member State's according tonational preference, particularly when it appears most of the obligations agreed at regional level are either not implemented or delayed for

1 Article 9 of the Community Treaty

2 Article 7 of the Community Treaty

various reasons. It is therefore paramount to have a legal framework that may mitigate the gaps and differences of preference in implementation of joint decisions.

2.2.7 Organization and management of regulatory functions

The enforcement of regulatory functions is carried out by National Medicines Regulatory Authorities (NMRAs) that discharge day to day duties. The corporate profile of NMRAs in the region varies Some are established by law as body corporates while others operate as departments of Ministries responsible for health. In either case the law provides for the establishment of a body responsible for medicines regulation in Burkina Faso, Cape Verde, Gambia, Ghana, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal and Togo. As shown in Table 5 below most NMRAs execute the functions indicated. It is however significant to note the following: Guinea Bissau neither carries out product assessment and registration/marketing nor performs medicine quality tests; Gambia, Niger and Liberia do not do GMP inspection; Niger and Guinea Bissau do not inspect distribution channels; Gambia and Guinea Bissau do not regulate generic substitution; and Gambia, Guinea Bissau, Mali and Togo do not control prescribing.

Table 5: Summary of functions executed by each National Medicines Regulatory Authority.

Function	Country												
	B/FASO	TOGO	C/VERDE	GAMBIA	GHANA	ALGERIA	NIGER	NIGERIA	LIBERIA	MALI	SENEGAL	RP/GUINEA	GN BISSAU
Licensing of Pharmaceutical Manufacturers	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Licensing of pharmaceutical imports	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Licensing of pharmaceutical wholesale trade	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Licensing of medicine retail/dispensing outlets	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Product assessment and registration/marketing authorization	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	×
Good manufacturing practice (GMP) inspection	✓	✓	✓	×	✓	✓	×	✓	×	✓	✓	✓	✓
Inspection of distribution channels	✓	✓	✓	✓	✓	✓	×	✓	✓	✓	✓	✓	×
Performing medicine quality tests/quality control laboratory	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	×
Regulating generic substitution	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	✓	✓	×
Control prescribing	✓	×	✓	×	✓	✓	✓	✓	✓	×	✓	✓	×
Coordination of medicine regulation centrally at national level	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

2.2.8 Recommendations

ECOWAS member states need to fast track the change of national laws regulating medicines so as to have a harmonised regional platform for accessing safe, quality and efficacious medicines. According to Article 9 of the Treaty, a decision may be passed by the Heads of State that compels member states to change the domestic legislations within specific times in favor of the harmonisation

of medicine regulation. After the decision has passed, each member state will be bound to publish in this gazette to facilitate it to become domestic law. This may shorten the parliamentary process of making laws. The other option would be for the region to have another protocol to complement the protocol that established WAHO. Both the recommended decision and a protocol, (which ever perceived to suit the region) on harmonisation of regulation of medicines is recommended to take into account among others things, the following:

a) Application of approximate medicine regulation laws which leads to uniform application of medicine registration and documentation in the region;

b) Use of common procedures for decision on approval of medicines registration which sets a precedent to the subsequent application for registration in any other member state NMRA;

c) Elimination of internal registration barriers that impede access to affordable medicines by all member states;

d) Harmonise registration charges of equivalent cost and remove discriminatory treatment to medicines registered among member states;

e) Export promotion and competitiveness through various incentive schemes on medicines within the region;

f) Medicine laws to be made with provisions that recognize decisions of each Member States to take precedence over the subsequent laws provided that the safety, quality and efficacy of medicine is not compromised;

g) The countries that do not have in place mission statements drawn out from the existing legislation and policies that regulate medicines should be encouraged to have their missions in place so as to set the broad direction of the entire goal of government commitment to safe and quality medicines; and

h) To allow a better and conducive environment for harmonisation of regulatory functions, it is recommended that WAHO as an already existing platform for the region on matters of health maintains oversight of the implementation status of these recommendations.

2.3 MEDICINE REGULATORY HARMONISATION AND REGISTRATION SYSTEM

This section deals with the following aspects of harmonisation: legal and regulatory requirements, guidelines for registration of medicines, the registration times and processes, assessment of applications of pharmaceutical products, factory inspections and testing of medicine samples for registration.

2.3.1 Legal and regulatory requirements

Data from the responding countries regarding the legal and regulatory requirements for the harmonisation process was reviewed and analyzed. The survey revealed that in all the 11 countries which responded (Burkina Faso, Cape Verde, Gambia, Ghana, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal and Togo) there is explicit provision in the legislation which provides the legal mandate for the NMRAs to register medicine. All the 11 countries were actively registering medicines. In 10 of the countries with the exception of Gambia, the registration requirements covered products for both public and private sectors procurement and distribution. In Gambia the registration requirement covers only the private sector.

Provisions for waivers in the registration process exist under certain circumstances in 10 countries

(Burkina Faso, Cape Verde, Gambia, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal and Togo). There is however no waiver in Ghana. The conditions for waivers vary from country to country. In Burkina Faso, a waiver is applied for drugs not yet approved, but deemed useful to the public following a medical prescription. In Gambia a waiver is applied for drugs donated, or urgently required in the country. In Nigeria, a waiver is applied for donated drugs which are to be used for specific programmes. For Liberia, in event of crisis or emergency, procedure for registration may be relaxed in line with the protocol of the Ministry of Health and Social Welfare. In Togo, medicines pre-qualified by WHO are given waivers. Senegal has a directive that products without a special permit must have an exceptional delivery by DPL in order to be eligible for a waiver.

2.3.2 Guidelines for registration of medicines

The relevant guidelines and reference standards for the registration of medicine in ECOWAS was reviewed and analyzed. There are guidelines for the registration of medicines in 10 countries namely, Burkina Faso, Gambia, Ghana, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal and Togo. Guinea Bissau however does not have a guideline. The guidelines vary from country to country. The reference standards used for review are: WHO and WHO-ICH by Ghana, WHO-PQ by Gambia, WHO-GS by Republic of Guinea, Re'glement No.06/2010/CM/UEMOA by Niger, previous circular by Senegal, WHO Blue Book and WHO documents by Togo.

The relevant guidelines and reference standards are as shown in Table 6 below.

Table 6: Guidelines for registration of Medicines in ECOWAS

Country	Name of guideline	Reference standard
Burkina Faso	Arr-2003-SG-341_MS DGPML conditions for issuing marketing Authorizations for drugs, consumables and reagents [2003] Instruction for the sessions of expert committees [2010]	
Gambia	Medicine Regulation[1986] Generic Guideline [2010]	WHO-PQ
Ghana	Guideline for allopathic drug registration [1999] Guideline for stability testing [1999] Guideline for conducting BE studies [1999] Guideline for clinical trials [1999] Guideline for labeling of products [1999]	WHO WHO-ICH
Liberia	Basic steps for product listing Application forms and samples evaluation Guideline for samples submission	
Niger	Regulation no. 101/MSP/DPHL of 03 April 1998, determining the elements of an application for market authorization [AMM]	Reglement No. 06/2010/CM/UEMOA WHO-GS
Nigeria	Guidelines for drug registration in Nigeria Guidelines for registration of locally manufactured drug products Guideline for registration of imported products	
Republic of Guinea	Repository for Terms of Registration and Authorization Market [AMM] of pharmaceutical products in the Republic Of Guinea.	Registration procedure of the countries in the sub-region
Senegal	Circular [2001]	Previous circular
Togo	Memorandum containing the procedures for registration (3/2009)	WHO Blue Book WHO documents

The scope of the guidelines covers NCES in Burkina Faso, Gambia, Ghana, Liberia and Togo. Four of the above countries with the exception of the Gambia have their scope of the guidelines being for Generics, Variations and Renewals as well. For the Republic of Guinea the scope is a general provision of drug registration of drug register-based medicine. In addition for the Republic of Guinea it also covers registration of medical devices and laboratory reagents. The duration is 5 years renewable (marketing authority MA 1995). When necessary there are manual registration procedures for countries in the sub region. The frequency of the revision of guidelines also varies from country to country: This is done annually in Liberia, every 2 years in Togo, and every three years in Ghana and when necessary in Republic of Guinea. In Niger the process is presently underway to comply with directives of the UEMOA.

The scope and frequency of revisions of guidelines is shown in Table 7 below.

Table 7: Scope and frequency of revisions of guidelines

Country	Scope of guidelines	Frequency of revision
Burkina Faso	NCES, Generics, Variations, Renewals	
Gambia	NCES	
Ghana	NCES, Generics, Variations, Renewals	Every 3 years
Liberia	NCES, Generics, Variations, Renewals	Annually
Niger		Underway to comply with directives of UEMOA
Republic of Guinea	1. General provisions of drug registration presentation of drug-register-based medicine herbal medicine 2. Registration of medical devices and laboratory reagents.	When necessary
Togo	NCES, Generics, Variations, Renewals	Every 2 years

2.3.3 Registration times and process

This section is about the process leading to registration of a product and the turn-around time for this to be undertaken. The requirements looked into included details of marketing authorization, which is an essential aspect of medicine registration.

2.3.3.1 Requirements for registration and market authorization

Marketing authorization (MA) involves the assessment of scientific information submitted by applicants including the GMP inspection of manufacturing sites for pharmaceutical products. It involves submission of pharmaceutical information, clinical and non clinical data with a view to ascertain the quality, efficacy and safety of a pharmaceutical product. Depending on the information submitted and the capacity of the NMRAs, additional reference information such as certificate of pharmaceutical product (CPP) and reference data from a SRA may be requested by the assessing NMRA.

A certificate of Pharmaceutical Products (CPP) is required in 11 countries namely: Burkina Faso,

Cape Verde, Gambia, Ghana, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal and Togo. The CPP is required at dossier submission in all the above 11 countries for all medicines/products including generic medicines (see Table 8 for details).

Table 8: Requirements and times of registration and market authorization of medicines.

Country	Reference document used for assessment	Timing	Type of products
Burkina Faso	CPP	At dossier submission	All medicines/products Generic medicines
Cape Verde	CPP	At dossier submission	All medicines/products Generic medicines
Gambia	CPP	At dossier submission	All medicines/products Generic medicines
Ghana	CPP	At dossier submission	All medicines/products Generic medicines
Liberia	CPP	At dossier submission	All medicines/products Generic medicines
Mali	CPP	At dossier submission	All medicines/products Generic medicines
Niger	CPP	At dossier submission	All medicines/products Generic medicines
Nigeria	CPP	At dossier submission	All medicines/products Generic medicines
Republic Of Guinea	CPP	At dossier submission	All medicines/products Generic medicines
Senegal	CPP	At dossier submission	All medicines/products Generic medicines
Togo	CPP	At dossier submission	All medicines/products Generic medicines

Stringent Regulatory Authority (SRA) approval is required for Marketing Authorization (MA) in 7 countries: Burkina Faso, Cape Verde, Mali, Niger, Nigeria, Republic of Guinea and Senegal (Table 9). WHO – Prequalification (WHO-PQ) is also required in the above countries. Marketing Authorization is required for all products and NCEs for less regulated markets and also for generic medicines. Stringent Regulatory Authority (SRA) approval is required for importation approval in Mali, Senegal and Togo while Cape Verde and Liberia require WHO-PQ. In Burkina Faso, WHO-PQ applies to records of ARVs, ACTs and anti-TB. Also to be noted, an MA can be given in the absence of WHO-PQ and SRA approval in some cases. The authorities which constitute an SRA are SRA-ICH in Mali, Nigeria and Republic of Guinea.

Table 9: Countries requiring SRA reference as basis for market authorization

Country	Reference requirement
Burkina Faso	SRA
Cape Verde	SRA,
Liberia	WHO-PQ and SRA
Mali	SRA
Niger	SRA
Nigeria	SRA
Republic of Guinea	SRA
Senegal	SRA
Togo	SRA

In Burkina Faso MA granted in other countries are recognized if the permits are from NMRAs with rigorous processes. In Gambia the MA from another country can be recognized if the capacity to evaluate a medicine is unavailable. In Ghana recognition is given in the case of epidemic and emergency situations. In Liberia recognition can be given where there is documentary evidence of limitation in laboratory procedures due to lack of basic reagents and equipment. In Niger, the MA's country of origin is a requirement for application for recognition. In the absence of this, an export license issued by the NMRA of country from which the drug is manufactured, or a certificate of free sale issued by the NMRA are acceptable. Nigeria recognizes MA granted by other countries especially for new molecules. Republic of Guinea recognizes cases where applications have been made for market authorization. The framework of UEMOA countries for registration is recognized by Senegal. In 9 countries – Burkina Faso, Gambia, Ghana, Mali, Niger, Nigeria, Republic of Guinea, Senegal and Togo, generic manufacturers can register their product when the innovator product is not registered in the countries. Liberia does not allow for such registration. In 7 of the countries (Burkina Faso, Ghana, Mali, Niger, Nigeria, Republic of Guinea and Togo) that gave positive responses, the generic manufacturer must submit bio-equivalence study using an innovator product approved by an SRA as reference when the innovator product is not registered. In all the above countries, right to reference the clinical data used in the innovators SRA filling can also be submitted by the generic manufacturer when the innovator product is not registered. In these 7 countries, published clinical data on the innovator product that is sufficient to demonstrate safety and efficacy can also be used. In Ghana, Burkina Faso, Niger and Togo, chemistry manufacturing controls can be submitted when the innovator product is not registered.

2.3.3.2 Assessment of applications for the registration of pharmaceutical products.

The role of different committees both administrative and technical that assess the applications for medicine registration is analyzed. This section also deals with the process for fast tracking of applications of medicines for various diseases.

There are Technical Committees responsible for assessing applications for the registration of pharmaceutical products in 10 countries namely: Burkina Faso, Gambia, Ghana, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal and Togo. In 6 of these countries (Burkina Faso, Ghana, Liberia,

Mali, Niger and Nigeria) the final decisions are made by the Registration Technical Committee, while the Board is responsible in Gambia and Senegal. In addition, the Ministry of Health makes the decision in Burkina Faso; the National Commissions of Medicine is responsible in Republic of Guinea; the National Commission VISA in Senegal and the National Commission of Registration in Togo. The frequency of meetings of the Technical Committees for Generics and NCEs vary from weekly in the case of Liberia to as when required in Gambia. The other countries meet between every 2-4 months. The Board for Generics and NCEs in Senegal meets every 3 months.

Gambia, Ghana, Liberia, Nigeria, Republic of Guinea and Senegal have a fast-track policy in place for high priority medicines. Niger and Togo do not have such a policy. The high priority medicines are for HIV/AIDS in 5 of these 6 countries with the exception of Senegal. Four countries (Gambia, Ghana, Liberia and Nigeria) consider medicines for TB to be high priority. Five countries (Gambia, Ghana, Liberia, Nigeria and Republic of Guinea) consider anti-malarial drugs to be of high priority. Generic products and NCEs are considered high priority only in Gambia. Medicines for treating diabetes and hypertension are of high priority in Republic of Guinea, while Burkina Faso considers products whose urgency is manifested by the Ministry of Health Programs. The prioritization policy is freely available to applicants in Liberia, Republic of Guinea and Senegal, but not freely available in Gambia, Ghana and Niger. Such policy information is included in the registration guidelines, national essential medicine list and published in the NMRA website in the Republic of Guinea. The information is made available on request in Nigeria. In Ghana although the policy is not made freely available nonetheless information is channeled through the Ministry of Health procurement directorate which ensures that the programme managers purchase such information. Gambia also gives the information if required. Applicants for fast track are notified if they qualify in Liberia and Republic of Guinea. However no such information is given in Gambia, Ghana, Niger and Nigeria. Four countries (Burkina Faso, Ghana, Nigeria and Republic of Guinea) have mechanisms for targeted registration times based on application type. No such mechanism is available in Gambia and Niger.

For countries that have fast track for medicines for HIV/AIDS, TB and Malaria, the targeted time varied from 45 days in Ghana and Republic of Guinea to 1 month to 3 months in Nigeria. The percentage of applications reviewed within target was 100% in Republic of Guinea for HIV/AIDS, 75% for TB and 50% for malaria. The fast track target time was 3 months for NCEs in Republic of Guinea with 100% of applications reviewed within target. Burkina Faso has a target time of 1 month for Generic products but only 20% of applications were reviewed within target time. The standard review times for medicines for HIV/AIDS, TB and Malaria are 3 months in Senegal and 4 months in Burkina Faso. The percentage of applications reviewed for all the diseases mentioned was 80% in Senegal. Burkina Faso also has a 3 months standard review time for malaria drugs but only 50% of applications were reviewed within target time. The standard review time for NCEs was 3 months in Ghana and Senegal and 4 months in Burkina Faso. Standard review time for generic products was 3 months in Ghana, Republic of Guinea and Senegal and 4 months for Burkina Faso. In this regard both Republic of Guinea and Senegal have 80% of applications reviewed within target. For other types of products there was no fast track mechanism in any country while Burkina Faso and Senegal have 4 months and 3 months target time with 80% of applications reviewed within target in Senegal.

2.3.3.3 Average registration times

This section reviewed three years data [2007-2009] for each country in terms of applications received, approvals, backlog and average registration times for the various medicines submitted for registration.

Four countries (Ghana, Republic of Guinea, Senegal and Togo) responded but only 3 were analyzed as Togo did not provide any statistics. Information from the other 3 countries was incomplete in most instances. For HIV/AIDS drugs 120 applications were received, 62 were approved for registration and there were 3 backlogs. The average registration times were, 1 month for the Republic of Guinea

for the 3 years, 3 months for Senegal for the 3 years and 3 months for Ghana for 2007 only. With respect to TB drugs, 25 applications were received, 20 products were approved in the 3 years for the 3 countries that answered part of the questionnaire. The number of backlogs was either zero or not supplied by all the countries. The average registration times were 3 months for Senegal, 1 month in 2008 for Republic of Guinea while Ghana did not supply any information. For malaria products, 394 applications were received, 279 were approved with 19 backlogs for the countries that supplied information. The average registration time was 3 months for the Republic of Guinea and Senegal in the 3 years while no information was received from Ghana. The NCEs had 80 applications with 55 approved and 18 backlogs although no information was supplied by Republic of Guinea in 2009. The generic products had the largest applications with – 3115 and 1074 approvals. There were only 9 backlogs from available information from the few responding countries. The average registration times were 3 months for Republic of Guinea and Senegal while no information was supplied by Ghana. Other products such as vitamins, anti-histamines and food supplements had 36 applications, 36 approvals and 10 backlogs. The average registration times were 6 months for Senegal and 3 months for Republic of Guinea for 2007. It needs to be said that this section has many gaps; to start with, only 3 out of 11countries filled this section. The backlogs and average registration times were also not filled for some years by some countries.

2.3.3.4 Factory inspection

Inspection of factories where manufacturing of the medicines are undertaken is an important aspect of the medicines registration process. It depends on availability of technical experts who may not be available in the individual countries. Joint inspection can be undertaken to minimize cost of factory inspection.

Six countries (Cape Verde, Ghana, Mali, Nigeria, Republic of Guinea and Senegal) have factory inspection policies, while there are no policies in Burkina Faso, Gambia, Guinea Bissau and Senegal. In Liberia and Togo policies are still being developed. The policies are freely available to applicants in the 6 countries mentioned above, and Liberia is still developing a policy. The policy is published on NMRA website in Mali and Nigeria while it is included in the guidelines/policy document in Ghana, Liberia, Nigeria and Republic of Guinea. Cape Verde uses other unidentified means.

Seven countries (Gambia, Ghana, Mali, Nigeria, Republic of Guinea, Senegal and Togo) inspect factories outside their own borders as part of the registration process. Burkina Faso, Cape Verde and Liberia do not have such policies. In Gambia the process is not mandatory. Manufacturer's track record is a strong indication for factory inspection in 6 countries namely: Gambia, Ghana, Mali, Nigeria, Senegal and Togo. With the exception of Nigeria, in the remaining 5 of these countries, product risk is taken into account if a factory inspection is required. Factory approval by a recognized competent authority is important in 5 countries (Gambia, Ghana, Mali, Republic of Guinea and Senegal), while product approval by another competent authority is important in Gambia, Nigeria and Senegal. WHO-PQ is taken into account by Gambia, Mali, Republic of Guinea and Senegal. Stringent Regulatory Authority (SRA) approval is important in Ghana and the Republic of Guinea. In Nigeria PICS is taken into account to determine if a factory inspection is required. Inspection will not be performed in Gambia if there is WHO-PQ, SRA approval granted by other regional bodies. In Ghana and Nigeria, inspection will not be done for companies in Europe and USA with valid GMP certificates with low risk products. In emergency situations and when there is lack of resources, the Republic of Guinea will not undertake a factory inspection.

2.3.3.5 Medicine samples tested for registration

An important aspect of medicine registration is the testing of samples to ensure their efficacy. This is done pre and post marketing of the approved medicines.

Nine countries, (Burkina Faso, Cape Verde, Ghana, Liberia, Mali, Nigeria, Republic of Guinea, Senegal and Togo) test medicine samples before registration, while this is not done in Gambia. However, Gambia in addition to the above 9 countries, carries out post-marketing surveillance. Although Niger does not carry out post marketing surveillance, the CSM may require a quality control prior to the issuance of the marketing authorization when it comes to generics.

The sample requirement in terms of number, type of batches and packaging vary from country to country. However this ultimately depends on the dossier submitted for registration. The samples are tested in national quality control laboratory in 5 countries (Burkina Faso, Ghana, Mali, Republic of Guinea and Senegal). The government analyst also performs the tests in Burkina Faso while local academic institutions and private laboratories are responsible for testing in Cape Verde. Quality control laboratories abroad are used in 7 countries (Liberia, Cape Verde, Gambia, Ghana, Niger, Republic of Guinea and Togo). Cape Verde, Burkina Faso, Gambia and Ghana also use mini laboratories which are either regional or in the districts. The law also provides for the registration of other products in 10 countries (Cape Verde, Gambia, Ghana, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal and Togo). These products include veterinary medicines in 7 countries (Cape Verde, Gambia, Ghana, Liberia, Mali, Nigeria and Republic of Guinea). Vaccines/biological are registered in 11 countries which includes additional 4 countries (Burkina Faso, Niger, Senegal and Togo). Traditional medicines are registered in 8 countries (Burkina Faso, Ghana, Liberia, Mali, Niger, Nigeria, Republic of Guinea and Senegal). Medical devises are legislated for registration in 6 countries (Burkina Faso, Gambia, Ghana, Liberia, Nigeria, and Republic of Guinea) while cosmetics are registered in Ghana, Liberia, Nigeria, Senegal and Togo. Prepackaged foods are registered in the above named countries with the exception of Liberia with Niger. Household chemical substances are registered in Nigeria while Ghana registers chemicals, detergents and water.

2.3.3.6 Conclusion and recommendations

Certain problems were identified in the responses given by NMRAs in the questionnaire. In the first instance only 10 NMRAs responded to this section on medicine registration systems. Amongst the NMRAs, responses to questions on application for prioritization, receipt of applications and factory inspection were given by only a few countries. In some sections responses were about 40% making it difficult to make conclusions. This may be due to lack of capacity. It was observed that only 5 countries responded to the section on applications for all the medicines for HIV/AIDS, TB, Malaria, NCEs and Generic products. Only 2 countries answered the question on percentage application reviewed within target. Although the number of backlogs recordedwas small, it has to be borne in mind that very limited statistics were provided by the 4 countries that responded. It is therefore recommended that:

a) Capacities of the NMRAs need to be improved to enable them to fulfill their statutory legal and regulatory functions.

b) Registration of medicines needs to be vigorously embarked on by the NMRAs. Factors responsible for the small number of registered medicines need to be determined so that remedial action can be taken.

c) In countries with resource constraints, sharing of information and facilities to register medicines in the sub-region must be encouraged.

d) The NMRAs that did not respond or provide statistics must be encouraged to do so. It might be necessary for a follow-up exercise to be carried out in future where all the NMRAs participate, so that an accurate picture can emerge.

2.4 Benefits and challenges of regional medicines regulatory harmonisation in ECOWAS

The NMRAs face challenges and experience benefits when it comes to harmonisation of medicines regulation in the sub-region. These are indicated in Table 10.

Table 10: Challenges, benefits and issues needed to support medicine registrations.

Country	Challenges	Benefits	Issues needing addressing
Burkina Faso	There are several programs for harmonisation The need to review each time the regulations Not all countries are at same level of technical performance	Having the same standards Information sharing Communication	Create for certain products, the possibility of having a centralized procedure Having a system of performance evaluation of WRNI so as to have in the region, one or two referent NMRAs Having a platform for sharing information within the region
Gambia	Weak NMRAs may heavily depend on others and spend little resources on capacity building Smaller markets may be overlooked Conflict of interest	Fast track registration Easy access to information across member countries Promote inter regional trade	Free movement of people and goods Common customs tariff Introduce budget line for regulatory authorities activities
Ghana	Inadequate knowledge of regulatory systems and processes of sister countries. Lack of communication between regulatory agencies within the sub region	Better control of medicines used in the sub region Reduction of substandard and counterfeit medicines in the sub region Upgrade of skills of regulatory staff in the area of registration within the sub region	Sharing of information among countries Training of regulatory staff so that staff come to same levels of understanding Commitment of member countries to own the harmonisation process and push for its success
Guinea Bissau	No existence of NMRA and its legal framework/legislative	Have the same level of information Have the same database on harmonisation what will build trust between MRA Strengthen political cooperation Mitigating or reducing duplication of registration Protect the regional market	Decision makers from political advocacy Collaboration, collection and compilation of records already available (WAHO,UEMOA/ MRA) support the regional pharmaceutical industries in good manufacturing practices

Country	Challenges	Benefits	Issues needing addressing
Liberia	The Liberia Medicines and Health Products Regulatory Authority was established in September, 2010 by an Act of the Legislature; it has no operational budget due to its enactment after the national budget was already finalized; Limited manpower and training	Effective coordination and collaboration Training opportunities Mechanisms for fast track registration for certain products	UEMOA-WAHO relationship Training opportunities for newly established NMRAs Identification of opportunities for technical support to newly established NMRAs
Niger	Problem of duplication of guidelines between UEMOA and WAHO	Effective coordination and collaboration Training opportunities Mechanisms for fast track registration for certain products	What is the program and the process that ECOWAS will adopt to achieve harmonisation of drug registration? Are there already strategies to strengthen the capacity of countries to submit NMRAs in this perspective? What are the programs planned by the organization regarding the recommendations of the evaluation used by NMRAs?
Nigeria	Different Capacity Political Will	Shortens decision time (enhances marketing authorization)	Build Technical and Human capacity Build Political Will Enhanced quality control capacity
Togo	To be at the same level on registration on the sub regional level	Facilitate the evaluation of dossiers for market approval	Will the NMRAs be on the same level with registration? Will the objectives of building capacity for the NMRAs be achieved?
Republic of Guinea		Decrease of poor quality drugs circulating in the sub-region The introduction of a single registration system for a pharmaceutical valid for the entire sub-region improving the implementation of regulatory functions	NMRA exists in all countries Sufficient staff in quality and quantity formed to implement the policies Means for the implementation of the National Pharmaceutical Policy (NPP)
Senegal		The granting of the MA will be more or less automatic if the manufacturer meets the requirements of the NMRA.	Hopefully, this harmonisation is beneficial for all member States

The NMRAs in Nigeria and the Republic of Guinea RECs identified important issues to facilitate harmonisation of medicine regulation. These are:

a) The work already done at UEMOA should be operationalized and moved to other states to adopt a broader level to enable progress;

b) Dedicated commitment to strengthening the capacity of NMRAs should be developed further; and

c) The rational use of medicines in the sub region and commitment to curbing the illicit drug market should be ensured.

Recommendations

To ensure greater value for harmonisation and benefits, the REC and associated NMRAs should:

a) Develop a regional programme for harmonising medicine registrations;

b) Build capacity for better sharing of resources;

c) Have greater awareness and appreciation of the benefits; and

d) Catalyze NMRA and REC political cooperation on harmonisation of medicine registrations.

2.5 STATUS OF FINANCIAL AND HUMAN RESOURCES IN NMRAs

2.5.1 SOURCES AND LEVEL OF FUNDING

The sources of NMRA financing are government subvention, industry fees and donor funding. In Burkina Faso, subvention from Government is 40% while in the Republic of Guinea, it is only 4%. Industry fees constitute 25% in the Republic of Guinea. The main donor partners are UNFPA, WHO and the EU. In Burkina Faso, Republic of Guinea and Republic Guinea, the donor contribution is 60, 15 and 20% respectively. The NMRA in Cape Verde, Liberia, Niger, Nigeria and Togo retain the whole amount due from industry fees while Burkina Faso, Ghana and the Republic of Guinea retain part of the total collection. The regulatory authorities in Burkina Faso, Gambia, Guinea Bissau, Mali and Senegal do not retain any fees. In this regard, the Ministry of Finance is responsible for sharing the industry fees. For example, Burkina Faso provide 20% of the total collections to the NMRA as discounts for staff at year end while the Republic of Guinea ensures that 50% is set aside for the NMRA. The collected industry fees are used to:

a) run the day to day financial needs of FDB in Ghana;

b) support the office operations such as production of data processing forms, payment of utility bills in Liberia;

c) capacity building including paying allowances for day to day management of the agency in Nigeria;

d) support the operation of the National Directorate of Pharmacy and Laboratory in the Republic of Guinea;

e) production and distribution of documents in the Republic of Guinea;

f) procurement and maintenance of equipment in the Republic of Guinea; and

g) support the Ministry of Health in Togo.

Recommendation

To strengthen NMRA programmes, adequate funding is required to support operations and regional activities. Consequently,

a) Government should provide adequate subvention to support programme implementation

b) NMRAs should access and use most of the industry fee

2.5.2 Health and pharmaceutical human resources in NMRAs and REC

Details of Health and Pharmaceutical Institutions and human resources in the ECOWAS region are provided in Table 11. The NMRAs have different human capacities responsible for medicine evaluations, distribution chain inspections, GMP inspections and laboratory analysis. The variation is also obtaining in the number of evaluators and associated specialized expertise for evaluating the quality and safety data. This seems to be dependent on the number of training institutions across the region. Ghana and Republic of Guinea has the highest numbers of physicians with over1500 each; while Cape Verde, Gambia, Mali and Nigeria did not indicate any numbers.

The NMRAs in Cape Verde, Ghana, Liberia, Nigeria and Senegal have a human resource development plan supporting the human capacity and capital development. Burkina Faso, Gambia, Guinea Bissau, Mali, Niger and Togo have yet to develop their own HRM plans. The Gambia is expected to develop one as part of its plan of action.

Table 11: Health and Pharmaceutical institutions and Human Resource for ECOWAS

Country	Burkina Faso	Cape Verde	Gambia	Ghana	Guinea Bissau	Liberia	Mali	Niger	Nigeria	Republic of Guinea	Togo	Senegal	TOTAL
No. of medical schools	4		1				1	1	12	2		1	
No. of pharmacy schools	1	0	0	3	1	1	1	0	8	2	1	1	
No. of other related schools	1	0	3	19	0	8	0	0	0		1		
No. of physicians	473			2968	150	160		405		1708	394	450	
No. of dentists	33			111	6	4		17		45		80	
No. of other medicines prescribers	697					425		2643		5771			
Total no. of pharmacists	2575	65	14	1637	15			140	15064	900	201	1200	
Total no. of pharmacy technicians	2170	3	1	177	40			5	1403	185			
Total no. of other formally trained pharmacy support staff	442		45	2801				1					

The human resource available in ECOWAS to facilitate medicine regulatory activities (evaluators, inspectors and Laboratory Analysts) is provided in Table 12.

Table 12: Human Resource Capacity for facilitating medicine regulatory activities in ECOWAS

Regulatory function	Established Posts	Filled Posts	Number of Qualified				Number of Specialized Training
			Diploma	BSc	MSc	PhD	
Evaluators	24	27		17	7	9	
Inspections (Total)							
Distribution Chain	21	14	0	12	0	2	20
GMP	7	10	0	10	2	3	2
Laboratory Analysis	9	33	8	20	5		6
Total	61	84	8	59	14	14	28

The summary of human resource facilitating medicine regulatory activities in ECOWAS reveals that the largest proportion hold a first degree.

2.5.2.1 Recommendations

The NMRAs and REC need to address the following:

a) Countries with medical personnel should support others;

b) NMRAs without the HRM plans should develop and implement their own plans;

c) Utilizing the human capital across the REC should be encouraged;

d) Investments in the training of the human capital for efficient implementation of various functions of regulation should be made; and

e) The REC should add value to the statistics of medical and ancillary personnel by keeping accurate records.

2.6 Pharmaceutical manufacturing sector in ECOWAS

2.6.1 Industry information

In the ECOWAS region, Nigeria has 100 manufacturing plants awhile Cote d'Ivoire has eight, and they produce the same number of generic products. Nigeria has 20-research based companies. The data reveals that all pharmaceutical companies are both research based and owned by the nationals in either country. It is interesting that Nigeria churns out 100 generic products while Cote d'Ivoire only five. The region has several industry associations working together promoting the manufacturing, importing, exporting and marketing of pharmaceutical products. For example, Nigeria has a national association of pharmaceutical manufacturers- the Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria (PMGMAN) while there is none in Cote d'Ivoire. In the former country, four pharmaceutical associations exist:

a) Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria (PMGMAN)

b) Nigeria Representatives of Overseas Pharmaceutical Manufacturers (NIROPHARM)

c) Association of Pharmaceutical Importers in Nigeria (APIN)

d) Indian Pharmaceutical Manufacturers and Importers in Nigeria (IPMIN)

These associations draw membership from pharmaceutical manufacturers, representatives of research-based overseas manufacturers, pharma importers and Indian pharma-business respectively.

Two regional associations obtain in the region: The West African Pharma Manufacturers Association (WAPMA), which was established in 2005 with the Secretariat in Accra. Its members are mostly from Nigeria and Ghana. The WAPMA is open to all pharmaceutical manufacturers. There is valuable interaction between the Pharmaceutical Industry and the NMRAs in Nigeria and this means that understanding the requirements for drug approval is required in Cote d'Ivoire. Both Cote d'Ivoire and Nigeria need the special notice and trademark issues respectively to be addressed in the harmonisation process. Industry identified main bottlenecks in getting a medicine registered. Their main frustrations are:

a) Obtaining the MA's prior from the countries origin

b) Adherence to definite timeframe

c) Harmonised SOPs for vetting samples, dossiers and inspection

d) Speed of laboratory analyses

e) Availability of reference standards, and

f) Data management (NAFDAC) in the process of establishing a robust database.

Industry and their associations receive adequate information from the NMRAs. In Cote d'Ivoire, the NMRA (i) provides useful and necessary information to manufacturers of pharmaceuticals, (ii) supports the industry to the best of its ability and (iii) ensures the pharmaceutical manufacturers know all the conditions for obtaining authorization to market. Similarly, the Nigerian NMRA (NAFDAC) adequately communicates with industry through its robust website and holds regular consultative meetings with industries. Due to this enormous support, industry considers an effective medicine registration process that provides reduced time for obtaining the MA, Standard Operating Procedures (SOPs) and ensure an on-line processing mechanisms.

In both countries, mechanisms have been developed which catalyses interactions between the industry and the NMRAs. In Cote d'Ivoire, a platform for regular exchange of information exists while in Nigeria, there are (i) consultations/consultative meetings, (ii) policy and regulation development and evolution and (iii) collaborative and facilitative regulations.

Industry generally has good and acceptable experiences in the medicine registration process/ system. The process is good and satisfactory in terms of effectiveness and efficiency. The REC engages industry very well since WAHO supports and engages the Nigerian Industry. This is further consolidated through the ECOWAS private sector desk. In order to achieve better partnership, the following are recorded:

a) Computerizing the procedure for submission of market authorization

b) Establishing an electronic archive/database

c) Providing continuous training for NMRA Staff

d) Facilitating recognition of Lab results from Public Analysis to ease pressure on NMRA Labs, and

e) Establishing bioequivalence facilities within ECOWAS

Industry further recommends that (i) the procedure for receiving documents for the processing of Market authorization and (ii) Timeline for Registration process should be made more efficient while the SOPs should be readily available.

Industry has varied views on the medicine regulatory harmonisation focusing on registration in the region. The industry in Ivory Coast welcomes the initiative while that in Nigeria appear cautiously optimistic. However, the industry in Nigeria expects benefits from medicines registration harmonisation. These are the elimination of duplications and better conservation of time and resources. However, industry in the same country feels strongly that the process is associated with major drawbacks such as risk of dumping, trust and erratic political will. Industry has previous experiences in medicines registration harmonisation and has thus greater understanding and reciprocity exists between Nigeria and Ghana. The success however is dependent on a gradual process recommended and more advocacy required in Nigeria. Consequently, industry expects the following for the harmonisation process:

a) Gradual processes being implemented;

b) Trust building;

c) Adequate advocacy implemented ;

d) Importers of medicines should not capitalize on MRH by registering in countries of relatively relaxed processes as a means of avoiding stringent regulatory scrutiny; and

e) Adequate checks and balances are strongly recommended.

Table 13: Pharmaceutical Production Status as provided by NMRAs for ECOWAS in 2010/2011

Country	Burkina Faso	Cape Verde	Gambia	Ghana	Guinea Bissau	Liberia	Mali	Niger	Nigeria	Republic of Guinea	Senegal	Togo	Total
Total number of pharmaceutical manufacturing plants	1	INPHARMA	0	38	0	-	1	1	216	1	4	3	
Total number of research based pharmaceutical industries	0	1	0	0	0	1	-	-	20	1	15	0	
Total number of Generic pharmaceutical products (including branded generics) manufacturers	0	1	0	38	0	-	0	1	216	1	3	2	
Total number of pharmaceutical plants owned by nationals (Government and Private)	1	1	0	34 nationals, 4 foreigners	0	-	0	1	216	0	0	1	

Table 14: Distribution of Pharmaceutical Industries in ECOWAS

Country	Burkina Faso	Cape Verde	Gambia	Ghana	Guinea Bissau	Liberia	Mali	Niger	Nigeria	Republic of Guinea	Senegal	Togo	TOTAL
Importers	-	1	10	50	2	12	38	38	407	32	9	-	
Wholesalers	-	0	10	477	0	18	50	15	607	32	7	7	
Government Hospital Pharmacies	-	3	6	123	100	19	9	8	-		22	53	
Private for Profit Pharmacies in 2010	-	33	10	1417	0	137	418	99	-	368	917	187	
Private not for Profit Pharmacies	-	0	10	188	0	400	0	3	-	-	1	NC	
Retailers Pharmacies	550 (private depots), 44 (DRD), 1352 (DMEG)	-	180	-	0	424	0	-	-	379	-	-	

2.6.1.1 Recommendation

The REC and NMRAs need full participation for a growing industry and greater profits from this sector. Therefore:

a) The REC and NMRAs should engage the industry and associations on the developments of medicine harmonisation registration, sharing clearly the benefits of medicine registration harmonisation;

b) Each NMRA should promote the establishment of national associations, where this is absent;

c) The REC and NMRA should dialogue with Governments to provide conducive environment for business ventures; and

d) Industries should be encouraged to form associations wherever this is possible.

2.6.2 Information sharing and stakeholders engagement

The NMRAs should engage various stakeholders to inform them on medicine regulatory processes in their country. The objective of the consultation is to:

a) Enhance better collaboration for the implementation of regulatory activities;

b) Make stakeholders part of the regulatory process and get their views in shaping the same;

c) Ensure the support and cooperation of all stakeholders;

d) Catalyze joint technical evaluation of registration documents; and

e) Engage partners in the Technical Committee for Drug Registration (CTEM) and expert committees and activities of DGPML

Nine countries (Burkina Faso, Gambia, Ghana, Mali, Nigeria, Liberia, Republic of Guinea, Senegal and Togo) have mechanisms for engagement of stakeholders, while Niger has no such mechanism. In the 9 countries the objective and procedures for engagement of the stakeholders vary. In Burkina Faso, the stakeholders are members of the technical committee for drug registration and are regularly invited to the activities of DGPML. In Gambia, they enhance better collaboration for the implementation of regulatory activities. In Ghana they are made part of the regulatory process and their views are sought in this regard. The procedure used include, stakeholder meetings, training programmes, circulars and issuing of health professional letters. In Liberia, the support and cooperation of all stakeholders is ensured, this is through formal communication and holding of stakeholders meetings. Togo engages its stakeholders through evaluation of registration documents.

The NMRAs publish medicines regulation guidelines widely to the public in Burkina Faso, Ghana, Liberia, Mali, Niger, Nigeria, Republic of Guinea, Senegal and Togo. This is achieved through the NMRAs website, making them freely available to applicants on request and selling to the potential applicants.

Six countries (Burkina Faso (www.dgpml.sante.gov), Ghana (www.fdghana.gov.gh), Mali (www.dirpharma.org), Niger (not included), Nigeria (www.nafdac.gov.ng) and Senegal (www.dirpharma.sentoo.sn) have a website while Gambia, Liberia, Republic of Guinea, Togo do not. for the website for Cape Verde is under construction. Important information on the websites include legislation in Mali and Nigeria, Guidelines in Burkina Faso, Ghana and Nigeria, Fees in Burkina Faso and Ghana, a list of registered products in Burkina Faso, Ghana and Nigeria, a list of rejected products in Burkina Faso, a list of banned products in Ghana and Nigeria. The list of authorized manufacturers was not specified. Various methods are utilized to disseminate information. For example, Burkina Faso produces hard copy and CD ROM for the national list of specialities and authorized generics. Nigeria utilizes official gazette, NAFDAC bulletins, NAFDAC guidelines and the Republic of Guinea publishes national nomenclature of pharmaceuticals and generics business each year. In Gambia, Ghana, Liberia, Mali, Niger, and Republic of Guinea the guidelines are sold to applicants on request.

2.6.2.1 Recommendation

The REC and NMRAs need to strengthen effective information access and sharing amongst themselves and with various stakeholders. Consequently, the following should be undertaken:

a) frequent updates of the websites giving recent information and resource materials

b) Developing proactive dialogue meetings with stakeholders

2.7 Conclusions and recommendations

2.7.1 Conclusions

NMRAs in the ECOWAS region are actively participating in various initiatives towards medicine registration harmonisation. Several countries are involved in similar activities in UEMOA for example. Concerted efforts and consolidation of regional medicines harmonisation are required to achieve access to safer, quality, more affordable and highly efficacious medicines by the communities. Therefore the following recommendations are made.

2.7.2 Recommendations

To facilitate greater medicine registration harmonisation, the region needs to address various issues relating to legislative framework, registration of medicines, sharing of information and capacity building.

2.7.2.1 Legal framework

ECOWAS member states need to fast track the change of national laws regulating medicines so as to have a harmonised regional platform for accessing safe, quality and efficacious medicines. According to Article 9 of the Treaty, a decision may be passed by the Heads of State that compels member states to change the domestic legislations within specific time-frames in favor of the harmonisation of medicine regulation. After the decision has passed, each member state will be bound to publish in the gazette to facilitate it to become domestic law. This may shorten the parliamentary process of making laws. The other option would be for the region to have another protocol to complement the protocol that established WAHO. Both the recommended decision and a protocol, (whichever is perceived to suit the region) on harmonisation of regulation of medicines is recommended to take into account among others things the following:

a) Application of approximate medicine regulation laws which leads to uniform application of medicine registration and documentation in the region;

b) Use of common procedures for decision on approval of medicines registration which encourages the precedent to the subsequent application for registration in any other member state NMRAs;

c) Elimination of internal registration barriers that impede access to affordable medicines by all member states;

d) Harmonise registration charges of equivalent cost and remove discriminatory treatment to medicines registered among member states;

e) Export promotion and competitiveness through various incentive schemes on medicines within the region;

f) Medicine laws be made with provisions that recognize decisions of each Member State to take precedence over the subsequent laws; provided that the safety, quality and efficacy of medicine is not compromised;

g) The countries that do not have in place mission statements drawn out from the existing legislation and policies that regulate medicines, should be encouraged to have their missions in place so as to set the broad direction of the overall goal of government commitment to safe and quality medicines; and

h) To allow better and conducive environment for harmonisation of regulatory functions, it is recommended that WAHO as an already existing platform for the region on matters of health maintains oversight of the implementation status of these recommendations.

2.7.2.2 Registration of medicines

Certain problems were identified in the responses of the NMRAs to the questionnaire. In the first instance only 10 NMRAs responded to this section on medicine registration systems. Amongst the NMRAs, responses to questions on application for prioritization, receipt of applications and factory inspection were given by only a few countries. In some sections responses were about 40%, thus making it difficult to make conclusions. This may be due to lack of capacity. It was observed that only 5 countries responded to the section on applications for all the medicines for HIV/AIDS, TB, Malaria, NCEs and Generic products. Only 2 countries answered the question on the percentage of

application reviewed within target. Although the number of backlogs was small, it has to be borne in mind that very limited statistics were provided by the 4 countries that responded. It is therefore recommended that:

a) Capacities of the NMRAs needs to be improved to enable them to fulfill their statutory legal and regulatory functions;

b) Registration of medicines needs to be vigorously embarked on by the NMRAs. Factors responsible for the small number of registered medicines need to be determined so that remedial action can be taken;

c) In countries with resource constraints, sharing of information and facilities to register medicines in the sub-region must be encouraged;

d) The NMRAs that did not respond or provide statistics must be encouraged to do so. It might be necessary for a follow-up exercise to be carried out in future where all the NMRAs participate, so that a correct picture can be seen; and

e) A regional programme for harmonising medicine registrations should be developed.

2.7.2.3 Sharing of information and stakeholder consultation

The REC and NMRAs need full participation for a growing industry and greater profits from this sector. Therefore:

a) The REC and NMRAs should engage the industry and associations on the developments of medicine harmonisation registration, sharing clearly the benefits of medicine registration harmonisation;

b) Each NMRA should promote the establishment of national associations, where this is absent;

c) The REC and NMRA should dialogue with Governments and other stakeholders to provide a conducive environment for business ventures;

d) Industries should be encouraged to form associations wherever this is possible;

e) The REC and NMRAs need to strengthen effective information access and sharing amongst themselves and with various stakeholders; and

f) The REC and NMRA should regularly update websites giving recent information and resource materials.

2.7.2.4. Capacity building

a) To ensure greater value for harmonisation and benefits, the REC and associated NMRAs should build capacity for better sharing of resources;

b) To strengthen NMRA programmes, adequate funding is required to support operations and regional activities. Consequently, Government should provide adequate subvention to support programme implementation and NMRAs should access and use most of the industry fees;

c) In order to address human resource constraints the following is recommended: countries with medical personnel should support others; NMRAs without HRM plans should develop and implement them; Utilization of the human capital across the REC should be harnessed; investment in the training of the human capital for efficient implementation of various functions of regulation is mandatory; and the REC should add value to the statistics of medical and ancillary personnel by improving record keeping.

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APPENDIX 1

CONTACT DETAILS OF RESPONDENTS TO THE ASSESSMENT INSTRUMENT FROM THE ECONOMIC COMMUNITY OF THE WEST AFRICAN STATES (ECOWAS)

Country/ Region	Affiliation	Name of Institution	Head of the Institution	Position	Contact details			
					Address	Telephone/Cell	Email	Website
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	PM**							

Country/ Region	Affiliation	Name of Institution	Head of the Institution	Position	Contact details			
					Address	Telephone/Cell	Email	Website
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