PROJECT INFORMATION DOCUMENT (PID)
IDENTIFICATION/CONCEPT STAGE

Report No.: PIDC46860

Project Name	West African Medicines Regulatory Harmonization
Region	AFRICA
Country	Western Africa
Lending Instrument	IPF
Project ID	P158363
Borrower Name	West Africa Health Organization (WAHO)
Implementing Agency	, Laboratório e Medicamento -Direcção-Geral de Estabelecimentos de Cuidados de Saúde, Directeur de la Pharmacie et du Médicament, Agência de Regulação e Supervisãode Produtos Farmacêuticos e Alimentares (ARFA), Pharmacy of Medicines and Diagnostiques (DPMED), Food and Drugs Authority (FDA), Liberia Medicine & Health Products Regulation Authority (LMHRA), National Agency for Food and Drug Administration and Control (NAFDAC), National de la Pharmacie et des Laboratoires Ministère de la Santé, Directeur général de la pharmacie, du médicament et des laboratoires, Directrice de la Pharmacie et du Médicament de la Côte d'Ivoire, Ministry of Health, Pharmacy, National Pharmaceutical Services, Pharmacy Board of Sierra Leone, la Pharmacie et duMédicament du Sénégal, la Pharmacie, du Médicament et desLaboratoires
Environment Category	C - Not Required
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Initiation Note Review Decision	The review did authorize the preparation to continue

I. Introduction and Context

Country Context

The Economic Community of West African States (ECOWAS), which comprises 15 countries (Benin, Burkina Faso, Capo Verde, Cote d?Ivoire, The Gambia, Ghana, Guinea, Guinea Bissau, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone, and Togo), is home to more than 310 million people. ECOWAS is a regional organization that serves to promote economic integration across the West Africa region. The region is very heterogeneous in terms of cultural, economic and human development. Overall, member states rank low on the United Nations Development Programme's (UNDP) human development index ; as of 2014, life expectancy at birth and gross national income per capita of countries in the region ranged from 45.6 to 75.1 years and $873 to $6,365 respectively.

Sectoral and Institutional Context

Access to medicines is a key element of a well-functioning health system. Strong governance of the

pharmaceutical sector and effective, independent, and transparent regulatory systems provide the necessary foundation for greater access to medicines.

Every country is obligated to regulate the pharmaceutical products sold within its borders. This includes, among others, pre-approval and scientific assessment of essential medicines (registration) so that citizens can access these medicines and be assured that they meet acceptable standards of safety, quality, and efficacy. But several constraints exist in fulfilling these obligations in developing countries especially in the Africa Region. Recent assessments by the World Health Organization (WHO) revealed that the fifteen countries in the West Africa Region do not have sufficient regulatory capacity to approve medicines for sale in a timely manner ensuring acceptable quality, safety, and efficacy standards. Lack of standardization and cumbersome and non-transparent processes for medicine registration impose huge demand on the manufacturers registering new drugs. They are often confronted with numerous and different regulatory requirements, delays in registration, and lack of transparency in the process. As a result, the availability of some much-needed medicines and vaccines for neglected tropical diseases and high burden diseases is delayed.

Harmonization of medicines regulation is a global trend, being led by the International Conference for Harmonization (ICH). Through ICH, developed countries have been working together for several decades to align their regulatory processes and establish a framework for division of labor and mutual recognition. While full global harmonization will be difficult to achieve, there has been an increasing convergence of technical standards and risk assessment concepts between the leading global agencies (USA, Europe and Japan) that is increasingly being adopted by large developing countries with significant exports into the developed world. Harmonization and international collaboration are simply common sense in an environment in which the demands on regulatory agencies are increasing in sync with the complexity of the regulated products and the growing risk awareness in societies. They also make a lot of economic sense as every interaction with a regulatory agency is associated with high labor costs on the side of the regulated industry, in particular if the documentation requirements are not standardized across countries.

The ECOWAS member or partner states are committed to a regional cooperation and integration framework. This commitment is outlined in the ECOWAS Treaty which calls for partner states to effectively align areas of common interest. Additionally, the West African Health Organisation (WAHO) was formed in 1987 when the Heads of State and Government from all fifteen ECOWAS countries adopted the Protocol creating the organisation. The Protocol, ratified by each ECOWAS government, grants WAHO status as a Specialised Agency 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." Since March 2000, WAHO has been the proactive instrument of regional health integration that enables high-impact and cost-effective interventions and programmes by: (i) Maintaining sustainable partnerships; (ii) Strengthening capacity building; (iii) Collecting, interpreting and disseminating information; (iv) Promoting cooperation and ensuring coordination and advocacy; and, (v) Exploiting information communication technologies.

Relationship to CAS/CPS/CPF

The proposed grant is line with the Bank's mission to end extreme poverty and promote shared prosperity. Insufficient availability of affordable and efficacious medicines is a major constraint to the health and potential earnings of people living in the ECOWAS region and have the greatest impact on the most vulnerable population. Medicines regulation is a core public health function and improved governance and harmonization with international standards will improve the availability of more efficacious medicines for neglected diseases as well as promote the growth of the local pharmaceutical industry. The project is also aligned with pillar III of the Regional Integration Assistance Strategy (RIAS) for the region (approved by the Board in 2008) "Building coordinated interventions to provide regional public goods." The RIAS specifically identifies regional and sub-regional programs to address the cross-border dimensions of disease prevention and treatment as an area of focus. An update of the RIAS Strategy went to the Board in April 2011 endorsing the overall thrust of the strategy. Specifically, it fits under Pillar III of the RIAS, as it will: (i) build capacities of NMRAs to harmonize policies, strategies and actions for the registration of essential medicines and vaccines, and (ii) promote coordinated cross country response in the West Africa region for the improved quality of essential medicines.

The AMRH initiative is well aligned with the HNP GP 2015-2030 Strategy that aims at ending preventable deaths by 2030 through Universal Health Coverage (UHC). The strategy would ensure that there would be 80% coverage of essential health services for the poorest 40% of the population and that all countries would score 80% or more in the "Health in All Policies Index." Health in All Policies (HiAP) is an approach to public policies across sectors that systematically takes into account the health and health systems implications of decisions, seeks synergies, and avoids harmful health impacts, in order to improve population health and health equity. Promoting the harmonization of medicines registration in Africa as a means to increase access to safe, effective, and good-quality essential medicines is an integral part of a well-functioning health system and therefore has a strong strategic fit with the health systems strengthening (HSS) and UHC focus of the Bank. Furthermore, there is a strong economic justification as harmonizing registration systems and protocols across several countries helps in reducing inefficiencies. This is expected to promote growth of the local pharmaceutical industry and make the region more attractive for potential foreign investors/manufacturers.

Finally, the health sector strategies of the fifteen ECOWAS countries recognize the burden of communicable and emergence of non-communicable diseases and the need to control them. Country Partnership Frameworks (CPFs) recently endorsed to guide the partnership between the World Bank and those countries include goals to strengthen the health systems, expand universal health coverage and promote regional integration.

II. Project Development Objective(s)

Proposed Development Objective(s)

To improve the availability of quality and safe medicines and vaccines in the Economic Community of West African States pharmaceutical market by harmonizing registration systems, improving efficiency and enhancing transparency in medicines and vaccines registration.

Key Results

The following results will be used to assess the grant performance:

i. Joint registration documents (guidelines and Common Technical Document format) are developed with WHO support and approved by ECOWAS MRH Steering Committee;
ii. At least 6 NMRAs participating in a joint assessment of submitted application(s) for registration of medicines/vaccines and taking the outcome as a basis for their regulatory decision;
iii. 6 or more NMRAs have functional websites and are sharing regulatory policies, legislation, guidelines and information on registered medicines and vaccines; and
iv. 4 or more NMRAs in the ECOWAS region have applied for International Standards Organization (ISO-9001) certification on quality management system for at least one (1) department.

III. Preliminary Description

Concept Description

Over the past five years, discussions on medicines regulatory harmonization have been taking place within African regional political structures and among various development partners. The consultative process will continue to be utilized to inform the detailed project design, which will enhance the capacities of the NMRAs of ECOWAS member countries for efficient and effective medicines registration processes via a collaborative regional approach that builds on the successes in Eastern Africa.

The grant will be financed by the multi-donor trust fund managed by the HNP GP. The project will be implemented by WAHO (West African Health Organization), which is in the best position for coordinating between WAEMU and the 15 NMRAs. The trust fund has already provided funding for WHO (for technical assistance provided to NMRAs within the context of the AMRH project to the East African Community) and NEPAD (capacity building for the technical and governance bodies created under AMRH, M&E support and troubleshooting of potential institutional bottlenecks that need higher level political intervention. Ongoing support from these two partners is expected and funding will be assured either from the Trust Fund or through direct financing from Gates Foundation or other donors. Gates Foundation has shown a very high commitment to the AMRH project and has been providing direct funding support to other partners and work streams in parallel to our trust fund.

IV. Safeguard Policies that Might Apply

Safeguard Policies Triggered by the Project	Yes	No	TBD
Environmental Assessment OP/BP 4.01		×	
Natural Habitats OP/BP 4.04		×	
Forests OP/BP 4.36		×	
Pest Management OP 4.09		×	
Physical Cultural Resources OP/BP 4.11		×	
Indigenous Peoples OP/BP 4.10		×	
Involuntary Resettlement OP/BP 4.12		×	
Safety of Dams OP/BP 4.37		×	
Projects on International Waterways OP/BP 7.50		×	
Projects in Disputed Areas OP/BP 7.60		×	

V. Financing *(in USD Million)*

Total Project Cost:	3	Total Bank Financing:	0
Financing Gap:	0		

Financing Source	**Amount**
Pharmaceutical Governance Fund	3

VI. Contact point

World Bank

Contact: Aissatou Diack
Title: Senior Health Specialist
Tel: 223-207-0223
Email: adiack@worldbank.org

Contact: Andreas Seiter
Title: Senior Health Specialist
Tel: 473-3629
Email: aseiter@worldbank.org

Borrower/Client/Recipient

Name: West Africa Health Organization (WAHO)
Contact: Xavier Crespin
Title: Dr.
Tel: 01122620970100
Email: wahooas@wahooas.org

Implementing Agencies

Name: , Laboratório e Medicamento -Direcção-Geral de Estabelecimentos de Cuidados de Saúde
Contact: Zeferina GOMES DA COSTA
Title: Dr.
Tel: 0112456183741
Email: zeferinagomes2011@hotmail.com

Name: Directeur de la Pharmacie et du Médicament
Contact: Yaya Coulibaly
Title: Dr.
Tel:
Email: Couliyaya2003@yahoo.fr

Name: Agência de Regulação e Supervisãode Produtos Farmacêuticos e Alimentares (ARFA)
Contact: Carla Djamila Reis
Title: Dr.
Tel: 0112382626410
Email: djamila.reis@arfa.gov.cv

Name: Pharmacy of Medicines and Diagnostiques (DPMED)
Contact: Christian Frederic Loko
Title: Prof.
Tel: 0110000000
Email: lochrifresim@outlook.com

Name: Food and Drugs Authority (FDA)
Contact: Hudu Mogtari
Title: Mr.
Tel: 01100000

Email: hudumogtari@yahoo.co.uk

Name: Liberia Medicine & Health Products Regulation Authority (LMHRA)
Contact: David Sumo
Title:
Tel: 011231886562019
Email: d.sumo@yahoo.com

Name: National Agency for Food and Drug Administration and Control (NAFDAC)
Contact: Paul Orhii
Title: Dr.
Tel: 0112348050442033
Email: paulorhii@yahoo.com

Name: National de la Pharmacie et des Laboratoires Ministère de la Santé
Contact: Kabine Souare
Title: Dr.
Tel: 011224628733804
Email: drsouare_kabine@yahoo.fr

Name: Directeur général de la pharmacie, du médicament et des laboratoires
Contact: Rasmané Semde
Title: Prof
Tel:
Email: rsemde@yahoo.fr

Name: Directrice de la Pharmacie et du Médicament de la Côte d'Ivoire
Contact: Rachelle Duncan
Title: Dr.
Tel: 01122501133674
Email: rachdunc2002@yahoo.fr

Name: Ministry of Health, Pharmacy
Contact: Messan Halimatou Allassane
Title: Dr.
Tel:
Email: docmeshali@yahoo.fr

Name: National Pharmaceutical Services
Contact: Markieu JANNEH KAIRA
Title: Mrs.
Tel: 0112209950777
Email: markieu@yahoo.co.uk

Name: Pharmacy Board of Sierra Leone
Contact: Wiltshire Johnson
Title: Mr.
Tel: 01123276602031
Email: marvic@hotmail.com

Name: la Pharmacie et duMédicament du Sénégal
Contact: Amadou Moctar DlEYE
Title: Prof
Tel: 011221338224420
Email: ctdieye@yahoo.fr

Name: la Pharmacie, du Médicament et desLaboratoires
Contact: Atany Nyansa
Title: Dr.

Tel: 01122890206221
Email: bnyansa@yahoo.fr

VII. For more information contact:

The InfoShop
The World Bank
1818 H Street, NW
Washington, D.C. 20433
Telephone: (202) 458-4500
Fax: (202) 522-1500
Web: http://www.worldbank.org/infoshop

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