

INTEGRATED SAFEGUARDS DATA SHEET

IDENTIFICATION / CONCEPT STAGE

Report No.: ISDSC16068

Date ISDS Prepared/Updated: 17-May-2016

I. BASIC INFORMATION

A. Basic Project Data

Country:	Western Africa	Project ID:	P158363
Project Name:	West African Medicines Regulatory Harmonization		
Team Leader(s):	Aissatou Diack, Andreas Seiter		
Estimated Date of Approval:	31-Oct-2016		
Managing Unit:	GHN07	Lending Instrument:	IPF
Financing (in USD Million)			
Total Project Cost:	3	Total Bank Financing:	0
Financing Gap:	0		
Financing Source			Amount
Pharmaceutical Governance Fund			3
Environment Category:	C - Not Required		

B. Project 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.

C. Project 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.

D. Project location and salient physical characteristics relevant to the safeguard analysis (if known)

The ongoing operation will be implemented within the fifteen ECOWAS member countries namely Benin, Burkina Faso, Capo Verde, Cote d'Ivoire, Gambia, Ghana, Guinea, Guinea Bissau, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone, and Togo.

E. Borrower's Institutional Capacity for Safeguard Policies

The Borrower is WAHO but the project will be implemented by each ECOWAS member country. Given that, the evaluation of safeguard management was based on the institutional capacity of each member country of the ECOWAS. Having say that, most member countries have benefitted from other IDA projects which provided sufficient capacity for understanding and applying safeguard policies. That means the implementing countries have adequate institutional and legal framework that would ensure satisfactory compliance with World Bank safeguard Policies. In particular, the Bank's involvement in the health sector has been significant and the clients have shown sufficient capacity and goodwill in implementing World Bank funded projects.

F. Environmental and Social Safeguards Specialists on the Team

II. SAFEGUARD POLICIES THAT MIGHT APPLY

Safeguard Policies	Triggered?	Explanation (Optional)
Environmental Assessment OP/ BP 4.01	No	The project aims to improve the condition of the pharmaceutical market in the Economic Community of West African States by harmonizing medicines registration systems, improving efficiency and enhancing transparency in medicines registration. To achieve that activities expected to be supported by the project are: training, meetings, joint regulatory inspections and dossier evaluations, inter-regional study tours and workshops, mentoring initiatives, consultant support and capacity buildings. Consequently, no civil works or activities will be undertaken within this operation which are associated with any adverse environmental impact. Taking this into account, the policy is not triggered and no environmental safeguard instrument is required because no adverse impacts are expected. Only best practices will be applied during the project implementation.
Natural Habitats OP/BP 4.04	No	The project is not expected to impact critical natural habitats.

Forests OP/BP 4.36	No	The project is not expected to have substantial impacts on Forests in the participating countries.
Pest Management OP 4.09	No	The project does not involve pest management.
Physical Cultural Resources OP/BP 4.11	No	The project activities are not expected to infringe or impact any social and cultural artifacts in the region.
Indigenous Peoples OP/BP 4.10	No	There are no Indigenous Peoples as defined by the World Bank in any member country of the ECOWAS
Involuntary Resettlement OP/BP 4.12	No	The project will not include any involuntary resettlement, land acquisition or restriction of access to resources.
Safety of Dams OP/BP 4.37	No	The implementation of the project will not entail the construction of new dam neither will any of the project activities rely on the performance of an existing dam or a dam under construction (DUC) that draw directly from a reservoir controlled by an existing dam or a DUC; diversion dams or hydraulic structures downstream from an existing dam or a DUC, where failure of the upstream dam could cause extensive damage to or failure of the new Bank-funded structure.
Projects on International Waterways OP/BP 7.50	No	This project will not involve extraction of water from any international waterways (any river, canal, lake, or similar body of water that forms a boundary between, or any river or body of surface water that flows through, two or more states, whether Bank members or not). In addition, the project will not impact any tributary or other body of surface water that is a component of any waterway described above.
Projects in Disputed Areas OP/BP 7.60	No	The project will not be located in Disputed Areas as defined by OP/BP 7.60.

III. SAFEGUARD PREPARATION PLAN

Appraisal stage ISDS required?: No

IV. APPROVALS

Team Leader(s):	Name: Aissatou Diack, Andreas Seiter	
Approved By:		
Safeguards Advisor:	Name: Maman-Sani Issa (SA)	Date: 16-May-2016
Practice Manager/ Manager:	Name: Trina S. Haque (PMGR)	Date: 17-Jun-2016

¹ Reminder: The Bank's Disclosure Policy requires that safeguard-related documents be disclosed before appraisal (i) at the InfoShop and (ii) in country, at publicly accessible locations and in a form and language that are accessible to potentially affected persons.