PROJECT INFORMATION DOCUMENT (PID)
ADDITIONAL FINANCING

Report No.: PIDA26027

Project Name	Africa Medicine Regulatory Harmonization Project (P155163)
Parent Project Name	AFCC2/RI-African Medicines Regulatory Harmonization Project (P128332)
Region	AFRICA
Country	Eastern Africa
Sector(s)	Health (100%)
Theme(s)	Health system performance (100%)
Lending Instrument	Investment Project Financing
Project ID	P155163
Parent Project ID	P128332
Borrower(s)	World Health Organization
Implementing Agency	NEPAD
Environmental Category	C-Not Required
Date PID Prepared/Updated	11-Jan-2016
Date PID Approved/Disclosed	11-Jan-2016
Estimated Date of Appraisal Completion	25-Jan-2016
Estimated Date of First Grant Approval	29-Feb-2016
Appraisal Review Decision (from Decision Note)	The review did authorize the team to appraise and negotiate

I. Project Context

Country Context

Context and Development Challenges

1. This project was established to address some of the key weaknesses faced by the six EAC NMRAs in the region in developing and implementing medicine registration procedures compatible with internationally accepted standards. The project is coordinated by the EAC Secretariat and implemented by the Partner States with technical support from the NEPAD and WHO. Supplementary grants were provided to the WHO and NEPAD to conduct technical assistance to EAC MRH project and enhance coordination. The East African Community, under the EAC treaty, has a regional integration agenda and the EAC Secretariat has been delegated the responsibility of coordinating regional activities leading to achievement of articles in the Treaty relating to health. In the project, these activities include organization of twinning programmes, training activities and meetings and ensuring participation of partner states. Through a virtual budget, EAC controlled and disbursed funds for activities and Partner states ensured that they benefited from the planned

activities. EAC entered into separate memoranda of understanding with WHO and NEPAD for effective collaboration under the Africa medicines regulatory harmonization programme.

2. The conditions for Additional Financing are met. The June 2014 mid-term review confirmed the project's satisfactory performance. The project has complied with all legal covenants and there are no outstanding audit issues. The activities to be supported through the AF are fully consistent with the current PDO which remains highly relevant and unchanged.

3. Consistent with the World Bank Guidelines for AF under OP 10.00, Investment Project Financing, the proposed AF to EAC and NEPAD is intended to address both a financing gap and for scaling up the development effectiveness of the project. The original project was intended to be implemented over five years. However, only a three year project was approved due to limitation of resources in the MDTF. The June 2014 Mid-Term Review recommended a second phase to build on the good progress towards the achievement of the development objective. Most of the planned activities (development of guidelines and standards, obtaining the necessary approvals and training in their use) have been completed. The second phase under AF is expected to support the project scale up in EAC partner states to maximize developmental impact and results by the effective implementation of the harmonized guidelines for medicines registration and good manufacturing practices. In the second phase of the project, most activities will be implemented at national level. These activities will mainly entail joint evaluation of Marketing Authorization applications and joint inspections of pharmaceutical factories for Good Manufacturing Practices. Installation and commissioning of the integrated information management system is expected to be completed during this period. The integrated IMS solution will complement the video conferencing equipment already installed in the NMRAs and a synergy will be created to expedite joint activities such as work sharing, sharing of regulatory information and this is expected to increase efficiency of NMRAs and expedited processes leading to increasing access to medicines in the region. The proposed addition of a new activity to monitor medicines safety, pharmacovigilance, will support efforts to enhance patient safety. The proposed AF will thus have a strong focus on country level implementation and regional experience sharing. The AF to NEPAD will enable it to sustain its TA to the project with a focus on political advocacy and enhancing coordination among partners and stakeholders.

4. During the MTR, the key challenges identified for the project (broader sectoral issues and project specific implementation constraints) were extensively discussed, including specific actions required under the proposed AF to ensure sustainability of the initiative. The World Bank Group, through its International Finance Corporation (IFC), is extending support for development of harmonized policies and laws and the NEPAD is working with the EAC Partner States NMRAs to establish Centers of Excellence in medicine regulation which will contribute to the sustainability of this project. The video conferencing equipment and shared IMS platforms procured under the project will expedite effective and timely information sharing and interactions between NMRAs.

5. With its strong convening power and effective fiduciary oversight, the World Bank continues to be uniquely placed to support the consolidation of results under AMRH and scale up of selective interventions. The Bank's ongoing engagement and policy dialogue at country and regional levels and proven ability to develop and scale-up standardized approaches for public sector reforms to improve services for the poor makes it a natural choice to support the AMRH initiative. Furthermore, the Bank can also draw lessons learned from the first phase of the AMRH effort and

address them to maximize impact. Following the MTR, the EAC and Partner States NMRAs have designed comprehensive action plans for this second phase of the program.

Sectoral and institutional Context

Sector and Institutional Context

1. Access to essential medicines is a key element of a well-functioning health system and every country is obliged to regulate the quality and price of pharmaceutical products circulating within its borders. Harmonization of medicine regulation is a global trend and led by the International Conference for Harmonization (ICH). The African Medicine Regulatory Harmonization (AMRH) initiative has been in existence for over five years and has successfully engaged key stakeholders to develop this sub-regional initiative in the African Continent. Donors have supported this initiative and financed the creation of a multi-donor trust fund hosted by the World Bank for the initial phase. Recognizing EAC's efforts to harmonize medicines regulation, the ICH has formally accepted EAC as a member of its global cooperation group. EAC is the first Regional Economic Community (REC) to secure a grant from the World Bank MDTF. Lessons learned from the first phase will inform both the second phase of implementation within the EAC member states as well as the design of similar initiatives with other RECs.

2. The EAC has played an important role in galvanizing commitment and helping member states to coordinate activities. EAC is a regional intergovernmental organization consisting of five partner states (Burundi, Kenya, Rwanda, Tanzania and Uganda) with a combined estimated population of about 135 million and a combined gross domestic product of roughly US$41 billion. The EAC Partner States remain highly committed to regional cooperation on medicines regulation. This commitment is outlined in the EAC Treaty of 1999 and the EAC Common Market Protocol of 2005 which calls for Partner States to effectively align their regulatory policies, strategies and practices. The six NMRAs in the EAC vary widely in institutional capacity and infrastructure as well as requirements to register new medicines. As a result, manufacturers have to fill multiple forms to obtain licenses to market new products which delays access to new medicines for the people of East Africa. Moreover, these inefficiencies adversely affect the growth of the local industry as well as access to vital, essential and necessary medicines to treat diseases of public health importance. Also, with variations in capacity and licensing requirements among the NMRAs, there is a continuing high risk of poor quality medicines circulating within the EAC Partner States.

3. The proposed AF complements and builds on activities supported by other development partners that have been collaborating with African regulators through capacity building activities. For example, WHO with funding from the EU and the Bill and Melinda Gates Foundation (BMGF) established an exchange program for technical staff from developing country NMRAs to work in the WHO Prequalification Program in Copenhagen and Geneva and to participate in WHO-led assessments. USAID supported a training center for medicines quality testing in Tanzania and assisted regulators in upgrading their national control laboratories. The German agency for international development (GIZ) assisted the Kenyan Pharmacy and Poisons Board for several years in strengthening their national drug quality control laboratory until it achieved WHO Prequalification. The Tanzanian Food and Drug Authority (TFDA) has already secured ISO 9001 certification and achieved WHO Prequalification for its drug quality control laboratory. The national laboratories of Kenya and Uganda have also been prequalified by WHO. Most heads of NMRAs in the EAC region as well as their staff have participated in these activities, which facilitated collaboration between the NMRAs and ensured that the experience from the past was

applied to the project.

4. Developments in the regional pharmaceutical industry have had a positive impact, strengthening the environment in which the AMRH Project is being carried out. With assistance mainly from Germany and UNIDO, professional associations were established and training offered for local manufacturers to better understand modern regulatory concepts and to allow them to compete in international markets (for example to enable them to bid for Global Fund financed procurements). With these ongoing initiatives, a positive relationship evolved between manufacturers and the regulators and more advanced manufacturers are supportive of stricter regulation that keeps sub-standard competitors out of their markets. Manufacturers also demand transparency of the regulatory process and adherence to global practices and standards in the required documentation.

II. Proposed Development Objectives

A. Current Project Development Objectives – Parent

To harmonize medicines registration systems and to improve efficiency and enhance transparency in medicines registration among the East African Community Partner States.

III. Project Description

Component Name

Regional Coordination and Capacity Building for Medicines Regulatory Harmonisation

Comments (optional)

The component will support completion of harmonized protocols at regional level and their adoption at national level; capacity building programmes; operations of the Regional Steering Committee in its oversight role; a Project Coordination Team for the day to day operational activity and reporting; and the Regional Technical Working Groups established under the project namely: medicines registration, current Good Manufacturing Practices inspection; information management systems; and quality management. An integrated information management system for for work and information sharing will be completed and installed. A sub component will be added to monitor quality of medicines and patient safety and strengthen pharmacovigilance in the EAC partner states.

Component Name

Institutional Development and Strengthening of National Medicines Regulatory Authorities

Comments (optional)

There are no changes proposed under this component. The project will continue to support capacity building of NMRAs, including support for additional staff training in areas of project management, assessment of quality and safety of medicines, and GMP inspections and twinning of newly established NMRAs with existing NMRAs in the region and implementation of quality management systems, including internal and external quality audits. Additional funding of $0.5 Million has been provided for NEPAD for political advocacy, scientific conference on medicines regulation in Africa and technical support to Regional Centers of Excellence (R Cores) and other regional economic communities (RECs) in Africa to develop new proposals for support under AMRH.

IV. Financing *(in USD Million)*

Total Project Cost:	3.90	Total Bank Financing:	0.00

Financing Gap:	0.00	

For Loans/Credits/Others	Amount
Borrower	0.00
Pharmaceutical Governance Fund	3.90
Total	3.90

V. Implementation

The PDO and the project components will be maintained under the AF.

VI. Safeguard Policies (including public consultation)

Safeguard Policies Triggered by the Project	Yes	No
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		×

Comments (optional)

VII. Contact point

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