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Report No: ICR127371

IMPLEMENTATION COMPLETION AND RESULTS REPORT

TF 10846, TF 12036 and TF A-2289

ON

GRANTS

IN THE AMOUNT OF US$ 10.449 MILLION

TO THE

EAST AFRICAN COMMUNITY
AND
NEW PARTNERSHIP FOR AFRICA'S DEVELOPMENT AGENCY

FOR THE

AFCC2/RI-AFRICAN MEDICINES REGULATORY HARMONIZATION PROJECT (P128332)

June 29, 2018

Health, Nutrition & Population Global Practice
Africa Region

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CURRENCY EQUIVALENTS

Exchange Rate Effective November 9, 2017

FISCAL YEAR
July 1 - June 30

Regional Vice President:	Makhtar Diop
Country Director:	Paul Noumba Um
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ABBREVIATIONS AND ACRONYMS

AF	Additional Financing
AM	Aide Memoire
AMRH	African Medicine Regulatory Harmonization
AU	African Union
BE	Bioequivalence
BMGF	Bill & Melinda Gates Foundation
CDC	Center for Disease Control
CHAI	Clinton Health Access Initiative
CTD	Common Technical Document
EAC	East African Community
ECOWAS	Economic Community of West African States
FM	Financial Management
GCG	Global Cooperation Group
GMP	Good Manufacturing Practices
ICH	International Conference of Harmonization
ICR	Implementation Completion Report
ICT	Information and Communication Technology
IDA	International Development Association
IMS	Information Management System
ISR	Implementation Status and Results Report
JA	Joint Assessment
MER	Medicine Evaluation & Registration
MDTF	Multi Donor Trust Fund
MTR	Mid-Term Review
NEPAD	New Partnership for Africa's Development
NMRA	National Medicine Regulatory Agency
NMRO	National Medicine Regulatory Officer
NPO	National Professional Officer
PAD	Project Appraisal Document
PCN	Project Concept Note
PMPA	Pharmaceutical Manufacturing Plan for Africa
PPB	Pharmacy & Poisons Board
PS	Partner States
PV	Pharmacovigilance
QMS	Quality Management System
REC	Regional Economic Community
RF	Result Framework
RIAS	Regional Integration Assistance Strategy
RTT	Regional Technical Team

RTWG	Regional Technical Working Group
SADC	Southern African Development Community
SC	Steering Committee
SOP	Standard Operating Procedure
TFDA	Tanzania Food & Drug Administration
TMEA	Trade Mark East Africa
TWG	Technical Working Group
UHC	Universal Health Coverage
USAID	United States Agency for International Development
WHO	World Health Organization

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DATASHEET

BASIC INFORMATION

Product Information

Project ID	Project Name
P128332	AFCC2/RI-African Medicines Regulatory Harmonization Project
Country	**Financing Instrument**
Africa	Investment Project Financing
Original EA Category	**Revised EA Category**
Not Required (C)	Not Required (C)

Related Projects

Relationship	Project	Approval	Product Line
Additional Financing	P155163-Africa Medicine Regulatory Harmonization Project	21-Apr-2016	Recipient Executed Activities

Organizations

Borrower	Implementing Agency
East African Community	NEPAD, EAC Secretariat

Project Development Objective (PDO)

Original PDO

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

FINANCING

	Original Amount (US$)	Revised Amount (US$)	Actual Disbursed (US$)
World Bank Financing			
TF-10846	5,549,200	5,549,200	5,549,200
TF-12036	1,500,000	1,500,000	1,500,000
TF-A2289	3,400,000	3,400,000	3,151,184
Total	**10,449,200**	**10,449,200**	**10,200,384**
Non-World Bank Financing			
Borrower	0	0	0
Total	**0**	**0**	**0**
Total Project Cost	**10,449,200**	**10,449,200**	**10,200,384**

KEY DATES

Approval	Effectiveness	MTR Review	Original Closing	Actual Closing
21-Mar-2011	13-Jul-2012	16-May-2014	30-Jun-2017	29-Dec-2017

RESTRUCTURING AND/OR ADDITIONAL FINANCING

Date(s)	Amount Disbursed (US$M)	Key Revisions
31-Dec-2014	4.63	Other Change(s)
11-May-2017	8.85	Change in Loan Closing Date(s)

KEY RATINGS

Outcome	Bank Performance	M&E Quality
Moderately Unsatisfactory	Moderately Unsatisfactory	Modest

RATINGS OF PROJECT PERFORMANCE IN ISRs

No.	Date ISR Archived	DO Rating	IP Rating	Actual Disbursements (US$M)
01	14-Oct-2012	Satisfactory	Satisfactory	0
02	17-May-2013	Satisfactory	Moderately Satisfactory	.50
03	30-Dec-2013	Satisfactory	Moderately Satisfactory	1.49
04	18-May-2014	Satisfactory	Satisfactory	2.53
05	25-Nov-2014	Satisfactory	Satisfactory	3.43
06	11-May-2015	Satisfactory	Satisfactory	4.28
07	01-Dec-2015	Moderately Satisfactory	Moderately Satisfactory	5.44
08	13-Jun-2016	Moderately Satisfactory	Moderately Satisfactory	5.55
09	29-Dec-2016	Moderately Satisfactory	Moderately Satisfactory	7.16
10	30-Jun-2017	Moderately Satisfactory	Moderately Unsatisfactory	9.11
11	28-Dec-2017	Moderately Satisfactory	Moderately Satisfactory	10.20

SECTORS AND THEMES

Sectors

Major Sector/Sector	(%)
Health	**100**
Health	100

Themes

Major Theme/ Theme (Level 2)/ Theme (Level 3)	(%)
Human Development and Gender	**100**
Health Systems and Policies	100
Health System Strengthening	100

ADM STAFF		
Role	**At Approval**	**At ICR**
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I. PROJECT CONTEXT AND DEVELOPMENT OBJECTIVES

A. CONTEXT AT APPRAISAL

Context

1. **Access to medicines** is a tremendous challenge to global public health. According to the WHO World Medicines Situation Report (2011), one third of the world's population lacks access to essential medicines. A significant portion of this population lives in Low and Middle-Income Countries (LMICs), especially in Africa. For these countries to attain Universal Health Coverage (UHC) and meet the SDG (3.8)[1], increased investments are critical not only to ensure that medicines are available and affordable, but also that they are safe, effective, and of good quality.

2. **Health sector challenges**: Strong governance of the pharmaceutical sector and effective, independent, and transparent regulatory systems provide the necessary foundation for greater access to medicines. Each country is obligated to regulate the pharmaceutical products sold on its market in order to assure the safety, quality, and efficacy of these products. However, a National Medicine Regulatory Agency (NMRA) situational assessment conducted by WHO and EAC in 2009[2] showed that countries in the East Africa Region[3] lacked sufficient regulatory capacity to approve medicines for sale on their respective markets in a timely manner. Weak regulatory capacity in the region combined with lack of standardization and non-transparent processes for medicines registration affects availability of essential medicines and vaccines for high burden diseases in the East African Community (EAC). In 2012, East Africa had a high burden of disease, mainly caused by communicable diseases, such as HIV, TB and lower respiratory infections. With nearly 133.5 million inhabitants in the region at the time, treatment of communicable diseases—of which access to medicines is essential—was a major priority.

3. **Global regulatory context**: In 1990, harmonization of medicines registration requirements became a global trend through the International Conference of Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH). This has led to the convergence of technical standards and risk assessment concepts for medicine registration between ICH countries, including the USA, Europe and Japan. The ICH Global Cooperation Group (GCG)[4] facilitates effective engagement and coordination among different regional medicine regulatory harmonization initiatives. The EAC Treaty of 1999, as amended in 2007, established the Partner states medicines regulatory harmonization as a goal. To advance this goal and increase access to medicines, the EAC Council of Ministers endorsed a comprehensive EAC regional proposal for medicine regulatory harmonization. The aim was to strengthen institutional capacity and adhere to standardized norms for medicines regulatory harmonization in the region. In 2010, the ICH formally accepted the EAC as a member of the GCG in recognition of its efforts to promote medicine regulatory harmonization.

[1] SDG 3.8: Achieve universal health coverage including financial risk protection, access to quality to essential healthcare services and access to safe, effective, quality and affordable medicines and vaccines for all.

[2] A situational analysis of NMRAs of Member States was performed by experts from EAC with support of WHIO between 27th July and 28th August 2009 to review the capacity in terms of medicine policy, legal and regulatory framework, procurement, distribution and management within the EAC

[3] Republics of Burundi, Kenya, Rwanda, Uganda and the United Republic of Tanzania.

[4] ICH Global Cooperation Group was formed in 1999 as a subcommittee of the ICH Steering Committee. Its objective is to make information available on ICH activities and guidelines to the public. The GCG created a set of principles intended to guide its activities as it answers request for information and response to non-ICH regulators and industry. For more on the GCG, see *Link*

4. **Sectoral and institutional context**: The EAC has 6 National Medicines Regulatory Agencies (NMRAs)—the Tanzania Food and Drugs Authority (Tanzania, Mainland); Zanzibar Food and Drugs Board (Tanzania, Zanzibar); Pharmacy and Poisons Board (Kenya); Ministry of Public Health (Burundi); Ministry of Health (Rwanda); and National Drug Authority (Uganda)—whose institutional capacity, infrastructure, and medicine registration requirements vary widely. For instance, manufacturers must fill multiple and different forms in each country as they seek to obtain licenses to market new products. In addition, Rwanda and Burundi perform very limited regulatory functions due to a lack of human resources, capacity, and legislative instruments. In the EAC region, these regulatory shortcomings have resulted in: (i) significant delays in the registration and distribution of essential medicines; (ii) poor growth of the local pharmaceutical industry, which is important for improving access to essential medicines; and (iii) high risk of poor quality medicines moving across the EAC Partner States. To address these challenges, several development partners are collaborating with NMRAs in the region to strengthen the various areas of regulatory functions. At the continental level, the African Medicines Regulatory Harmonization (AMRH)[5] initiative was launched in 2009 to establish and improve standards and requirements related to the regulation of and access to safe, high-quality medicines for the African population. Under the AMRH initiative, the World Bank created a Multi Donor Trust Fund (MDTF071682) to support regional economic communities (RECs) to improve regulatory harmonization. Recognizing the alignment of the AMRH initiative with the EAC Treaty of 1999, the EAC Partner States—through the EAC Secretariat and with technical support from the New Partnership for Africa's Development (NEPAD) and WHO—prepared the first regional MRH proposal to receive a grant under the AMRH.

5. **Link to Higher level objectives**. The grant—the EAC Medicine Regulatory Harmonization Project (the Project)—was aligned with the World Bank's "Africa Regional Strategy"[6] to enhance governance and public-sector capacity to improve systems for delivering basic health services. Medicines regulation is a core public health function. Improved governance and harmonization of medicine registration requirements with international standards will improve access to medicines and contribute to improved health outcomes. In addition, the project was fully consistent with the following regional strategies: (i) the Regional Integration Assistance Strategy (RIAS)[7], specifically Pillar III on Coordinated Interventions to provide Regional Public Goods; (ii) the EAC Fourth Strategic Development Plan (2011-2015), which prioritized improving access to safe, effective, affordable and quality medicines (Section 7.4); and (iii) the NEPAD's AMRH Strategic Plan (2011-2015). At the global level, the project contributed to the achievement of SDG 3, which aims to provide access to safe, effective, quality and affordable essential medicines and vaccines – which is important for attaining UHC.

6. **The rationale for the Bank's engagement** in the AMRH initiative was in alignment with two areas of the Bank's global strategies: 1) the 2007 Health Nutrition and Population Strategy which focuses on governance, accountability, and transparency; and 2) the orientation of IDA-16 to support initiatives that foster regional integration. Furthermore, the MDTF (TF071682) supported the effort to facilitate regional medicines

[5]The AMRH Consortium consists of the New Partnership for African Development, (NEPAD) Coordinating Agency, World Health Organization (WHO), Pan African Parliament (PAP), Bill and Melinda Gates Foundation (BGMF), UK Department for International Development (DFID), Clinton Health Access Initiative (CHAI), and Swiss Development Cooperation, US Government.

[6] The Africa Regional Strategy (2011-2021) was developed by the World Bank to support Africa's transformation and provides the framework in which to embed country strategies.

[7]The RIAS provides a strategic framework to guide the World Bank's assistance in support of regional integration and regional programs in Sub-Saharan Africa (SSA).

harmonization in 2 to 3 Regional Economic Communities (RECs) in Africa, with the EAC being the first. The World Bank was uniquely placed not only to facilitate the AMRH initiative, but also to manage the MDTF for the following reasons: (i) strong convening power; (ii) comparative advantage in fiduciary oversight; (iii) complementarity with existing engagement at country and regional levels; and (iv) ability to develop and scale-up standardized approaches for public sector reforms to improve services for the poor.

Project Development Objectives (PDOs)

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

Key Expected Outcomes and Outcome Indicators

8. The key expected outcomes were: harmonized medicines registration systems; improved efficiency in medicines registration; and enhanced transparency in medicines registration among EAC Partner States. The following four PDO indicators were used to measure project performance: (i) NMRAs participating in the harmonized medicine registration based on internationally recognized policies and standards; (ii) NMRAs piloting electronic submission of applications for registering medicines; (iii) NMRAs sharing regulatory policies, legislation, guidelines and information on registered medicines on their websites; (iv) NMRAs receiving International Standards Organization (ISO-9001) certification on quality management system. In addition, there were four intermediate outcome indicators: (i) Harmonized guidelines, including SOPs and manuals for registration of medicines and GMP inspection developed based on internationally recognized policies and standards; (ii) NMRAs operationalizing a common information management system for medicine registration developed by the regional technical working group; (iii) Staff trained in medicine regulation; and (iv) NMRAs implementing quality management systems. An additional intermediate indicator on developing a comprehensive strategy for strengthening pharmacovigilance in EAC Partner States was added during Additional Financing.

9. The Theory of Change presented in Figure 1 illustrates how the project's activities and related outputs were to contribute to the expected outcomes.

Theory of Change

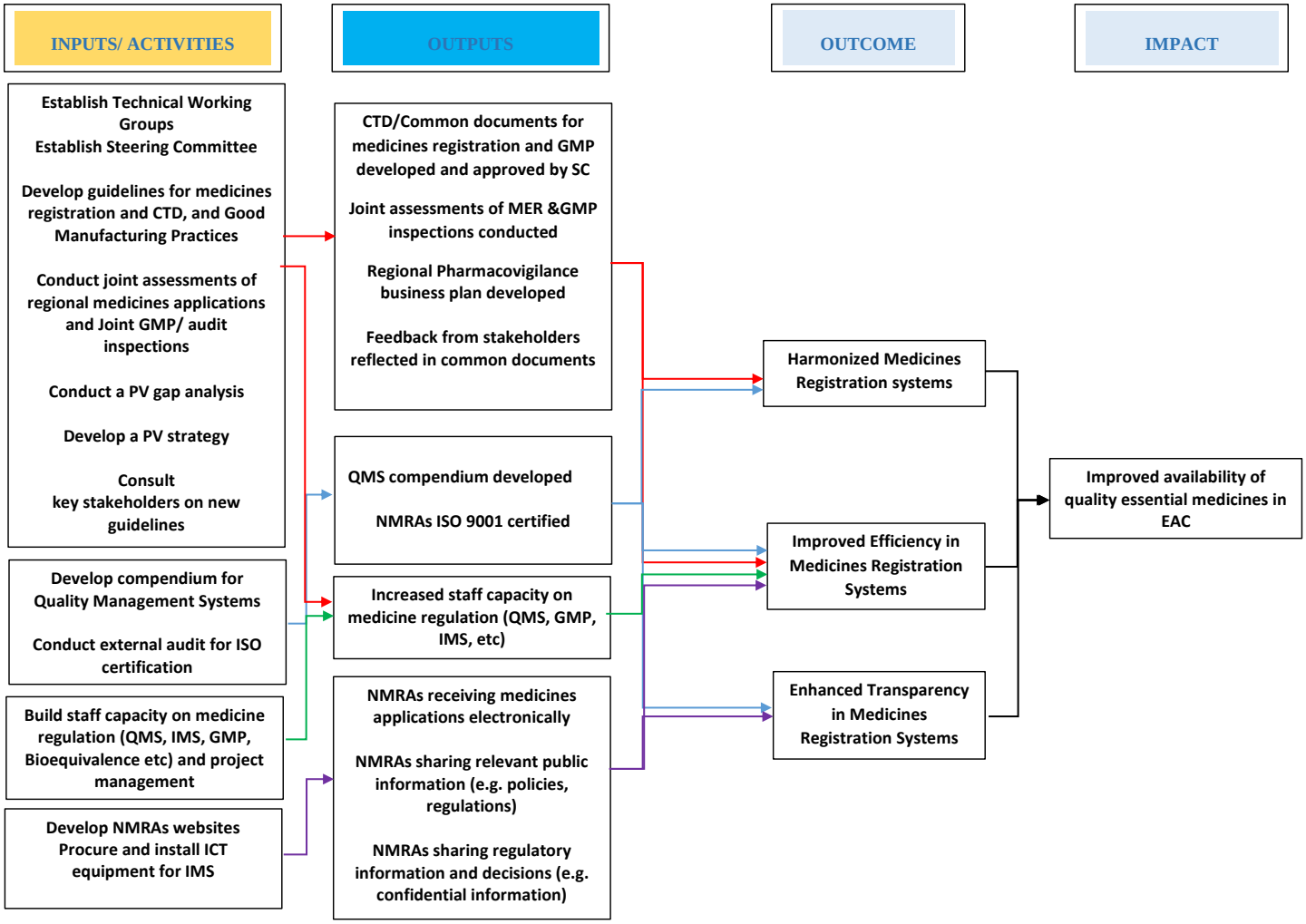

Figure 1: Theory of Change

Components

10. The original project was supported by a grant of US$5.549 million to EAC and US$1 million to NEPAD. The project consisted of two components.

11. **Component 1** - regional coordination and capacity building for medicines regulatory harmonization (US$2.40 million) to support activities of harmonization at regional level and establishment of a regional steering committee for direction and oversight and a project coordination team. The core activities supported by Component 1 included: (i) creating Technical Working Groups(TWGs) for each regulatory function; (ii) developing standardized guidelines and a Common Technical Document (CTD) for medicines registration and GMP by the regional technical working groups; (iv) establishing a Steering Committee; (iv) conducting a Pharmacovigilance (PV) gap analysis and developing a regional PV strategy; (v) stakeholder consultations on standardized guidelines; and (vi) capacity building of NMRA staff.

12. **Component 2** - institutional development of national medicines regulatory authorities (US$3.13 million) to support NMRAs capacity building and activities at national level. Although the activities to be implemented by NEPAD (mainly regional coordination and advocacy) were mentioned as part of Component I, funding for these activities was not allocated from the estimated cost of US$ 2.40 million for this component. Rather, NEPAD was financed (US $1 million – TF12036) by the MDTF under a separate grant agreement signed in September 28, 2012.Component 2 supported activities at the NMRA/country level covering costs of personnel, in-country workshops and consultations, consultant support, supply of ICT equipment and software, and development of QMS and IMS, including development/upgrading of NMRAs websites.

13. To achieve the PDO, the project was to implement the above activities to improve the following medicine regulatory functions at both national and regional levels by standardizing regulatory requirements and enhancing institutional capacity for implementation:

(i) **Medicines Evaluation and Registration (MER)**: Standardization of medicine registration requirements - guidelines, including standard operating procedures (SOPs) and manual for medicines registration based on internationally recognized policies and standards.
(ii) **Good Manufacturing Practice (GMP)**: Standardization of requirements for GMP, which is the minimum standard that medicine manufacturers must meet in their production processes. Typically, as part of medicine registration, a NMRA inspects the manufacturing site of the product submitted for marketing authorization to verify compliance with GMP standards.
(iii) **Quality Management Systems (QMS):** Development and utilization of harmonized Quality Manuals and SOPs, and ISO certification.
(iv) **Information Management Systems (IMS)**: Establishing and operationalizing common information systems for medicines registration.
(v) **Pharmacovigilance(PV)**: Development of a strategy to strengthen PV in the region (added during Additional Financing)

14. In terms of the responsibilities of the implementing partners, at the regional level**,** the EAC Secretariat was responsible for implementing the project through a dedicated Project Coordination Team. NEPAD was responsible for advocacy and engaging with EAC senior policy makers and ministers, as well as facilitating coordination across the regional economic blocks. At the national level, the NMRAs were responsible for project implementation in their respective countries. Each lead NMRA constituted a TWG for which it was responsible. For example, the Tanzania NMRA was the lead for the TWG on Medicines Evaluation and Registration.

B. SIGNIFICANT CHANGES DURING IMPLEMENTATION (IF APPLICABLE)

Revised PDOs and Outcome Targets

15. The PDO remained the same.

Revised PDO Indicators

16. A new activity on Pharmacovigilance (PV) and a corresponding intermediate result indicator were added as part of the Additional Financing project. The new indicator reads as follows: *A comprehensive strategy for strengthening PV in EAC Partners States is prepared.*

Revised Components

17. The original project was intended to be implemented over 5 years. However, a 3-year project was approved due to a limitation of resources in the MDTF. For this reason, and others discussed later, in 2016, Additional Financing of US$3.9million was approved ($3.4 million to EAC and $0.5 million added to NEPAD grant under TF12036) for the project to complete activities and scale-up successful interventions. Although neither of the project components was revised, a new activity on PV was added to Component 1. The aim of this new activity was to develop a strategy to strengthen PV in the EAC region to support efforts to enhance patient safety – a key regulatory function which was not included in the project initially. At the time of AF, the project had supported the following activities: (i) establishment and operation of the Steering Committee; (ii) development of standardized protocols for medicines registration, GMP and QMS; (iii) delivery of a series of capacity building events for the staff of the EAC and NMRAs in medicines registration; and(iv) joint assessment of 5 market authorization applications.

Other Changes

18. Two level II restructurings were approved, in December 2014 and May 2017 respectively, as well as an Additional Financing (in 2016) for the project. Further details are provided below.

19. **First restructuring**: A level II restructuring was approved in December 2014 to extend the Closing Date of the project from December 31, 2014 to June 30, 2016. The restructuring was necessary to prevent the interruption of implementation while the requests from EAC and NEPAD for Additional Financing of the second phase of the project were being considered by the Bank.

20. **Additional Financing (AF)**: An AF in the amount of US$3.4 million and US$0.5 million was granted to the EAC and NEPAD respectively, bringing the total project funds to US$ 10.45 million: $ 1.924,936 was added to Component 1, bringing the total estimated cost to approximately $4.48 million while$1.475, 064 was added to Component 2, increasing its total estimated cost to $4.96 million. The NEPAD Grant (TF12036) increased to $1.5 million. The new disbursement estimates were modified accordingly. The AF supported the EAC to: (i) complete activities being implemented; (ii) scale-up successful interventions in the EAC Partner States to maximize development impact and results; and (iii) sustain NEPAD's technical assistance with a focus on political advocacy and enhancing coordination among partners and stakeholders.

21. **Second restructuring**: A second level II restructuring was approved in May 2017 to extend the Closing Date from June 30, 2017 to December 29, 2017. This was due to multiple factors including implementation delays between the end of activities under the original project and the start of the Additional Financing and political issues such as: (i) the inclusion of South Sudan as a member of the EAC regional economic community in 2016, requiring some adjustments in activities; and (ii) political tensions in Burundi, which slowed down the implementation of the activities requiring participation from all the countries. The inclusion of South Sudan in

the EAC, however, did not significantly impact the cost of project. The project made a conscious effort upon the accession of South Sudan to the EAC to incorporate the country into the project where feasible to allow them to learn from the other countries and build capacity. The inclusion of South Sudan was only for regional and already planned activities. For example, a representative of South Sudan attended the last supervision mission in November 2017 and the Steering Committee held in December 2017. For these reasons, the ICR will not include reference to South Sudan.

22. In addition to updating the RF to include an indicator for PV, the target dates for indicators were changed to align with the new revised Closing Date of December 29, 2017.

Rationale for Changes and Their Implication on the Original Theory of Change

23. As noted earlier, the first level II restructuring was necessary to ensure that ongoing activities would not be interrupted while waiting to get the AF approved. The second level II restructuring, on the other hand, was to complete remaining activities that had been delayed due to political tensions in Burundi. As explained previously, the AF was consistent with the initial plan to extend the project upon successful completion of the first phase of the project and availability of funds. Adding the PV activity was very relevant as it is a fundamental part of a well-functioning medicines regulatory system to ensure the monitoring of medicines and patient safety. Furthermore, the inclusion of PV to the project was important given that a 2009 NMRA situational study showed that the EAC countries significantly lacked capacity in this key area. The above changes were not expected to have any implication on the theory of change as the PDO and the project components essentially remained the same.

II. OUTCOME

A. RELEVANCE OF PDOs

Assessment of Relevance of PDOs and Rating

24. Relevance of PDO is rated as **High**.

25. The project is consistent with Pillar 2 of the World Bank's ten-year Africa Strategy 2011: "vulnerability and resilience", addressing the high risk of idiosyncratic shocks, including health system reforms. Governance and public-sector capacity are the cornerstones of the Africa Strategy (World Bank, 2011).

26. At the (Africa) regional level, the project remains aligned with the agenda set at the continental level as it contributes to promoting access to medicines and developing a scientific and regulatory framework in Africa by building stronger national medicines regulatory authorities. For instance, the African Union Executive Council Decision {EX.CL/Dec.857 (XXVI} in 2015 endorsed the milestones for the establishment of a single medicines regulatory agency in Africa within the context of the AMRH initiative and the Pharmaceutical Manufacturing Plan for Africa framework (PMPA). The AMRH initiative, by aligning with the African medicines regulations, helped to facilitate the implementation of the continental free trade agreement launched in March 2017 that enables free movement of goods, including pharmaceuticals.

27. Similarly, at the EAC level, the project is aligned with the EAC Vision 2050 focusing on access to and distribution of medicines through harmonized health and health-related legislation and regulations. A Regional Pharmaceutical Manufacturing Plan of Action (2017-2027) was approved by the Council of Ministers in 2017 to advance access to medicines goals and to enhance inclusive growth in the health sector. The project is consistent with this plan as developing the local industry by strengthening the regulatory capacity was a key aspect envisaged to improve access to medicines in the region. Furthermore, the project objectives contributed to joint actions towards prevention and control of diseases implemented under the EAC common market by ensuring a strong collaboration across national medicines regulatory agencies to accelerate the availability of good quality medicines in the region.

28. At the national level, all country health sector strategies also support improving access to essential medicines. As an example, the Big Four agenda[8] announced by the Kenyan government in February 2018 focuses on universal health coverage and the development of the local pharmaceutical industry. In Rwanda, the Medical and Pharmaceutical laboratory, which ensures the quality of imported and locally manufactured medicines, is a key component of the 2015 Health Sector Policy. The project supports both priorities by ensuring better regulation of medicines marketed in EAC and enhancing the capacity of local industry through robust regulation.

29. Finally, the project contributes to the development of the main regulatory functions recommended by the WHO as a priority for strengthening national medicines regulatory authorities, namely: (i) product registration; (ii) licensing of manufacturing, importation, and distribution and (iii) control of medicine promotion and information. Therefore, the project's focus on harmonizing regulatory requirements for medicines registration remains highly relevant in the context of improving access to quality, efficacious, and safe medicines in East Africa.

[8] The Big Four Agenda was announced by the Kenyan government on February 2018 and includes 4 priorities to implement by 2022: (i) boosting food security, (ii) rolling out affordable healthcare, (iii) creating 500,000 jobs and (iv) building low-cost housing.

ACHIEVEMENT OF PDOs (EFFICACY)

Assessment of Achievement of Each Objective/Outcome

30. **Achievement of PDO/ Efficacy is rated– Modest.**

The assessment of the project PDO for this ICR is unpacked into the following 3 objectives:

- To harmonize medicines registration systems among the EAC Partner states
- To improve efficiency in medicines registration among the EAC Partner states
- To enhance transparency in medicines registration among the EAC Partner states

The discussion below summarizes achievement of the three objectives.

Harmonization of medicines registration systems among EAC member states: Rating- Modest

31. The PDO indicator for this objective is: *NMRAs participating in the harmonized medicine registration based on internationally recognized policies and standards.* The target, as per the RF, is 3 out of 6 NMRAs, which was exceeded. Although this target was exceeded, harmonization of medicine registration systems (i.e. full interoperability of national systems with regional system) was not achieved as explained below.

32. To achieve this objective, the project sought to standardize requirements for medicines registration, including GMP—which at appraisal stage varied across countries—at national and regional levels. At project appraisal there was no regional procedure for medicine registration. In other words, medicines could only be registered at the national level. Recognizing the critical importance of ownership to the success of the regional harmonization process, the project established many Regional Technical Working Groups (TWG) including —MER, GMP and PV—made up of technical experts from all of the NMRAs to standardize medicines registration requirements for both national and regional applications. For PV, the focus of the TWG was to develop a regional PV strategy. WHO provided technical assistance for the development of the harmonized guidelines. In addition to the establishment of the TWGs, a Project Steering Committee (SC) was established to review and adopt the technical guidelines for the various regulatory areas. To strengthen political buy-in at the highest level within government, NEPAD provided political advocacy by developing an AU Model Law on Medical Products Regulation to facilitate the regional harmonization effort. Tanzania, Zanzibar, Kenya, Rwanda, and Burundi either adopted the Model Law or are currently in the process.

33. By Mid-Term Review (2014), a compendium (Guidelines, SOPs, Manual) for MER and GMP each had been developed by the respective TWG and endorsed by the Steering Committee. In 2015, a Common Technical Document (CTD) was approved and adopted for the region. Since then, 5 out of the 6 NMRAs (except Burundi) have, to a large extent, adapted the compendium and all 6 NMRAs are using the CTD. As the CTD is based on the WHO and ICH CTDs, it is easier for manufacturers to leverage the dossiers they use in most international submissions in the EAC countries. Thus, manufacturers no longer must fill multiple forms in each country in the region to obtain licenses to market new products. The project also met its target of developing a PV strategy for strengthening and harmonizing PV systems in the region. The strategy was developed in September 2017, and presented at the 12th Steering Committee meeting held in Uganda from March 6 to March 9, 2018.

34. Despite the progress noted above, the objective of harmonization of medicines registration systems in the EAC region has not been achieved. This is because standardizing medicines registration requirements per se is not an end but a means to an end. In fact, utilization of standardized requirement at both national and regional levels is necessary for harmonization. To elaborate, so far, the project has succeeded in standardizing medicines registration requirements at both national and regional levels. In terms of utilization, at the EAC level, there seems to be full compliance with the regional standards. However, at country level, compliance has only been partially achieved. In interviews with NMRAs, the ICR team noted that countries were at different levels in terms of utilization of the standards for several reasons: (i) lack of human resources (technical expertise); (ii) lack of physical infrastructure for implementation; and (iii) inconsistency in the application of new standards. For example, in Kenya, due to lack of bioequivalence (BE) study centers in the region, the board of the NMRA (PPB) decided to exempt local manufacturers for BE studies. As a result, Kenya is the only country in the region that allows a waiver for bioequivalence (BE) studies for local manufacturers. See Table 1 below for the status of utilization of the standardized guidelines by country. Given the varying regulatory capacity in the region at appraisal stage, the project team should have been realistic in terms of what was feasible regarding harmonization of medicines registration systems in the EAC region. With 3 less resourced NMRAs in the region –Rwanda, Burundi and Zanzibar (based on the 2009 NMRA situational assessment that informed the project) –attaining harmonization within 5 years was ambitious. Despite this caveat, the indicator for this objective (3 out of 6 NMRAs participated in the harmonized medicines registration system), was met. However, the essence of medicine registration harmonization is to have all countries involved adopting and utilizing the standard requirements. Standardizing the requirements for medicines registration would have been a more appropriate indicator. For these reasons, **achievement of this objective is rated Modest.**

Table 1: Utilization of Standardized Guidelines by Country at project closing

Regulatory areas		Kenya	Tanzania	Uganda	Burundi	Zanzibar	Rwanda	Comments
MER	Introduction of Common Technical document (CTD)	Yes	Yes	Yes	Yes	Yes	Yes	
	Compliance with regional standards for joint assessments	Yes	Yes	Partially	Yes	Yes	Yes	Uganda requires additional information for some products in order to complete the joint assessments process.
	Bioequivalence studies required for generics at national level	No	Yes	Yes	Yes	Yes	Yes	Due to lack of BE study centers in the region, the PPB has exempted local manufacturers of BE studies.
GMP	Recognition of joint GMP inspection certificate	Partially	Partially	Partially	partially	partially	Yes	Lack of clarity on the relationship between a national and regional GMP certification. National GMP inspections are still required.
	Use of standardized GMP guidelines	Yes	Yes	Yes	Partially	Partially	partially	Lack of capacity to fully utilize the standardized guidelines.

QMS	Implementation of QMS and ISO certification	Partially	Yes	Partially	No	Yes	No	Kenya and Uganda were in the process of getting certified. Burundi and Rwanda were not able to implement QMS due to a lack of capacity.

Source: BCG End-term Evaluation Report and key informants' interviews during ICR mission

Improve efficiency in medicines registration among the EAC member States: Rating – Modest

35. To improve efficiency in medicines registration at both national and regional levels, the project supported the following activities:(i) introduction of the CTD format for medicines registration; (ii) introduction of a joint assessment (JA) process; (iii) introduction of joint GMP inspections; (iv) electronic submission of applications; (v) establishment of a QMS system; and (vi) staff training in all regulatory areas. Before the project, it took more than two years on average to register medicines at the national level, including the process for inspection of GMP for registered medicines or new applications. As noted earlier, at the regional level, there was no system in place for medicine registration. Hence, this project established a new system for registering medicines at the regional level. The following explains the extent to which these activities have contributed to improving efficiency in medicines registration.

36. As mentioned earlier, the introduction of a CTD format made medicines registration more efficient by standardizing the format across countries in the region. As a result, the timeline for registration reduced significantly from 24 months on average to 10 to 12 months on average[9]. However, this reduction may not necessarily have been solely due to the CTD format. Other factors to consider are: increased human resource capacity, improved quality of applications, and increased response rate of applicants to queries.[10]

37. As for the JA process, although the project RF did not provide a target, an interview with TFDA, the lead NMRA for MER, confirmed that an informal target of 18 products registered by year 5 was set. Of the 49 applications submitted for JA, only 9 have been recommended for registration between 2014 and December 2017 (Figure 2). In comparison to the ZaZiBoNa Initiative[11] which seeks to harmonize medicines registration systems for 4 countries – Zambia, Zimbabwe, Botswana and Namibia — where 156 products[12] were jointly assessed and 90 of them recommended for registration between July 2015 and November 2017 (within a 2 and half year period), the EAC project target of 18 products was less ambitious. Although both initiatives had different approaches, they had similar objectives, were carried out over a similar period, and presumably had similar capacity to review and recommend applications at the regional level.

[9] Information sourced from Boston Consulting Group end-term evaluation Report and confirmed by clients during the ICR mission.
[10] Information sourced from Boston Consulting Group end-term evaluation.
[11] The ZaZiBoNa Initiative promotes a collaboration model to facilitate access to good-quality medicines through work-sharing in assessment of medicines and inspection of medicine manufacturing and testing facilities among 4 countries: Zambia, Zimbabwe, Botswana and Namibia. For more on this initiative, see *Link*
[12] Information sourced from the Boston Consulting Group end-term evaluation Report.

38. Likewise, the RF did not provide a target for national registrations using the harmonized guidelines. However, various aide memoires (AMs) and clients' progress reports to EAC indicate a target of at least 75 products registered for Kenya, Tanzania and Uganda; and at least 50 products registered for Zanzibar, Rwanda, and Burundi. At project closing, Kenya (1676), Uganda (277), Tanzania (232), and Rwanda (437) surpassed the target. However, Burundi (18) and Zanzibar (42) did not meet the target.

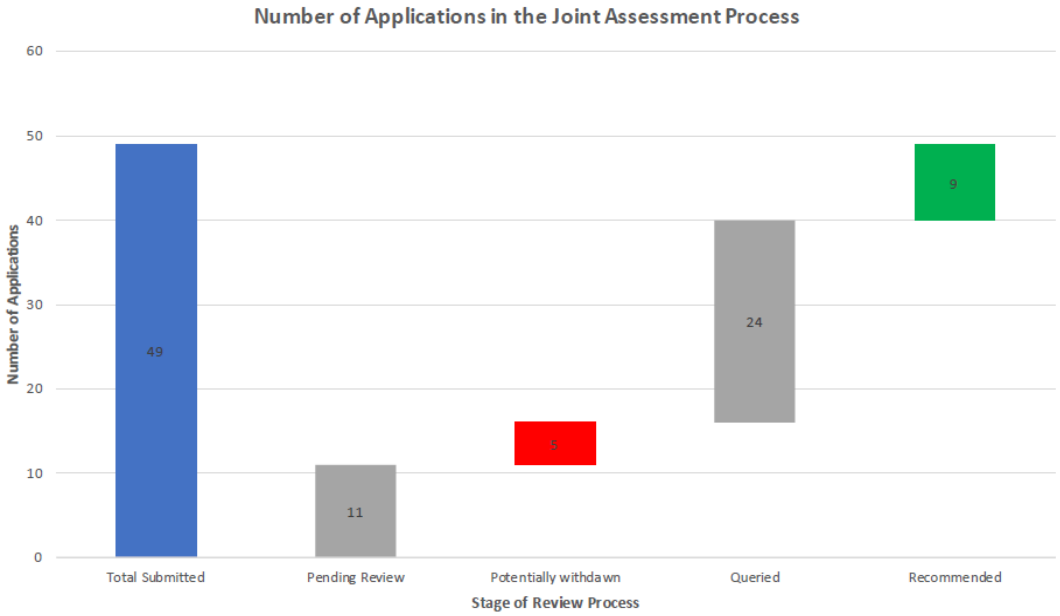

Figure 2[13]: Number of Applications in the Joint Assessment Process between 2014 and December 2017

39. Good Manufacturing Practice (GMP) is a crucial element of a robust registration system. Under the project, 14 joint inspections were conducted and 11 certificates issued as part of the harmonization process. These joint inspections were supposed to reduce the number of inspections conducted by each NMRA, resulting in a more efficient system. As there was no target in the RF nor the AMs for joint inspections, it is difficult to determine whether 14 joint inspections are significant in terms of how they contribute to assessing the achievement of this objective (efficiency). The ICR team notes, though, that this is a commendable achievement since there was no system for joint inspections prior to the project. However, during the ICR mission, NMRAs and other stakeholders raised several challenges associated with the joint inspection system which affects efficiency. Key among these is a lack of clarity on the relationship between a national and regional GMP certification. It is not always clear if a regional GMP certification supersedes a national GMP and would therefore waive the requirement for a national GMP certificate to be renewed if a regional GMP certificate is issued prior to the expiration of a national GMP. In practice, however, this is not the case as national and regional GMPs inspections are conducted in parallel, defeating the very purpose of a joint GMP system. Other challenges included inadequate coordination between the MER and GMP audits for product registration; difficulty with scheduling inspections (inspectors not given enough notice, issuance of travel clearance for inspectors, etc.); and the lack of a single point of contact for the payment of GMP certificate fees.

[13]Information sourced from the Boston Consulting Group End-term Evaluation Report and confirmed by clients during ICR mission.

40. Regarding the electronic submission of applications, all NMRAs started piloting the electronic submission of applications for registering medicines, exceeding the target of 3 NMRAs. Although this indicator is not described in the RF, within the context of medicines registration, electronic submission of applications entails applying through an online platform; whereas application in electronic format involves applying through CD or USB. In the EAC region, NMRAs are currently receiving applications in an electronic format either through their website portals (Uganda, Kenya and Rwanda) or through CDs or USBs (Burundi, Tanzania and Zanzibar). During the ICR mission, most stakeholders applauded this significant milestone in medicines registration, which is contributing to a more efficient system of submission of applications. Linked to electronic submission of applications is an intermediate result indicator for at least 3 countries to have operationalized a common IMS for medicines registration. The aim of the IMS was to facilitate information sharing on medicines registered across NMRAs in order to avoid duplication of efforts in MER and GMP specifically, and the other regulatory areas in general, resulting in improved efficiency. The IMS consists of two components: (i) national systems (NMRAs); and (ii) a regional portal linked to the national systems.

41. At project closing, 4 NMRAs out of 6 (except Burundi and Zanzibar) had either operationalized or upgraded their national IMS to be linked to the regional platform, exceeding the target. The regional portal was developed, but it was not functional at the end of the project. While the target for this indicator was achieved, there is very little (at best) information on medicines registration applications being shared among the NMRAs. Similarly, interoperability remains an issue as IMS in the NMRAs are not the same: the NMRAs in Kenya and Tanzania have different systems from the other NMRAs. Furthermore, there is still a lack of clarity on what kind of information should be shared on medicines registration among the NMRAs and who should have access. While the 10th Steering Committee report gives an indication of information that will be shared among NMRAs through the IMS—including registering of products, registered premises, registered GMP sites, recalls and alerts, Partner States guidelines, laws and policies, client service charters, publications, EAC harmonized technical guidelines and statistical data— this appears to be very comprehensive and would not likely have been achieved within the project period. These issues require policy dialogue by the Council of Ministers to move this agenda forward and ensure cooperation.

42. The implementation of a Quality Management System (QMS) that was supposed to result in ISO certification of NMRAs was also intended to improve efficiency by standardizing and strengthening regulatory and non-regulatory processes in all NMRAs. Only Tanzania and Zanzibar received ISO certification before the end of the project, therefore partially meeting the target of 3 NMRAs. Kenya and Uganda applied for certification and are on track to be certified by June 2018. Uganda became ISO certified in June 2018. Burundi, on the other hand, currently does not have adequate technical and financial capacity to implement a QMS while Rwanda lacks an autonomous regulatory agency. Feedback from the NMRAs during the ICR mission suggests that the establishment of a QMS greatly improved efficiency and quality of work. Specifically, quality of services improved due to a customer survey, better clarity of timelines for every stage of the process for medicines regulation, as well as inputs and outputs for each regulatory function. In sum, a QMS has contributed significantly to improved internal business processes.

43. Finally, the project supported staff training in medicines regulation, which enhanced capacity and contributed to improved efficiency. A total of 233 staff members from NMRAs and the EAC were trained

during the project on areas such as MER, GMP and QMS—surpassing the target of 75 staff set initially. Furthermore, capacity was enhanced through the following: twinning of strong NMRAs with less resourced NMRAs (e.g. Zanzibar mentioned that the twinning activities were very beneficial for the less resourced agencies such as itself); peer-to-peer learning through joint assessments and joint inspections; and cross-country learning through development of guidelines and compendia for different regulatory functions. During the ICR mission, strong improvement in terms of capacity-building for MER and GMP was reported by most of the NMRAs. A WHO Benchmarking study conducted in February 2018 confirmed these improvements, especially for Tanzania, which was rated level 3 on a 4-point scale (with 4 being the highest) of NMRA maturity. Table 2 below summarizes the achievement for the PDO indicators, Intermediate Result Indicators and other indicators used to measure the PDO- 2 objective (efficiency).

Table 2: Achievement and rating of PDO-2 (Efficiency)

PDO Indicator	Intermediate Result Indictor (IRI)	Other Indicator	Baseline	Target	Achievement	Rating of Efficiency
1) NMRAs participating in the harmonized medicines registration based on internationally recognized policies and standards	1) Harmonized guidelines including SOPs and manuals for registration of medicines and GMP inspection developed based on internationally recognized policies and standards	Introduction of the CTD format	0	3 NMRAs	6 NMRAs, Target exceeded	Modest
		Joint Assessment	0	***18 products recommended***	Target not achieved	
		Assessments at national level	***0***	***75 products registered by TZ, KQ and UG by year 5 50 products registered by BR, RW and ZR by year 5***	Target not achieved	
		Joint GMP inspections	***0***	***No target set but 14 inspections conducted***	No target set	
2) NMRAs started piloting the electronic submission of applications for registering medicines	No indicator	No indicator	0	3 NMRAs	6 NMRAs, Target exceeded	
No PDO indicator	2) NMRAs operationalizing common information management system for medicine registration developed by the regional technical working group	No indicator	0	3 NMRAs	4 NMRAs, Target exceeded	
No PDO indicator	3) Staff trained in medicine regulation	No indicator	0	75 staff	233 staff, Target exceeded	
4) NMRAs received ISO 9001 certification on quality management systems	4) NMRAs implementing quality management system	No indicator	0	3 NMRAs	2 NMRAs Target partially achieved	

Informal targets (not in the RF) are italicized and bolded. TZ - Tanzania; KQ -Kenya; UG – Uganda; BR -Burundi; RW – Rwanda; and ZR -Zanzibar.

Enhance transparency in medicines registration among the EAC member states: Rating- Substantial

44. The last of the 3 project objectives was to enhance transparency in medicines registration. The PDO indicator for this objective is: NMRAs sharing regulatory policies, legislation, guidelines and information on registered medicines on their website. The target, as per the RF, is 3 out of 6 NMRAs, which was exceeded.

45. To enhance transparency towards the public and among NMRAs, the project supported the development of a regional website and national websites for each NMRA for sharing their respective policies, legislation, guidelines, etc. In assessing this objective, the ICR authors applied the relevant aspects of the Transparency and Confidentiality section of the WHO Benchmarking Tool for the Review of Drug Regulatory Systems, listed and described in Annex 6. This tool was developed to assess national medicines regulatory systems and it defines transparency as "*the degree to which regulatory procedures and decision criteria are made public and communication between the regulatory authority, its clients, and the consumers*".

46. At project closing, a regional website (EAC MRH) had been developed (www.mrh.eac.int). Four NMRAs (Tanzania, Uganda, Kenya and Zanzibar) had either developed or updated their national websites and have links to the EAC MRH website. In the case of Rwanda and Burundi, websites can be accessed through their respective ministries of health. All NMRAs are either sharing most public documents such as regulations and guidelines on their websites or have links to the regional website where such public documents can be found, thus, exceeding the target of 3 NMRAs.

47. Furthermore, efforts were made during the development of standardized guidelines and compendia to involve all stakeholders, including the pharmaceutical sector (local manufacturers, importers, and International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), to provide feedback. For instance, in Kenya, a stakeholder meeting was convened to discuss the implementation of the new guidelines for medicines registration. Tanzania and Zanzibar launched customer satisfaction surveys to improve the quality of services. NMRAs in Kenya, Tanzania and Zanzibar indicated that enhanced transparency has contributed to more accountability and has contributed to increased internally-generated revenue.

Justification of Overall Efficacy Rating

48. Of the 4 PDO indicators, 3 were either achieved or surpassed and one was partially achieved. In terms of intermediate result indicators, all 5 were either achieved or surpassed. Despite these achievements, utilization of standardized documents—which was central to effectively harmonizing medicines registration systems in the sub-region—was not consistent across countries. For this reason, as well as limited national capacity, the project was unable to fully achieve the overall project development objective, which focused on harmonization—rather than standardization. Similarly, there were significant shortcomings in efficiency that led to suboptimal results. Thus, the overall efficacy rating is **Modest.**

Overall PDO	To harmonize medicines registration systems among the EAC member states	To improve efficiency in medicines registration among the EAC member states	To enhance transparency in medicines registration among the EAC member states
Modest	Modest	Modest	Substantial

C. EFFICIENCY

Assessment of Efficiency and Rating - Modest

49. **Implementation efficiency** is considered **Modest**. Project implementation was guided by the Operations Manual which included a detailed execution plan. At project closing, 98 percent of the grant had been disbursed. All the activities including IMS, QMS, and the implementation of the joint activities were started as planned. However, overall efficiency was affected by several factors. Implementation of the project had delays of about 14 months which impacted the planned activities and the expected outcomes. They included (i) delays in recruitment of project staff; (ii) delays in disbursement and (iii) delays in approval of AF. The delays in recruitment due to internal processes and negotiations affected efficiency and slowed down the implementation. The first AM in November 2012 indicated that only regional activities had started, with national activities only beginning in April 2013. Delays in disbursement also occurred during the project. For instance, NMRAs annual reports indicated that these delays resulted in most joint activities not being undertaken on schedule. In addition, the EAC did not provide financial support to NMRAs to implement activities in a timely manner. Lastly, the implementation was interrupted for a period of 6 months due to lack of resources during the period when the AF was being processed. The EAC Secretariat was not able to use retroactive financing made available under the AF due to lack of its own resources or funding from other donors. Although the Operations Manual provided terms of reference for the EAC, NMRAs and partners, implementation efficiency was affected by poor coordination among different stakeholders leading to duplication of effort and suboptimal results. For example, the organization of joint assessments encountered significant delays and led to fewer products having been recommended for registration than planned.

50. Regardless of the above bottlenecks, gains made by each NMRA by implementing the different activities that contributed to institutional strengthening improved the overall efficiency. For instance, through IMS implementation, Kenya PPB increased its revenue significantly and could leverage internal and external resources from the government, Trade Mark East Africa (TMEA), Clinton Health Access Initiative (CHAI) and Center for Disease Control (CDC).

51. **Cost-benefit:** The costs for this project were minimal at US$ 0.06 per person based on an estimated population of 168.8M in the region in 2016 and the total project costs of US$ 10.2M.From an economic point of view, the use of substandard medicines can have serious negative public health externalities, such as the development of medicines resistance, one of the major public health threats. In this case, consuming substandard medicines by single individuals could lead to costs for the entire society in the form of reduced

medicine efficacy and increased risks of death. Thus, from a health systems perspective, effective regulation ensures that already strained resources (public or private) for health are not wasted, and costs for additional medical consultations and hospitalizations are avoided.

52. At the macroeconomic level, the reduction in regulatory barriers and efficiencies through standardized, simplified, and internationally recognized registration processes has been shown to be associated with greater domestic and foreign investments, which, in turn, are expected to create jobs and boost the economic productivity of the country. A recent study by the University of Cambridge (2012) demonstrated that the regional harmonization of the regulatory framework in Eastern Africa brings significant economic benefits to both regulators and pharmaceutical companies. Under a scenario of harmonized medicines regulation, the 5-year costs per product for pharmaceutical companies were estimated to drop from US$ 5.7M to US$ 1.7M, while the 5-year revenue for the regulator was to increase from US$72,800 to US$ 117,200. Furthermore, assuming a 50 percent increase in the number of medicines registered in the region because of the improved registration process, the regulator's 5-year revenue is expected to increase from US$ 52.2 million to US$ 140.6 million.

D. JUSTIFICATION OF OVERALL OUTCOME RATING

Overall Rating	Relevance	Efficacy	Efficiency
Moderately Unsatisfactory	High	Modest	Modest

E. OTHEROUTCOMESANDIMPACTS (IFANY)

Gender

53. The design of the project did not specifically consider the project's direct impact on gender. Both the PAD and AF documents name the following as the key beneficiaries of the project: NMRAs, Ministries of Health, and citizens of East African Community Partner States. For this reason, there is no data available measuring positive or negative impact on gender. The ICR authors note, however, that many female technical staff from the NMRAs and EAC benefitted from the numerous capacity building activities supported by the project to strengthen institutional capacity. 32 percent of staff trained in various aspects of medicines regulation were female. Furthermore, medicines for reproductive health and for children were considered in the call for Expression of Interest for applicants.

Institutional Strengthening

54. Institutional strengthening was at the core of the project as the two components specifically focused on this aspect. The 6 NMRAs benefitted from capacity building in various aspects of medicine regulation. At the institutional level, capacity of all 6 NMRAs was enhanced in medicines evaluation and registration, GMP, QMS and IMS—all of which contributed to improved efficiency in the discharge of their regulatory functions. For

example, Kenya reported that the project contributed to systems improvement as PPB systems were upgraded as part of IMS; QMS and systems audits resulted in improved transparency and accountability; MER enhanced quality of medicine assessments and reduced the time taken to assess products at national level from 24 to 10 - 12 months. Furthermore, the project successfully helped Zanzibar transition from the Food, Drug, and Cosmetic Board under ministry supervision, to a semi-autonomous Zanzibar Food and Drug Agency. The project, which included formal trainings and a twinning program with Kenyan PPB, also helped the newly established ZFDA in building solid capabilities in a short time, adopting more advanced regulatory guidelines as well as becoming ISO certified.

55. In addition to the above, staff capacity in all NMRAs was increased as those who trained as Assessors in medicines registration, Inspectors for GMP, and Lead Auditors for QMS compliance and implementation of quality management systems subsequently served as trainers in their areas of expertise in all the respective NMRAs. All NMRAs indicated that the development of the compendia for GMP, MER, and GMP helped expand their capacity as they learned from more skilled and qualified colleagues from other NMRAs and technical experts from SwissMedic and WHO. Similarly, participation in joint assessments and joint GMP contributed immensely to increasing capacity in these regulatory areas. The joint assessments and GMP promoted exchange of technical knowledge and facilitated cross-country learning, which in turn, increased knowledge and capacity.

56. At the EAC Secretariat, the project helped improve capacity in project management skills, procurement and financial management. The project team participated in training in Bank disbursement and procurement policies and processes, as well as reporting obligations to better equip them to comply with Bank rules.

57. The project also enhanced infrastructure capacity at the national level through the installation of complete video conferencing facilities and 2 data severs in each of the 6 NMRAs and at the EAC Secretariat. These developments facilitated virtual meetings and reduced the number of face-to-face meetings.

Poverty Reduction and Shared Prosperity

58. Safe, quality, and efficacious medicines play an important role in healthcare. Weak medicine regulatory systems lead to circulation of poor quality medicines, resulting in low medicine efficacy, which in turn, could contribute to increased mortality and morbidity. By enhancing regulatory capacity in the EAC region, this project has contributed to increasing the availability of much-needed quality and safe medicines and vaccines for communicable diseases, especially for the poor. Furthermore, improved efficiency and transparency in medicines registration is likely to lead to more competitive markets, improved access to new medicines, better quality of medicines in circulation, and ultimately better health outcomes.

III. KEY FACTORS THAT AFFECTED IMPLEMENTATION AND OUTCOME

A. KEY FACTORS DURING PREPARATION

59. The PDO, while relevant and timely, was rather ambitious given the wide variation in regulatory capacity across NMRAs in the EAC region. This was raised in the internal PCN review held in May 2011 and the meeting

recommended the team to consider changing the objective from achieving a harmonized system to facilitating the process of countries adopting similar registration systems or standardizing the registration protocols. An NMRA situational assessment conducted in 2009 among others— which informed the design of the project—revealed that 3 of the 6 NMRAs in the project (Burundi, Rwanda and Zanzibar) had limited personnel (Rwanda and Zanzibar) and inadequate technical capacity and physical infrastructure (Burundi). They also lacked enabling laws that would allow them to carry out regulatory functions needed to approve market authorization for medicines. This was compounded by the fact that in order to achieve **harmonization, these weak NMRAs would have had to build institutional and legislative capabilities comparable to** the strong NMRAs (Tanzania, Uganda and Kenya). Moreover, additional capacity would have had to be built in even the strong NMRAs. A similar harmonization effort in the Association of South East Asian Nations (ASEAN) took over 10 years. In developing the PDO, the project considered lessons learned from other regional projects, one of which was ***being realistic in what can be achieved in a regional operation which is inherently complex***, but this lesson was not applied. Furthermore, no action was taken to correct these identified gaps during the AF and restructuring.

60. Project preparation was carried out using a participatory approach, and included formal engagement with key stakeholders, such as local industry groups (pharmaceutical companies), implementing agencies (EAC and NMRAs), technical partners (WHO and NEPAD), and development partners (Bill &Melinda Gates Foundation) to identify gaps to be supported by the project. Likewise, well-defined institutional and implementation arrangements clarifying the roles and responsibilities of implementing partners were designed to avoid duplication of efforts and enhance coordination. A results framework informed by the WHO/NEPAD institutional assessments established a baseline for the project.

61. The overall implementation risk at appraisal was deemed to be high. Key risks were summarized in the PAD and appropriate mitigation measures were put in place at preparation. These included measures to enhance operational and technical capacity of both EAC and NMRAs and ensuring effective coordination between Partner States and EAC, and between EAC and other key partners supporting the project (i.e., NEPAD and WHO). However, while the risks posed by the weaker NMRAs were correctly assessed at preparation, they were not reassessed during implementation.

FACTORS DURING IMPLEMENTATION

62. **Factors that positively affected project implementation**

- Recruitment of full time project staff at the EAC Secretariat and the National Medicines Regulatory Officers (NMROs) for each of the NMRAs ensured adequate attention to project implementation.
- Training of EAC staff on World Bank procurement and financial management processes and policies contributed to improved compliance with PFM.
- Conducting external audits helped to ensure credibility and accountability; it also allowed to identify issues early on to put in place corrective measures, (e.g. 2013 external audit).
- The constitution of the technical working groups for each regulatory function ensured greater collaboration among NMRAs' staff and promoted harmonization and standardization of practices in the region.
- Establishing the Steering Committee ensured a continuing dialogue on policy and technical aspects of the project among stakeholders and was a platform to address implementation bottlenecks.

- NEPAD's political advocacy role was critical in addressing and resolving high level policy issues in Member States (Burundi and Rwanda) in order to accelerate implementation.
- The involvement of the pharmaceutical industry provided an opportunity for constructive feedback on the development of regulatory guidelines.
- The grant became effective in July 2012 and first disbursement was made in November 2012. Despite the delay in accessing the project funds, the EAC facilitated implementation of the regional activities using its own resources and World Bank video conferencing facilities. This prevented further delays in implementation.

63. **Factors subject to implementing entities control**

Coordination: As noted earlier, this project involved regional and national activities, making coordination key for this project. During the ICR mission, it was often emphasized that coordination of regional activities was challenging, leading sometimes to delays. For planning purposes and to ensure good attendance, joint assessments of regional medicine applications and joint inspections should have had a clear calendar of upcoming activities and meeting documents circulated sufficiently in advance to allow for preliminary review. This was not the case: meetings were sometimes held without sufficient notice and therefore assessors, inspectors, and other technical experts could not make the necessary arrangements to attend or obtain clearance from their respective ministries/agencies. For instance, assessors were expected to receive the documents well in advance of the meetings to enable the first assessor to review and the second assessor to review the work of the first assessor prior to discussion of an application at the joint assessment. The lack of coordination may be partly due to the lack of clarity of roles and responsibilities both within the EAC Secretariat (project staff) and between the EAC Secretariat and the NMRAs. This was further compounded by the lack of clarity on the division of labor between the EAC Secretariat and the NMRAs for each of the Technical Working Groups. Furthermore, NMRAs faced challenges in coordinating joint activities and their own national activities. This is because joint activities were not always seen as part of NMRAs' staff daily priorities due to conflicting tasks at national level. As a result, efficiency of the joint meetings was hindered, with less qualified staff from the NMRAs attending the meetings and the meetings being rescheduled, leading to implementation delays.

Human resources and organizational capacity: Project implementation at the country level was delayed. This was because of the length of time required to fully comply with EAC procedures for recruitment of project staff and the 6 National Medicines Regulatory Officers (NMROs). As a result, the appointments were completed in March 2013 and these staff started working from April 2013, almost one year after project effectiveness. Thus, the limited EAC staff supporting the project were overstretched with several responsibilities. This challenge, coupled with lack of support for NMROs at country level, resulted in implementation delays in both national and regional level activities. However, once project staff and NMROs were appointed, implementation began in earnest and gained steam.

In addition, the main thrust of the project was to improve capacity to enable NMRAs to effectively participate in the harmonized registration system. Despite strong capacity building in less resourced NMRAs, Burundi, Rwanda and Zanzibar still face understaffing issues and lack of key expertise. For example, with only 6 pharmacists in Burundi, it was unable to meet the target of registering 50 medicines using the new CTD format by the end of the project. Similarly, with only 12 pharmacists in Zanzibar, the discharge of new regulatory functions (MER and GMP)

is creating mounting pressure on the limited technical staff.

Overall the slow start of the project due to prolonged recruitment of project staff, coupled with other implementation challenges (late submission of no objections), weak project management capacity, as well as a break in implementation (between January and April 2016, pending approval of the AF) contributed to delays and resulted in a February 2017 request by the Secretariat for a no-cost extension of the project to December 2017 in order to complete the remaining activities.

Legislation and regulations: An enabling legislative framework is a prerequisite for harmonizing requirements for medicines registration. Standardized requirements for medicine registration need to be aligned with national laws on medicines registration. Although the Model Law for Medicinal Products Regulation was introduced by NEPAD to facilitate harmonization efforts, all countries are still not at the same stage in domesticating this law.

64. **Factors subject to World Bank control**

Retroactive financing to avoid interruption in implementation: In 2016, it became apparent that there would be a financing gap of US$119,000 between January and March. During the January 2016 implementation supervision mission, the EAC Secretariat informed the task team that they would not be able to provide any funds to continue implementing project activities, including staff salaries. Thus, the Secretariat requested support from the Bank in the form of retroactive financing as the Additional Financing was being considered. Consequently, an amount of US$ 120,000 was made available as retroactive financing under the proposed project to finance activities implemented between January 1, 2016 and the date of the Amended and Restated Agreement for the Additional Financing. However, because the EAC Secretariat had no funds to pre-finance project activities, the retroactive financing was eventually never utilized.

65. **Factors outside of government control**

Conflict and instability: Political issues at national level also impacted the implementation of the project leading to delays. As noted previously, political tension in Burundi slowed down the implementation of the activities that required participation from all the countries, leading to one of the two reasons for the second level II restructuring. Furthermore, in 2015, implementation was scaled down due to a travel ban in Burundi caused by political instability. Specifically, Trade Mark East Africa (TMEA), the firm supporting countries with IMS, could not travel to Burundi due to the political instability.

BANK PERFORMANCE, COMPLIANCE ISSUES, AND RISK TO DEVELOPMENT OUTCOME

A. QUALITY OF MONITORING AND EVALUATION (M&E)

M&E Implementation

66. M&E implementation is rated **Modest**

67. The task team produced 11 ISRs during project implementation (which was adequate for the duration of the project) and included sections on issues for management actions. The ISRs tracked the indicators in the RF. In addition, the AMs also tracked the indicators in the RF as well as indicators such as the number of medicines assessed and registered at national and regional levels, which were not included in the RF, but necessary for monitoring efficiency.

68. According to the PAD, because this was a system strengthening project, M&E data was primarily qualitative. M&E data was to be generated from administrative records, information made available on NMRAs' and EAC's websites, and by documented reports. Data collection tools included Excel spreadsheet and Word tables. In practice, however, the frequency of NMRAs reporting to EAC was inconsistent. For example, while NMRAs were required to provide annual progress reports, they sometimes produced quarterly reports. Similarly, details on the number of medicines assessed and registered using the CTD also varied, with some NMRAs providing more details than others. Furthermore, there was no reporting on NMRAs sharing public information (policies, guidelines, etc.) on their websites, although this was supposed to be reported on quarterly. Annual reports were shared with partners but data/information was not validated as stated in the PAD (WHO National Professional Officers were expected to validate country data). The ICR authors note that NMRAs' reports were detailed and included sections on Challenges and Recommendations, which provided an opportunity to take corrective actions and provide the needed support to NMRAs lagging in implementation.

69. Finally, gaps in M&E implementation included (i) the lack of an M&E focal point on the project staff at the EAC Secretariat; and (ii) the absence of reporting on M&E by NMRAs. Although M&E implementation had gaps, no changes were made during AF and restructuring.

M&E Utilization

70. M&E utilization is rated **Modest**.

71. Data collected during implementation was used to inform corrective measures to improve overall project achievements. For instance, implementation issues raised in the annual progress reports and data collected on number of medicines assessed and registered at national and regional levels as well number of joint GMP inspections were also presented to the different stakeholders including partners (WHO, NEPAD,) and donors (BMGF) at the Steering Committee meetings. The Committee deliberated upon these issues and proposed practical solutions for addressing them. The EAC Secretariat and the task team also reviewed data collected for the project as well as implementation challenges raised in the annual and quarterly reports and proposed recommendations for timely action.

Justification of Overall Rating of Quality of M&E

72. Overall M&E is rated as **Modest.**

Overall rating	M&E Design	M&E Implementation	M&E Utilization
Modest	Modest	Modest	Modest

B. ENVIRONMENTAL, SOCIAL, AND FIDUCIARY COMPLIANCE

Procurement

73. The main procurement for the project included ICT infrastructure, hardware and software, and office equipment for the EAC and NMRAs. Initially, the EAC had limited procurement capacity and knowledge of Bank procurement procedures, resulting in the late start in procurement activities (late 2014). To address this challenge, EAC enhanced its procurement capacity by recruiting additional procurement staff who were then trained in procurement under World Bank guidelines and procedures, which enhanced knowledge and skill in procurement activities under the project. Also, EAC project procurement staff made constant and regular recourse to the Bank Procurement Specialist to clarify procurement issues. This enabled the EAC project team to successfully complete most of the packages that were planned to be procured under the project. At project closing, the contract for Translation of Compendium Documents in French for Burundi was the only contract that was not completed; however, this contract was initiated late and there were indications that the deliverable would not be ready by the project closing date. As a result, the contract had to end with some of the documents having not been translated. It was made clear to the EAC Secretariat at the time of the mission in November 2017 that goods and services not delivered by the project closing date were not eligible for financing under the project.

Financial Management

74. At project design, to minimize delays in funds flow and reduce the number of audits, the task team adopted a virtual budget for disbursement of project funds to NMRAs. This method allowed NMRAs to procure small value services for training, workshops, and individual consultants following agreed procedures within the approved work plan. Payments were then made directly by the EAC Secretariat to vendors and consultants. For operational costs, each NMRA incurred the expenditures and shared documented claims seeking reimbursement from the EAC Secretariat. During implementation, however, there were delays in processing reimbursements for operational cost to NMRAs. These delays were addressed by simplifying the reimbursement process.

75. Regarding the virtual budget, NMRAs raised concerns about this arrangement during implementation. For example, some of the training expenditure budgeted at the country level was also shown as expenditure incurred at the regional level. By MTR, it was clear that this arrangement was not working well and was identified as one of the operational challenges for the project. To address this challenge, the EAC Secretariat was requested to clarify the processes/arrangement for the virtual budget in the Operations Manual, but this was never done. During interviews with NMRAs, the virtual budget was identified as one of the project weaknesses due to a lack of transparency on how project funds earmarked for virtual budgeting were spent.

76. Furthermore, there were delays in submitting the first initial advance request ($500K), the first 2 IFRs (July 2012 – September 2012 and October 2012 – December 2012), and monthly withdrawal applications. After project staff were trained in Bank FM procedures and policies and additional staff were hired (recruitment of project accountant), FM improved significantly. By MTR, the project team was submitting timely, quality external audits, IFRs, and withdrawal applications to the Bank. Additionally, FM issues raised

during supervision missions and by the external auditors were addressed in a timely manner.

77. Finally, in the first year of implementation, the disbursement rate was low due to a few factors, including delays in: (i) recruiting project staff, (ii) submitting monthly withdrawals, and (iii) procuring ICT software and hardware. As noted above, once the EAC Secretariat hired additional FM staff and trained existing staff, by MTR there was a slight increase in disbursement from 38 percent (March 2014) to 52 percent (June 2014). Although disbursement improved, the overall disbursement rate by the end of the project was 98 percent with a small unutilized balance, but this did not affect achievement of project objectives.

C. BANK PERFORMANCE

Quality at Entry

78. The task team worked closely with the EAC, NMRAs, technical partners (NEPAD & WHO) and donors (BMGF), and consulted with relevant stakeholders, including industry, during project preparation to ensure greater alignment between project objectives and key strategic documents at regional and continental (AU) levels. Consultation also ensured strong endorsement and commitment by NMRAs.

79. Project design was simple with only two components. The project was informed by institutional assessments of NMRAs conducted by WHO, and it sought to address some of the key recommendations from the assessment. Establishing TWGs, with the NMRAs taking the lead in the development of harmonized documents for medicines registration ensured ownership. Recognizing that several partners were involved in the implementation of the project, the task team proposed a clear institutional and implementation arrangement, with well-defined roles and responsibilities of key partners. Mitigation measures were put in place to address key risks identified at appraisal, which for this project were cross cutting—from operational to governance risks. Furthermore, to the extent possible, necessary measures were put in place to enhance the capacity of both the EAC Secretariat and NMRAs, and to provide project management support.

80. Despite the above, there were gaps in design which were not properly addressed such as the broadness of the PDO and issues with the results framework, including selection of indicators, gaps in indicators, and the lack of clarity of some of the indicators. Also, the two key areas lacking in the task team composition were a seasoned Operations Officer, and an M&E Specialist to guide the team in the formulation and review of the PDO and the results framework. In view of these gaps, Bank quality at entry is rated **Moderately Unsatisfactory**.

Quality of Supervision

81. Besides the first supervision mission, joint supervision missions—led by the task team together with representatives from WHO and NEPAD—were conducted with the EAC Secretariat throughout the project. In addition to the joint supervision missions, the task team conducted separate missions (immediately after the EAC missions) to NEPAD in May and November of 2017. The mission team was diverse and included procurement and FM staff. Except for the November 2016 and 2017 missions, the NMRAs were not invited to most of the supervision missions; however, there were several technical missions to the project countries. These technical missions were conducted in each of the project countries and provided an opportunity to

interact with the NMRAs. Furthermore, industry was fully engaged in the harmonization process and their feedback obtained and considered to improve the process. For example, during the November 2017 supervision mission, industry was invited to share their feedback. Also, the task team along with WHO and NEPAD, participated in most stakeholder consultation/validation meetings for pharmaceutical policy, draft CTD and guidelines for GMP inspections. In addition to above, the task team also participated in all Steering Committee meetings where implementation progress and challenges were discussed and addressed.

82. As noted earlier, the task team conducted 11 supervision missions (two per year) and submitted 11 ISRs. Missions addressed implementation bottlenecks as well as procurement, financial management, and project management challenges. However, there were some shortcomings: (i) In 2014, 3 missions were conducted (March, June & December) whereas only 1 mission was conducted in 2015; (ii) issues around the virtual budget reappeared several times in the AMs but the EAC did not clarify the processes/arrangement for the virtual budget in the Operations Manual. As noted earlier, because of this, NMRAs felt that the virtual budget was not transparent and did not work well. Furthermore, while the project had an Operations Officer on the team, the staff was a technical expert in medicines regulation but was unfamiliar with Bank operations. Having a seasoned operational staff person on the project could have helped avoid the delays in the preparation of the AF, and address gaps in the project design and the RF during restructuring and AF.

83. Bank quality of Supervision is rated **Moderately Unsatisfactory.**

Justification of Overall Rating of Bank Performance

84. Overall Bank performance is rated as **Moderately Unsatisfactory**.

Overall rating	Quality at Entry	Quality of Supervision
Moderately Unsatisfactory	Moderately Unsatisfactory	Moderately Unsatisfactory

D. RISK TO DEVELOPMENT OUTCOME

85. The EAC remains deeply committed to its Vision 2050 to strengthen and harmonize health and health- related policies, strategies and plans, including medicines regulations. Although some of the risks noted at appraisal are still relevant, such as capacity variance among NMRAs, the risk to development outcome is considered moderate given continued commitments from the EAC and NMRAs to sustain the medicines regulatory harmonization initiative. For instance, a roadmap for the implementation of the next phase of the program has been developed. In addition, a Technical Cooperation Framework, allowing bilateral recognition of approvals of medicines registration (an aspiration of the project which was achieved by project closure) has been created and will be approved by the Council of Ministers in April 2018.

86. At national level, most of the Partner States have passed or updated their laws to comply with the Model Law for Medicinal Products Regulation. This law will allow Partner States (Rwanda and Burundi) who at project closing did not have the appropriate legal framework in place to do so, thereby creating an enabling environment to sustain the harmonized standards and practices developed through the project. Also, there is political will on the part of Partner States to sustain and build on investments made by the project. For instance, in Zanzibar, the Ministry of Health has mainstreamed full regulatory functions into the government budgeting process after project closing.

87. Furthermore, sustainability of project investments can also be guaranteed through the fees charged by NMRAs for regulatory services. For example, Kenya and Tanzania NMRAs are currently able to maintain and sustain their IT related activities—hitherto supported by the project—from their own internally generated resources. For regional activities—joint assessments and joint GMP inspections—which were introduced and funded by the project, the Steering Committee held on March 2018 discussed at length a short to medium term sustainability plan, including fees for regional activities to fund and sustain these activities. To operationalize the sustainability plan, Partner States would need to adopt a regional policy on joint reviews and develop an operational plan detailing how these activities will be coordinated, how regional fees will be set, and how regional fees will be distributed among NMRAs in the region. For the regional PV developed with project funds, resources have been secured from USAID to fund implementation.

88. Finally, a few activities have been undertaken by the EAC and the NMRAs since project closing to maintain momentum. For instance, a Regional Technical Team (RTT) involving staff members from different NMRAs has been created to ensure continued commitment to regional activities. The RTT is expected to, among other activities, provide technical support and facilitate joint regulatory activities (joint assessments, joint inspections and PV).

V. LESSONS AND RECOMMENDATIONS

The project provides useful lessons that could inform similar regional projects in the other regional economic communities such as ECOWAS and SADC.

89. **Establish a realistic, coherent, and clear PDO in order to improve project performance and effectiveness.** Future regional projects seeking to harmonize medicines registration should establish a realistic PDO that is aligned to the RF, and is clear in terms of what the project seeks to achieve and how progress will be monitored, tracked, and revised. Medicine registration harmonization is a long-term process and involves NMRAs with varying capacities (technical and financial). For this reason, it is recommended that the design of such projects consider a phased approach starting with standardizing registration requirements, aligning these with national polices, building institutional capacity at national level, then moving towards regional harmonization of systems (full interoperability of national systems with regional system). The RF could be informed by the WHO Data Collection Tool for the Review of Drug Regulatory Systems, which provides an array of indicators for each regulatory function.

90. **Assess risks and develop and implement mitigation measures before risks impact project performance.** Risk assessments and mitigation measures are critical to the achievement of such a complex regional project. Therefore, project design should take into consideration these inherent risks, develop appropriate mitigation measures and review these regularly during implementation. Ongoing review is essential to ensure that mitigation measures remain relevant and can be applied before project performance is affected. Ongoing review can also help to determine if appropriate alternative measures should be considered. Issues raised at Quality at Entry in this ICR could have been resolved during

restructuring and AF.

91. **Jointly develop clear institutional and implementation arrangements to address the complex coordination requirements inherent to regional harmonization of medicines registration.** These arrangements (i.e., division of labor) should clearly be outlined during project design, explicitly formalized, and then reviewed and revised during implementation in order to ease coordination. This is particularly important in cases where key partners must combine or leverage their capacities. During project preparation, both the PAD and Operations Manual articulated the roles of the EAC Secretariat, the EAC project team, Steering Committee, NEPAD, NMRAs and other technical partners involved in the project. During implementation, however, the delineation of roles became blurred, particularly between the EAC Secretariat and the MRH team and between the EAC Secretariat and the NMRAs. There was also a lack of distinction between partner/policy coordination (NEPAD and the EAC Secretariat) from technical coordination (NMRAs and EAC Secretariat). Reviewing and adjusting institutional and implementation arrangements during implementation could help avoid duplication of efforts and better clarify roles.

92. **Consider operational details of virtual budgeting and clearly communicate them to clients in order to ensure transparency and accountability.** While the introduction of virtual budgeting was an innovative solution to address the complexity of managing funds for small value services across 6 NMRAs, the lack of transparency in its use, undermined its overall utility. To address this in the future, operational details could be provided in an Operational Manual and discussed with clients to create ownership and build confidence in the process. Also, implementation arrangements for virtual budgeting should be reviewed from time to time and corrective measures applied to improve transparency.

93. **Take into account the capacity and limitations of implementing agencies in order to avoid unnecessary setbacks.** Specifically, the internal processes of an implementing agency should be taken into consideration during project design. Delays in the EAC project were mainly due to internal bureaucratic processes of the implementing entity—the EAC Secretariat. The delay in recruitment due to internal processes and negotiation impacted efficiency and slowed down implementation. Similarly, the EAC was unable to provide financial support, in a timely manner, to NMRAs to implement activities due to lengthy approval processes required for disbursement of funds/implementation of activities.

94. **Allocate additional resources for institutional strengthening in less-resourced NMRAs to facilitate their eventual full participation in the harmonized system over the long term.** For example, while twinning activities and other capacity building efforts were very beneficial for the less resourced NMRAs (Rwanda, Burundi, and Zanzibar), significant time—beyond five years—is necessary to bridge the gap between less-resourced NMRAs and the stronger NMRAs as this requires a number of factors, including: (i) greater political will and support; (ii) additional investments in human resources and infrastructure, and; (iii) an enabling legal and regulatory environment. Similarly, the varied capacity across NMRAs affects the pace of harmonization and could potentially serve as a disincentive for less resourced NMRAs to utilize harmonized standards in the long term. In the future, similar projects should invest additional resources in less resourced NMRAs and consider, during design phase, the potential impact of political economy challenges on achieving development objectives.

95. **Leverage Bank operations at the country level to address emerging issues.** Some of the issues on weak institutional capacity and inadequate infrastructure, which became evident during implementation, could have been incorporated into Bank operations at the country level. This lesson is especially relevant since there was a strong alignment between the regional project objectives and national health sector strategies in all the project countries. In addition, as this regional project was endorsed by the EAC Council of Ministers as a priority for the region, and the Council is responsible for setting overall policy for health in the region, it could have advocated for the next phase of the project to be funded through regional IDA.

ANNEX 1. RESULTS FRAMEWORK AND KEY OUTPUTS

A. RESULTS INDICATORS

A.1 PDO Indicators

Objective/Outcome: Harmonized medicines registration systems; improved efficiency in medicines registration; and enhanced transparency in medicines registration.

Indicator Name	Unit of Measure	Baseline	Original Target	Formally Revised Target	Actual Achieved at Completion
NMRAs participating in the harmonized medicine registration based on internationally recognized policies and standards	Number	0.00 12-Jul-2012	0.00 31-Dec-2014	3.00 29-Dec-2017	6.00 29-Nov-2017
Comments (achievements against targets):					

Unlinked Indicators

Indicator Name	Unit of Measure	Baseline	Original Target	Formally Revised Target	Actual Achieved at Completion
NMRAS started piloting the electronic submission of applications for registering medicines	Number	0.00 12-Jul-2012	0.00 31-Dec-2014	3.00 29-Dec-2017	4.00 29-Nov-2017

Comments (achievements against targets):

Indicator Name	Unit of Measure	Baseline	Original Target	Formally Revised Target	Actual Achieved at Completion
NMRAs sharing regulatory policies, legislation, guidelines and information on registered medicines	Number	0.00 12-Jul-2012	0.00 31-Dec-2014	3.00 29-Dec-2017	3.00 29-Nov-2017

Comments (achievements against targets):

Indicator Name	Unit of Measure	Baseline	Original Target	Formally Revised Target	Actual Achieved at Completion
NMRAs received ISO 9001:2015 certification	Number	0.00 11-Jul-2012	0.00 31-Dec-2014	3.00 29-Dec-2017	2.00 29-Nov-2017

Comments (achievements against targets):

A.2 Intermediate Results Indicators

Component: Harmonize medicine registration systems

Indicator Name	Unit of Measure	Baseline	Original Target	Formally Revised Target	Actual Achieved at Completion
Harmonized guidelines	Number	0.00	0.00	3.00	5.00

including SOPs and manuals for registration of medicines and GMP inspection developed based on internationally recognized policies and standards		12-Jul-2012	31-Dec-2014	29-Dec-2017	29-Nov-2017
Comments (achievements against targets):					

Unlinked Indicators

Indicator Name	Unit of Measure	Baseline	Original Target	Formally Revised Target	Actual Achieved at Completion
NMRAs operationalizing common information management system for medicine registration developed by the regional technical working group	Number	0.00 12-Jul-2012	0.00 31-Dec-2014	3.00 29-Dec-2017	3.00 29-Nov-2017
Comments (achievements against targets):					

Indicator Name	Unit of Measure	Baseline	Original Target	Formally Revised Target	Actual Achieved at Completion
Staff trained in medicine regulation	Number	0.00 11-Jul-2012	0.00 31-Dec-2014	75.00 29-Dec-2017	233.00 29-Nov-2017
Comments (achievements against targets):					

Indicator Name	Unit of Measure	Baseline	Original Target	Formally Revised Target	Actual Achieved at Completion
NMRAs implementing quality management systems	Number	0.00 12-Jul-2012	0.00 31-Dec-2014	3.00 29-Dec-2017	4.00 29-Nov-2017
Comments (achievements against targets):					

Indicator Name	Unit of Measure	Baseline	Original Target	Formally Revised Target	Actual Achieved at Completion
Gap analysis report and a strategy for pharmacovigilance formulated and ready for implementation	Yes/No	N 17-May-2016	Y 31-Dec-2014	Y 29-Dec-2017	Y 29-Nov-2017
Comments (achievements against targets):					

B. KEY OUTPUTS BY COMPONENT

Objective/Outcome 1: to harmonize medicine registration systems	
Outcome Indicators	1. NMRAs participating in the harmonized medicine registration based on internationally recognized policies and standards 2. No outcome Indicator 3. NMRAs received ISO 9001 certification

Intermediate Results Indicators	1. Harmonized guidelines including SOPs and manuals for registration of medicines and GMP inspection developed based on internationally recognized policies and standards 2. Gap analysis report and a strategy for Pharmacovigilance formulated and ready for implementation 3. NMRAs implementing quality management systems
Key Outputs by Component (linked to the achievement of the Objective/Outcome 1)	1. Harmonized guidelines and standards developed 2. Pharmacovigilance strategy developed 3. ISO certification received by 2 countries and QMS implemented in 4 countries
Objective/Outcome 2: to improve efficiency in medicine registration	
Outcome Indicators	1. NMRAs participating in the harmonized medicine registration based on internationally recognized policies and standards 2. NMRAS started piloting the electronic submission of applications for registering medicines 3. NMRAs received ISO 9001 certification
Intermediate Results Indicators	1. Harmonized guidelines including SOPs and manuals for registration of medicines and GMP inspection developed based on internationally recognized policies and standards 2. NMRAs operationalizing common information management system for medicine registration developed by the regional technical working group 3. NMRAs implementing quality management systems 4. Staff trained in medicine regulation
Key Outputs by Component (linked to the achievement of the Objective/Outcome 2)	1. Harmonized guidelines and standards developed 2. IMS implemented in 5 countries

	3. ISO certification received by 2 countries and QMS implemented in 4 countries 4. 233 staff trained
Objective/Outcome 3: to enhance transparency in medicine registration	
Outcome Indicators	1. NMRAs sharing regulatory policies, legislation, guidelines and information on registered medicines on their websites 2. No outcome indicator 3. NMRAs received ISO 9001 certification
Intermediate Results Indicators	1. 2. NMRAs operationalizing common information management system for medicine registration developed by the regional technical working group 3.NMRAs implementing quality management systems
Key Outputs by Component (linked to the achievement of the Objective/Outcome 3)	1. Each NMRA has a website and a regional website has been developed 2. IMS implemented in 5 countries 3. ISO certification received by 2 countries and QMS implemented in 4 countries

ANNEX 2. BANK LENDING AND IMPLEMENTATION SUPPORT/SUPERVISION

A. TASK TEAM MEMBERS

Name	Role
Preparation	
Supervision/ICR	
Apollo Muhairwe	Task Team Leader(s)
Gisbert Joseph Kinyero, Raymond Joseph Mbishi	Procurement Specialist(s)
Mercy MataroSabai	Financial Management Specialist
Claudia Ocana	Counsel
Alexandra C. Bezeredi	Social Safeguards Specialist
Gandham N.V. Ramana	Team Member
Harriet E. N. Kiwanuka	Team Member
Cassandra De Souza	Team Member
Juliet Allen Gombya-Ssembajjwe	Team Member
Chitambala John Sikazwe	Team Member
TandileGuguZizileMsiwa	Team Member

B. STAFF TIME AND COST

Stage of Project Cycle	Staff Time and Cost	
	No. of staff weeks	US$ (including travel and consultant costs)
Preparation		
FY12	40.375	134,946.32
FY13	0	3,062.84
Total	**40.38**	**138,009.16**
Supervision/ICR		
FY13	54.312	169,334.25

FY14	50.306	193,537.88
FY15	44.400	159,662.69
FY16	56.475	313,923.87
FY17	68.900	627,154.64
FY18	72.637	478,892.94
Total	**347.03**	**1,942,506.27**

ANNEX 3. PROJECT COSTBY COMPONENT

Components	Amount at Approval (US$M)	Actual at Project Closing (US$M)	Percentage of Approval (US$M)
Regional Coordination and Capacity Building for Medicines Regulatory Harmonization	2.40	4.48	100
Institutional Development and Strengthening of National Medicines Regulatory Authorities (NMRAs)	3.13	4.96	100
Total	**5.53**	**9.44**	**100**

ANNEX 4. EFFICIENCY ANALYSIS

Economic Benefits and Costs from supporting the AMRH Initiative

The economic and societal benefits of investments to strengthen the medicines regulatory processes are understood to be significant, despite the availability of quantitative evidence due to lack of routine data collection on medicines use and from underdeveloped pharmacovigilance systems in LMICs, and the inherent challenges in estimating the costs from delayed access to medicines or the cost of administering substandard medicines. The expected economic benefits resulting from the EAC project are highlighted below. The costs for this project were minimal at US$ 0.06 per person based on an estimated population of 168.8M in the region in 2016 and the total project costs of US$ 10.2M.

The circulation of safe, effective and quality medicines: From an economic point of view, the existence of market failures justifies the need for regulating the medicines industry and ensuring the circulation of safe, effective, quality medicines. Firstly, the market is characterized by an *'information asymmetry'* between those who manufacture/sell medicines and patients/consumers, who are unable to assess the quality, safety or efficacy of medicines purchased. Secondly, the use of substandard medicines can have serious *negative public health externalities* such as the development of medicines resistance, one of the major public health threats. In this case, consuming substandard medicines by single individuals could lead to costs for the entire society in the form of reduced medicine efficacy and increased risks of death. For example, a study conducted by WHO in 2003 on the quality of antimalarial medicines showed that in sub-Saharan African countries only 58 percent of the medicines tested had an acceptable level of chloroquine content and only 25 percent had acceptable dissolution properties. The poor-quality chloroquine may be among the causes of the high rate of resistance in these countries. Effective medicines regulation can therefore minimize the economic costs resulting from unsafe, inefficacious, suboptimal quality medicines otherwise borne by patients, health systems, and the overall economy. Finally, patients accessing safe and effective medicines respond to treatment promptly and effectively, thus avoiding prolonged therapies, long-term complications, and even premature death. For example, the International Policy Network estimated the death toll caused by fake drugs for malaria and tuberculosis alone at 700,000 cases per year. From a health system perspective, effective regulation ensures that already strained resources (public or private) for health are not wasted, and costs for additional medical consultations and hospitalizations are avoided.

Improved investments, higher revenue for regulators, and growth of the local pharmaceutical industry: At the macroeconomic level, the reduction in regulatory barriers through standardized, simplified, and internationally recognized registration processes has been shown to be associated with greater domestic and foreign investments, which, in turn, are expected to create jobs and boost the economic productivity of the country (Cambridge, 2012). Specifically, the market for medicines in Africa is expected to represent a US$ 45 billion opportunity by 2020, thus representing an immense prospect for economic development for the region (IMS, 2014). In turn, higher economic growth is expected to translate in higher investments in health (Bedir, 2016), and thus improve population's health and economic productivity. A recent study by the University of Cambridge (2012) demonstrated that the regional harmonization of the regulatory

framework in Eastern Africa brings significant economic benefits to both regulators and pharmaceutical companies. Regulators benefit from notable increases in fee revenue, which can provide the previously lacking resources for increasing capacity, improving technologies, and enforcing regulations and thus preventing counterfeit/substandard medicines entering and circulating on the market. At the same time, pharmaceutical companies save significant resources from labor division and fast-tracked processes, which reduce the human capital costs. The study estimated the average human capital costs sustained by pharmaceutical companies in each country under a scenario of no harmonization: 100 full-time equivalent (FTE) days for inspections, 5-7 FTE for submitting the registration documents and 300-420 days to complete the submission. Under a scenario of harmonized medicines regulation, the 5-year costs per product for pharmaceutical companies were estimated to drop from US$ 5.7M to US$ 1.7M, while the 5-year revenue for the regulator to increase from US$72,800 to US$ 117,200. Furthermore, assuming a 50 percent increase in the number of medicines registered in the region because of the improved registration process, the 5-year regulator's revenue is expected to increase from US$ 52.2 million to US$ 140.6 million.

ANNEX 5. BORROWER, CO-FINANCIER AND OTHER PARTNER/STAKEHOLDER COMMENTS

SUMMARY PROGRESS REPORT ON IMPLEMENTATION OF THE EAST AFRICAN COMMUNITY MEDICINES REGULATORY HARMONIZATION (EAC-MRH) PROJECT

1.0 FIVE (5) YEAR PROGRESS REPORT ON IMPLEMENTATION OF EAC-MRH PROJECT

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

Goal: To establish a harmonized and functioning medicines regulatory system within in accordance with national and internationally recognized policies and standards.

Launched: 30th March 2012

Objectives

1. To implement an agreed common technical document for registration of medicines in EAC Partner States
2. To implement a common information management system for medicines registration in each of the EAC
3. To implement a quality management system in each of the EAC Partner States' NMRAs
4. To build regional and national capacity to implement medicines registration harmonization in the EAC
5. To create a platform for information sharing on the harmonized medicines registration system to key
6. To develop and implement a framework for mutual recognition based on Chapter 21, Article 118 of the East African Community Treaty

East African Community: -Republics of Burundi, Kenya, Rwanda, Uganda, South Sudan and United Republic of Tanzania. The Republic of South Sudan became a full member of the EAC on 5th September 2016.

EAC Secretariat: Coordination and Harmonization

EAC Partner States National Medicines Regulatory Authorities (NMRAs): Implementing Agencies.

AMRH Partners: - WHO /Swissmedic**(Technical)**, AU-NEPAD Agency **(Policy Advocacy)**, BMGF, DFID& SDC **(Funding)**, WB (Funding & Administrator of AMRH Trust Fund), MSH|SIAPS, USAID, USP/PQM (Technical &Financial)

Regulatory Function	Key Milestones	Year Milestone/Critical Indicators to be Achieved	Indicators of Success	Progress
Medicines Registration	EAC CTD for registration of medicines implemented	March 2015	An agreed common technical document for registration of medicines in EAC	(i) EAC Compendium of Harmonized Technical Guidelines for Registration of Medicinal Products adopted by

	in at least three EAC Partner States by the end of year three and in all Partner states by end of year 5		Partner States established by end of year 2	the 29th Meeting of the EAC Council of Ministers **(EAC/CM29/Decision 36)** on 20th September 2014 (ii)All EAC Partner States NMRAs with exception of the Republic of Burundi and Republic of South Sudan are implementing EAC CTD
		March 2017	At least 75 medicines registered per NMRA under the MRH scheme by TFDA, NDA and PPB by end of year 5 At least 100 applications submitted to NMRAs under the CTD format by the end of year 5	**Data as of May 2017** **(i)** PPB, Kenya: -1676 Medicinal Products registered 2475 products submitted **(ii)** NDA, Uganda: -705 Medicinal Products registered out of 837 products submitted **(iii)** TFDA, Tanzania: -76Medicinal Products registered out of 799 products submitted
		March 2017	At least 50 medicines registered per NMRA under the MRH scheme by ZFDB, Burundi and Rwanda by end of year 5 At least 100 applications submitted to NMRAs under the CTD format by the end of year 5	**Data as of May 2017** **(i)** PTF, Rwanda: -297 Medicinal Products out of 792 products submitted **(ii)**DPML, Burundi: - 10 Medicinal Products registered out of 90 products submitted **(iii)**ZFDB,Tanzania: -19 Medicinal Products registered out of 64 products
		March 2017	At least 18 medicines approved under the joint assessments scheme by end of year 5	Thirty-eight(38) applications received for EAC joint assessment and registration All medicinal products dossier have been evaluated Eight (8) products recommended for joint registration

Good Manufacturing Practices	EAC Common GMP Inspection Guidelines adopted least three EAC Partner States by the end of year three and in all Partner states by end of year 5	March 2015	EAC Joint GMP Inspections Conducted and Joint Decisions/Outcomes Made	(i) EAC Compendium of GMP Guidelines for Inspections of Medicines Manufacturing sites adopted by the 29th Meeting of the EAC Council of Ministers **(EAC/CM29/Decision 36)** on 20th September 2014 (ii) A total of fourteen (14) EAC Joint GMP Inspections conducted. Eleven (11) Pharmaceutical Manufacturing Facilities have been issued with EAC GMP Compliance Certificate. Three (3) Manufacturing sites awaits CAPA implementation and review Pharmaceutical Manufacturing Facilities Sites Location: - India (7), Uganda (2), Tanzania, Kenya (2) Egypt (2) and Morocco (1)
Quality Management Systems (QMS)	Quality Management System implemented in each of the EAC Partner States' NMRAs by end of year 3	March 2015	At least 3 NMRA ISO certified by the end of year 3	(i) EAC Compendium of QMS Guidelines for NMRAs adopted by the 29th Meeting of the EAC Council of Ministers **(EAC/CM29/Decision 36)** on 20th September 2014 (ii) Review of EAC QMS Requirements and Manual online with ISO 9001:2015 is ongoing (iii) TFDA have been ISO 9001:2008 and currently is in the process of recertification for ISO 9001:2015 External Audit for NDA to be conducted in November 2017 For PPB, pre-inspection by external audit has been done. Formal inspection to be carried out 31st December 2017 ZFDB, Pre-assessment and assessment by external auditors. Plans to apply for ISO 9001:2015 Certification
Information	A common	March 2016		(i) Status of implementation of

Management System	information management system for drug registration operational in all EAC Partner States' NMRAs and linked regionally by end of year 4			IMS (see separate sheet) (iii) Videoconference Facilities procured and installed in all six (6) EAC Partner States NMRAs (ii) Procurement of 40 Tablets
Policy, Legal and Regulatory Reforms	EAC framework for mutual recognition based on Chapter 21, Article 118 of the East African Community Treaty developed by end of year 5	March 2017	Six (6) NMRAs recognizing regulatory decisions made by other NMRAs based on mutual recognition framework by end of year 5	(i) EAC Cooperation Framework Agreement developed and validated. Awaiting adoption by the EAC Policy Organs (ii) EAC Medicines and Health Technologies Policy developed and validated. Awaiting adoption by EAC Policy Organs (iii) EAC Medicines and Health Technologies Strategic Plan developed and will be reviewed and validated in September 2017 (iv) Enactment of National Laws to establish semi-autonomous NMRAs – Rwanda Food and Drugs Authority (RFDA) Act of 2014, Republic of Rwanda and Zanzibar Food and Drugs Authority Act of 2017, United Republic of Tanzania (v) Reviewed national laws against the AU Model Law on regulation of Medicinal Products, for the Republic of Rwanda, Burundi and Kenya. A desk review will be conducted forZFDB URT and Republic of South Sudan, while for TFDA-Tanzania, review and stakeholder's consultation will be conducted later (vi) High Level Policy Advocacy on establishment of ABREMA with

				Parliamentarians of the Republic of Burundi
Capacity Building in Regulatory Sciences and Quality Management	A pool of experts created at national and regional level with competency in regulatory sciences and project management RCORE's established for Assessment, Inspections,	March 2015	(i)At least 2 regional centers of excellence in training assessor and GMP inspector established in the EAC region by end of year 5 (ii) At least 25 EAC and NMRA MRH project staff trained on management of MRH by end of year 5 (iii) At least 24 assessors trained in assessment of quality, safety and efficacy of medicines by end of year 5 (iv) At least 24 inspectors trained on GMP inspection by end of year 5	(i) Trained 35 NMRAs staff on QMS lead auditing (ii)Trained 30 Assessors from EAC NMRAs (iii) Trained 40 EAC NMRAs staff on basic and advanced GMP (iv) Trained EAC NMRAs Staff on the use and application of IMS (v) Trained 12 staff from EAC Partner States NMRAs on GCP and Clinical (Contract) Research Organization (CRO) Inspections (vi) Three (3) Twinning Sessions conducted for each set of EAC Partner States NMRAs in Dossier Evaluation and GMP Inspections: - PPB/ZFDB; TFDA/DPML/SDFC; NDA& PTF (vii) Two (2) EAC RCORE for Medicines Registration and Pharmacovigilanceare operational i.e. TFDA/MUHAS and PPB/Nairobi University
Pharmacovigilance	(i) (ii) (iii) (iv) **(v)**	EAC PV Proposal endorsed by the EAC Policy Organs Development of EAC PV Systems Assessment Tool and Manual Assessment of PV Systems in EAC Partner States NMRAs and Piloting of the PV Tool conducted from 16th February to 10th March 2017. EAC Pharmacovigilance Business Plan developed, awaiting approval by Ministers in May 2018.		
EAC Expert Working Group	(vi) **(vii)**	Seven (7) EWG established to undertake technical work of EAC-MRH project: - MER, GMP, QMS, IMS, Regulatory Reforms, PV & PMS Performance: -Good, activities conducted through VC and face to face meetings		
Forum of Heads of NMRAs	(i) (ii) (iii) **(iv)**	Established by the 12thOrdinary meeting of the EAC Sectoral Council of Ministers of Health held on 22nd June 2016 (EAC/Health/12SCM/Decision 038)to oversee implementation of EAC MRH programme Benchmarking visit to European Medicines Agency, 17-19 May 2017 7th Forum of Heads of NMRAs held on 27th to 28th July 2017 recommends development of a concept note for a business case to establish East African Community Medicines Agency A task force has been established to oversee development of a concept note		

EAC-MRH Steering Committee	(i)	Established by the 5thOrdinary meeting of the EAC Sectoral Council of Ministers of Health held on 1st April 2011(EAC/Health/SCM 05/Decision 19)to provide administrative and technical oversight of implementation of the EAC MRH programme
	(ii)	Considered and approved a set of EAC harmonized guidelines for MER, GMP, QMS and IMS
End-Term Evaluation of EAC-MRH Programme	(i)	End term evaluation of EAC-MRH Programme conducted and concluded in December 2017 by Boston Consulting Group.
Sustainability of EAC-MRH Programme	(i)	Roadmap/Strategy for post EAC-MRH implementation developed, awaits approval by EAC Ministers of Health

2.0 CHALLENGES

(i) The current application procedure for EAC central registration and EAC joint GMP inspections use the national systems of Tanzania Food and Drugs Authority (TFDA) of the United Republic of Tanzania and National Drug Authority (NDA) of the Republic of Uganda respectively for application filling and coordination of the process;

(ii) The EAC region has not yet harmonized its regulatory fee structures and guidelines. Applicants are required to pay application fees according to each of the EAC Partner States requirements;

(iii) The timelines for review and registration of medicinal products at regional level have been prolonged primarily due to lack of a regional system and structure dedicated to handle and process applications; non-existence of streamlined application and payment procedures; low quality dossiers by applicants; and sluggish response to queries by applicants;

(iv) Slow progress in the establishment of two autonomous medicines regulatory agencies in the Republic of Rwanda and Burundi which hinders integration in medicines regulatory aspects;

3.0 PROPOSED SOLUTIONS

Continuity of the EAC centralized product registration and joint GMP inspections is a priority for the Forum of Heads of NMRAs as the current funding phase for the EAC MRH is indicated to be 31st December 2017. The following are proposed solutions;

(i) Streamlining administrative and EAC procedures for assessment and GMP inspections both at National and Regional level: EWG for MER & GMP;

(ii) EAC to define timeframes for applicants of Product registration to respond to queries; a lapse period should be included that makes the application unviable: EWG on MER

(iii) Enhancing capability of EAC shared portal to facilitate sharing of information including assessment reports and assessment outcomes: validation of the IMS system conducted from 30th August to 1st September 2017;

(iv) EAC Secretariat and NMRAs to carry out advocacy including sharing of materials about joint procedures widely to stakeholders;

(v) EAC to follow risk based approaches in assessment and GMP inspections/Finalize and desk review procedure for GMP inspections for SRA approved and WHO prequalified products

(vi) Appointment of technical officers at NMRAs level to continue implementation of EAC-MRH program at Partner States level;

(vii) Development of the concept note for Business Case on EAC Medicines Agency: Interim, Lean coordination unit to be established to sustain joint activities;

(viii) Roadmap/Strategy for Post EAC-MRH Implementation to be developed to define EAC priorities and stepwise implementation of regulatory systems strengthening and harmonization initiatives; and

(ix) Mobilization of financial resources and fully integration of Republic of South Sudan into EAC-MRH initiatives.

4.0 ACKNOWLEDGEMENT

The EAC Secretariat acknowledges the strong partnership and collaboration by the African Medicines Regulatory Harmonization Programme Partners namely the World Health Organization (WHO), African Union New Partnership for Africa's Development (AU-NEPAD Agency), Bill and Melinda Gates Foundation (BMGF) and other Development Partners who played a critical role in the success of the project. Our sincere gratitude also goes to Swiss Development Corporation (SDC), Swissmedic, Trademark East Africa (TMEA), Management Science for Health (MSH)/SIAPS, US/PQM and United States Agency for International Development (USAID) The role-played by Implementing agencies, the EAC Partner States and the National Medicines Regulatory Authorities (NMRAs) cannot be overemphasised.

The EAC Secretariat Health Department team led by both Dr. Stanley S. Sonoiya and Ms. Jane H. Mashingia was a success factor. The EAC Secretariat management and supporting directorates of Information Technology (IT), Procurement, Financeand Human Resources, EAC Policy Organs and East African Legislative Assembly (EALA) contributed to the success of the project.

The East Africa Community Medicines Regulatory Harmonization Programme is a blueprint for the continent, lessons learnt and documented best practices should guide design of similar project for other Regional Economic Communities (REC's) to address challenges of access to medicines and health technologies.

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Borrowers' comments:

Borrower/Implementer	Comments
East African Community	• **Paragraph 32:** The procedure for medicines registration exists and is being reviewed. • In Table 1, the meaning of partial implementation is unclear, and consider NDA is ISO 9001:2015 Certified since April 2018; • **Paragraph 37:** The initial approach by ZaZiBoNa and EAC MRH were a bit different, we can check and verify. • Table 2, consider information in Annex 5 (Borrower's Completion Report) and the Report of the 10th EAC MRH Programme Steering Committee on the numbers of registered products per NMRAs. • **Paragraph 64:** EAC had no resources to fund EAC –MRH activities in January 2016 while the additional financing was being processed.
Kenya Pharmacy and Poisons Board	• The Pharmacy and Poisons Board adopted the EAC guidelines effective January 2015. • Stakeholder sensitization on EAC Medicines Registration guidelines was done in March 2018. • The decision to exempt local manufacturers of bioequivalence (BE) studies was agreed between the Board and the industry due to lack of BE Study centers in the region, but not due to a lack of alignment between the standardized guidelines and national laws as indicated by World Bank in their report. • The Board is planning to develop a list of products to be exempted from BE as the institution develop an implementation plan for BE compliance.
Rwanda Food and Drugs Administration	• By the time the project was closing, the law establishing Rwanda FDA had been gazette. Also, Rwanda was the first to implement the standardized guidelines for registration and GMP in January 2015. • Rwanda FDA currently performs all regulatory functions.

ANNEX 6. SUPPORTING DOCUMENTS (IF ANY)

WHO Data Collection Tool for the Review of Drug Regulatory Systems

The WHO Data Collection Tool for the Review of Drug Regulatory Systems was developed to assess national medicines regulatory systems. It aims at strengthening national regulatory system and control capacity through an assessment of the situation, the identification of specific needs, and the provision of appropriate technical support and training. Specifically, the Tool reviews the existing legal framework, regulations and controls activities with regard to medicinal products and medical devices in order to assess the national regulatory capacity against a set of predefined parameters. It identifies gaps and develops strategies to address them.

The structure of the Tool is based on the main regulatory functions of medicine regulatory system: the registration of the pharmaceutical products; the licensing of the different actors; the regulatory inspection; the medicine control laboratory; the monitoring of clinical trials; the control of medicines promotion and advertisement; national regulatory authority, including transparency and confidentiality. There are 18 questions on transparency and confidentiality, 6 of which are used to assess efficacy of transparency in the ICR. These are as follows:

- There is a documented policy on public disclosure of information with exemptions/exceptions
- Information on legislation, regulations, procedures and guidelines are publicly available and are kept up to date on websites or other mechanisms used to ensure the proper availability of information
- The information on decisions are publicly available, including the negative decisions in specific cases (i.e. when legislation permits) in a timely manner
- The Information on outputs of regulatory functions performed are publicly available and kept up to date (web sites or other mechanisms)
- A competent contact person or a public relations unit is established and known by the interested parties
- The NRA regularly organizes meetings with the key stakeholders and open days for the public

References:
(1) Key Bank Documents:

Project Appraisal Document
Aide Memoires
Operations Manual
Implementation Status and Results Report Sequence 11. December 2017. Available at: *Link*
Implementation Status and Results Report Sequence 10. June 2017. Available at: *Link*
Implementation Status and Results Report Sequence 09. December 2016. Available at: *Link*
Implementation Status and Results Report Sequence 08. June 2016. Available at: *Link*
Implementation Status and Results Report Sequence 07. December 2015. Available at: *Link*
Implementation Status and Results Report Sequence 06. May 2015. Available at: *Link*
Implementation Status and Results Report Sequence 05. November 2014. Available at: *Link*
Implementation Status and Results Report Sequence 04. May 2014. Available at: *Link*
Implementation Status and Results Report Sequence 03. December 2013. Available at: *Link*
Implementation Status and Results Report Sequence 02. May 2013. Available at: *Link*
Implementation Status and Results Report Sequence 01. October 2012.Available at: *Link*

(2) Borrower ICR

(3) Data sets used to assess outcomes

EAC MRH Annual reports
NMRAs Annual Reports for EAC MRH
Steering Committee Reports
Technical Working Group Reports
Heads of NMRAs Forum Reports

(4) Analytical studies related to the project

EAC. 2009. *East Africa Community National Medicines Regulatory Agencies Situational Analysis*
GIZ. 2011. *Baseline Survey of the Local Pharmaceutical Manufacturing Capacity for Human and Veterinary Medicines and Medical Supplies within the East African Community Partner States.*
The Boston Consulting Group. *2017. EAC Medicines Regulatory Harmonization Program: End –term Evaluation.*

(5) Other documents

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Bedir S. (2016). Healthcare Expenditure and Economic Growth in Developing Countries. Advances in Economics and Business 4(2): 76-86.

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World Health Organization. 2007. WHO Data Collection Tool for the Review of Drug Regulatory Systems. Available at: *Link*
World Health Organization.2011. The World Medicines Situation Available at: *Link*
International Policy Network Press Release (2013). Fake drugs kill over 700,000 people every year - new report. Retrieved from: http://archive.is/ipW8i.

World Health Organization (2016). Improving the quality of medical products for universal access. Retrieved from: http://www.who.int/medicines/regulation/fact-figures-qual-med/en/. Accessed on 27/05/2018.