Report Number : ICRR0021313

1. Project Data

Project ID	Project Name	
P128332	African Medicines Reg.Harmonization	
Country	**Practice Area(Lead)**	**Additional Financing**
Africa	Health, Nutrition & Population	P152364,P155163,P155163
L/C/TF Number(s)	**Closing Date (Original)**	**Total Project Cost (USD)**
TF-10846,TF-12036,TF-A2289	30-Jun-2017	6,549,207.00
Bank Approval Date	**Closing Date (Actual)**	
21-Mar-2011	29-Dec-2017	

	IBRD/IDA (USD)	Grants (USD)
Original Commitment	10,449,200.00	10,449,200.00
Revised Commitment	10,449,200.00	10,449,200.00
Actual	10,200,383.87	10,200,383.87

Prepared by	Reviewed by	ICR Review Coordinator	Group
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2. Project Objectives and Components

a. Objectives

According to the Grant Agreement of 3/21/12 between the East African Community (EAC) and the Bank, the objectives of the project were to harmonize medicines registration systems and to improve efficiency and enhance transparency in medicines registration among the EAC Partner States. The objectives in the Project Appraisal Document and ICR (p. 7) are identical.

Note: The EAC is a regional intergovernmental organization.

Project scope: The project was a regional operation that included six National Medicines Regulatory Authorities (NMRAs) in the EAC region: Kenya, Tanzania, Zanzibar, Uganda, Burundi, and Rwanda.

b. Were the project objectives/key associated outcome targets revised during implementation?

No

c. Will a split evaluation be undertaken?

No

d. Components

1. Regional Coordination and Capacity Building for Medicines Regulatory Harmonization (Appraisal: US$2.40 million; Actual: US$5.48 million).

Provision of support to develop regional harmonized protocols, including standard operating procedures and manuals by the regional technical working groups and capacity building for medicine regulation.

Provision of support for the establishment and operation of: (a) the Regional Steering Committee providing direction and oversight for the project; (b) a Project Coordination Team for day-to-day operational support and reporting; and (c) four Regional Technical working Groups that would respectively take technical the lead in medicines registration, Good Manufacturing Practices (GMP) inspections, information management systems, and quality management systems.

Provision of support for a systems requirement study for on-line registration and to develop a national and regional web-based data management information system for sharing information on medicines registration across the EAC region.

Note on additional financing: An additional financing of 4/21/16 continued project activities and added a new activity on pharmacovigilance under this component for developing a strategy to enhance the safety of medicines and patients as an important regulatory function.

2. Institutional development of national medicines regulatory authorities (Appraisal: US$3.13 million; Actual: 4.96 million).

Provision of support to build capacity of Partner States' NMRAs, including support for additional staff and training in areas of project management; quality assessment and safety of medicines; and GMP inspections. Provision of support for NMRAs and implementation of quality management systems, including internal and external audits.

Note on overall project governance: The Secretariat of the EAC at the regional level was the main agency responsible for the project and its implementation. It was supported by the six NMRAs listed in Section 2a, while the World Health Organization (WHO) and the New Partnership for Africa's Development Agency (NEPAD) provided technical assistance in regulatory aspects, political advocacy and coordination. (Note: NEPAD represents an economic development program of the African Union aimed at accelerating economic co-operation and integration of African countries in the world economy.)

e. Comments on Project Cost, Financing, Borrower Contribution, and Dates

Costs and financing. The original project consisted of a grant of US$ 5.55 million to the EAC dated 3/21/12 from the Global Medicines Regulatory Harmonization Initiative Trust Fund administered by the Bank. It was followed by a supplemental grant of US$1 million on 9/28/12 to finance NEPAD's technical assistance to the project. Additional grant financing on 4/21/16 provided an incremental amount of US$3.9 million (consisting of US$3.4 million to EAC and US$0.5 million to NEPAD) to strengthen and support the completion of the originally planned activities. The total project cost aggregated at US$10.4 million, and the actual disbursed amount was US$10.2 million.

Dates. The project was approved on 3/21/11 and became effective on 7/13/12. The Mid-Term Review was carried out on 5/16/14. A level 2 restructuring on 12/15/14 extended the project closing date to 6/30/16. The extension was intended to prevent the interruption of implementation while additional financing was being considered by the Bank. The additional grant financing that was approved on 4/21/16 also extended the closing date to 6/30/17. On 5/15/17, the closing date was further extended to 12/29/17 to address implementation delays, including delays caused by political tensions between Burundi and Rwanda; and to include South Sudan in already planned regional activities to provide the team of South Sudan with learning opportunities about the project (ICR, p. 11). The original closing date was 3/31/15, and actual closing was on 12/29/17.

3. Relevance of Objectives

Rationale

A situational assessment on NMRAs carried out by WHO and EAC in 2009 showed that countries in East Africa lacked sufficient regulatory capacity to approve medicines for sale on their respective markets in a timely manner (ICR, p. 5). The assessment also showed that the lack of standardization and non-transparent processes for medicines registration affected the availability of essential medicines and vaccines for high burden diseases, including lower respiratory infections, HIV, and tuberculosis. Hence, access to medicines for the treatment of communicable diseases constituted a public health priority for about 133.5 million inhabitants in the region in 2010. These findings were in line with known global patterns indicating

that, while medicines are usually available, they cannot be accessed in a timely manner due to lengthy, numerous, and diverse regulatory requirements, and because of non-transparent processes in registering new medicines.

The project objectives remain largely consistent with Pillar 2 of the World Bank's ten-year Africa Strategy 2011: "vulnerability and resilience," as governance and public sector capacity were cornerstones of the Africa Strategy (ICR, p. 11). The objectives remain consistent with the World Bank Strategy for Health, Nutrition, and Population Results, 2007: Healthy Development, and with the orientation of IDA-16 to support initiatives that foster regional integration (ICR, p. 6). However, the objectives were not appropriately pitched for the major variability in country capacities, and such variability persisted at project closing. According to the ICR (p. 22), this issue was raised in the internal project concept note review, where the meeting recommended changing the project objective from achieving a harmonized system to a more realistic standardization of protocols for medicines registration. One of the project lessons highlighted the fact that further additional multisectoral support (legal, political, human resources, and infrastructure) was needed to bridge the gap between less-resourced NMRAs and stronger NMRAs to facilitate the attainment of the collective regional objective of harmonizing medicines registration systems in the region.

The objectives remain aligned with EAC Vision 2050 focusing on access to and distribution of medicines through harmonized health-related legislation and regulations. A Regional Pharmaceutical Manufacturing Plan of Action (2017-2027) was approved by the Council of Ministers of the region in 2017 (ICR, p. 12) to advance access to medicines and to enhance inclusive growth in the health sector. At the national level, the ICR (p. 12) noted that all health sector strategies in the involved countries support improving access to essential medicines through better regulation of medicines marketed in the EAC and through facilitation of related processes used by local industry. WHO continues to recommend, as a priority, the strengthening of national medicines regulatory authorities, namely: (i) product registration; (ii) licensing of manufacturing, importation, and distribution; and (iii) control of medicines promotion and information.

Rating
Substantial

4. Achievement of Objectives (Efficacy)

Objective 1

Objective
Harmonize medicines registration systems among East African Community partner states.

Rationale
Establishing a steering committee and technical working groups, developing guidelines and Common Technical Documents for medicines registration, conducting joint assessments of regional medicines applications and joint GMP inspections, conducting pharmacovigilance gap analysis, and consulting key

stakeholders could reasonably be expected ultimately to contribute to harmonized medicines registration systems when they are universally applied by the countries involved.

Outcomes

The project developed a compendium of guidelines, standard operating procedures and a manual for Medicine Evaluation & Registration and GMP. The compendium was endorsed by the Steering Committee and all six NMRAs with the expectation that it would become easier for manufacturers to leverage the dossiers that they use in international submissions in EAC countries without having to fill multiple forms in each country in the region to obtain licenses to market new products. The project also developed a pharmacovigilance strategy for harmonizing vigilance systems in the region. The outcome indicator set by the project on NMRAs with harmonized medicine registration based on internationally recognized policies and standards increased from a 0 baseline in 2012 to 6 in 2017, exceeding the target of 3 (Note: this indicator fits better the theory of change as an intermediate results indicator).

While important progress was made in standardizing the requirements for medicines registration, the objective of actual harmonization of medicines registration systems in EAC region was not achieved (ICR, pp. 13-14). Utilization and compliance with common standardized guidelines at the country level was only partial (ICR, pp. 14-15). The variability levels in utilization was due to the lack of human resources with technical expertise and infrastructure, and a lack of alignment of new standards with national laws (ICR, p. 14). The ICR concluded that harmonization of medicines registration is a long and complex undertaking that can be achieved only when all six countries adopt and utilize commonly agreed standards and processes. The Borrower's comments (ICR, p. 50) stated that the EAC Region has not yet harmonized its regulatory fee structures and guidelines, and that applicants are required to pay application fees according to the requirements of each of the individual EAC Partner States.

Rating
Modest

Objective 2
Objective
Improve efficiency in medicines registration among East African Community partner states.

Rationale
The introduction of Common Technical Documents for medicines registration, joint assessments, joint GMP inspections, electronic submissions of applications, establishment of a quality management system, training in regulatory areas, and timely regulatory decisions would plausibly contribute to improved efficiency in medicines registration systems.

Intermediate Results:

- Staff trained in medicine regulation increased from a 0 baseline in 2012 to 233 in 2017, exceeding the target of 75.
- NMRAs implementing quality management systems increased from a 0 baseline in 2012 to 4 NMRAs in 2017, exceeding the target of 3 NMRAs.

Outcomes

In the context of joint inspections and assessments, the ICR (p. 16) stated that national and regional GMP inspections were conducted in parallel, defeating the very purpose of a joint GMP system (ICR, p. 16), which was supposed to reduce the number of inspections conducted by each NMRA, thus contributing to a more efficient system. According to the ICR (p. 16), nine applications were recommended for registration out of 49 applications during the period 2014-2017. There was no target for national registrations using harmonized guidelines. Also, 14 joint GMP inspections were conducted and 11 certificates were issued. The ICR stated that it was difficult to determine whether these 14 GMP joint inspections were significant in terms of their contribution to efficiency. There was a lack of clarity on the relationship between the national and regional GMP certification, and whether a regional GMP certification supersedes a national one to waive the requirement for a national GMP certificate to be renewed. The ICR also noted inadequate coordination between the Medicine Evaluation & Registration and GMP audits for product registration, difficulties in scheduling inspections at short notice and for travel clearances, and lack of a single point of contact for the payment of GMP certificate fees.

The number of NMRAs starting electronic submission of applications for registering medicines reached four NMRAs, exceeding the target of three. In addition to staff training, the project twinned strong NMRAs with less resourced NMRAs, and facilitated peer-to-peer learning through joint assessments and joint inspections. There were some capacity building improvements, but the ICR (p. 32) noted that varied capacities across NMRAs affected the pace of harmonization. To bridge the gap between less-resourced NMRAs and stronger NMRAs, additional political, legal, human-resources, and infrastructure support was needed. Only two NMRAs (Tanzania and Zanzibar) received ISO 9001 certification by the end of the project, short of the target of three (ISO is the International Organization for Standardization, and ISO 9001 is the international standard that specifies quality requirements under which organizations could demonstrate their ability to consistently provide products and services that meet customer and regulatory requirements).

The Borrower’s comments (ICR, p. 50) included the following conclusions:

- The timelines for review and registration of medicinal products at the regional level have been prolonged primarily due to the lack of a regional system and structure dedicated to handling and processing

applications; non-existence of streamlined application and payment procedures; low-quality dossiers by applicants; and sluggish response to queries by applicants.

- Slow progress in the establishment of two autonomous medicines regulatory agencies in the Republic of Rwanda and Burundi hindered the integration of medicines regulatory aspects.

Rating
Modest

Objective 3
Objective
Enhance transparency in medicines registration among East African Community partner states.

Rationale
Procuring and installing information and communication technology equipment and developing NMRAs' websites, facilitating NMRAs' functions for receiving medicines applications electronically, and sharing relevant information on policies, regulations and decisions could reasonably be expected to contribute to enhanced transparency in medicines registration systems.

Outcomes

The project developed a regional website and national websites for each NMRA for sharing regulatory policies, legislation, guidelines, and information on registered medicines. At project closing, four NMRAs (Tanzania, Uganda, Kenya, and Zanzibar) had either developed or updated their national websites and had links to the regional website, thus exceeding the target of three NMRAs. The Rwanda and Burundi websites could be accessed through their respective ministries of health. Therefore, all NMRAs were either sharing relevant public documents on their websites or had links to the regional website (ICR, p. 19). The ICR also stated that progress was made in involving pharmaceutical sector stakeholders to provide feedback on the proposed regulations. Kenya convened a stakeholder meeting to discuss the implementation of new guidelines for medicines registration. Tanzania and Zanzibar launched customer satisfaction surveys to improve the quality of regulatory services. According to the ICR, NMRAs in Kenya, Tanzania, and Zanzibar reported improved accountability due to enhanced transparency.

In assessing the above progress, the ICR stated that it also referred to the Transparency and Confidentiality Section of the WHO Benchmarking Tool for the Review of Drug Regulatory Systems, which 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" (ICR, p. 20, and further information available in Annex 6 of the ICR, p. 53).

Within the larger spectrum of items that were shared across partner states such as legislation, policies, and guidelines, there was a shortcoming in sharing processes and evaluation modalities of medicines registration applications among NMRAs (TTL clarifications, 8/22/18).

Rating
Substantial

Rationale

The aggregation of two partly achieved objectives with one almost fully achieved objective indicates a Modest rating for overall efficacy.

Overall Efficacy Rating
Modest

Primary reason
Low achievement

5. Efficiency

The PAD (p. 22) did not undertake a traditional economic analysis, but it offered reasonable generic arguments. It stated that the lack of standardization in medicines registration delays access to essential medicines for the citizens of East Africa. It stated that harmonization of medicines registration was expected to promote growth in the local pharmaceutical industry, expand its market, and attract investments by international pharmaceutical companies, which in turn would contribute to reducing prices, thus benefiting the poor. The PAD concluded that regulatory harmonization at the regional level made economic sense.

The ICR also offered generic arguments noting that 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, would be expected to create jobs and boost economic productivity. The ICR (p. 43) stated that project costs of US$10.2 million were minimal, at US$ 0.06 per person based on an estimated population of 168.8 million in the region in 2016. This ICR Review notes that this is rather a weak argument for efficiency.

There were significant shortcomings in the efficiency of implementation. Implementation delays impacted planned activities and outcomes (ICR, p. 20). According to the ICR, staff recruitment delays due to internal processes affected efficiency and slowed down project implementation. National activities started only in the

third year. NMRAs' annual reports indicated that most joint activities were not undertaken as scheduled, and the EAC did not provide financial support to NMRAs to implement activities in a timely manner. In 2015, implementation was scaled down due to a travel ban in Burundi caused by political instability. The approval of the additional financing in 2016 was delayed, and implementation was interrupted for a period of six months (ICR, p. 20) reportedly because of the lack of resources during the period when the additional financing was being processed.

Although the project's Operations Manual provided terms of reference for the EAC and NMRAs, implementation efficiency was negatively affected by poor coordination among different stakeholders leading to duplication of efforts and suboptimal results (ICR, p. 20). During project implementation, significant delays were encountered in organizing joint assessments, which impacted the number of products recommended for registration. Feedback to the ICR mission emphasized that coordination of regional activities for joint assessments and joint inspections was challenging without a clear calendar of upcoming activities and without advance circulation of the required technical documents prior to regulatory meetings. Assessors, inspectors, and technical experts could not make the necessary arrangements to attend or obtain clearance from their respective agencies for meetings at short notice.

Virtual budgeting at the regional level lacked transparency (see Section 11b) and was identified as a challenge and as a project weakness. For operational costs, the EAC did not provide financial support to NMRAs in a timely manner due to lengthy approval processes (ICR, p. 32). Despite capacity building efforts, the less resourced NMRAs in Burundi, Rwanda, and Zanzibar continued to face challenges of lack of expertise and understaffing, thus affecting the discharge of regulatory functions.

Efficiency Rating
Modest

a. If available, enter the Economic Rate of Return (ERR) and/or Financial Rate of Return (FRR) at appraisal and the re-estimated value at evaluation:

	Rate Available?	Point value (%)	*Coverage/Scope (%)
Appraisal		0	0 ☐Not Applicable
ICR Estimate		0	0 ☐Not Applicable

* Refers to percent of total project cost for which ERR/FRR was calculated.

6. Outcome

Relevance of objectives is rated Substantial as the objectives were responsive to the needs of the EAC region and remained largely consistent with Bank strategies and EAC Vision 2050. Efficiency is rated Modest in view of insufficient economic analysis and significant shortcomings in the efficiency of implementation. Efficacy is rated Modest as the objectives were only partly achieved. Therefore, overall Outcome is rated Moderately Unsatisfactory, reflecting significant shortcomings in the project's preparation and implementation.

a. Outcome Rating

Moderately Unsatisfactory

7. Risk to Development Outcome

While institutional capacity and its variability among the countries remain a risk, the EAC is reportedly committed under its Vision 2050 to strengthening and harmonizing health policies and strategies, including for the regulation of medicines. According to the ICR (p. 30), a roadmap for implementing the next phase of the program was developed. Also, a Technical Cooperation Framework, allowing bilateral recognition of approvals of medicines registration, has been developed by project closure and was planned to be submitted for consideration and approval by the Council of Ministers. According to the ICR (p. 30), most of the Partner States are updating their laws to create an enabling environment for harmonized standards and practices; and there is political will on the part of Partner States to sustain and build on investments and progress made by the project, e.g., in Zanzibar, the Ministry of Health has mainstreamed regulatory functions into the government budgeting process after project closing. The fees charged by NMRAs for regulatory services are expected to help in sustaining their activities, and funds for pharmacovigilance have been secured from the United States Agency for International Development. The ICR (p. 31) stated that, since project closing, a Regional Technical Team involving staff members from different NMRAs has been created to maintain continued commitment to joint regional activities.

8. Assessment of Bank Performance

a. Quality-at-Entry

Project preparation was informed by an institutional assessment of NMRAs that was carried out by WHO in 2009. The project team worked closely with the EAC, NMRAs, and other partners such as WHO and NEPAD, and held stakeholder consultations, including with the pharmaceutical industry, to endorse planned activities. Project risks, largely related to capacities of implementing agencies and overall governance, were identified, and mitigation measures were put in place. Based on information provided by the PAD (pp. 31-42), fiduciary aspects were adequately prepared.

Overall implementation arrangements were delineated, but there was a lack of clarity about concrete roles and responsibilities (ICR, p. 24) both within the project staff of the EAC Secretariat, and between the EAC Secretariat and NMRAs, further compounded by a lack of clarity on the division of labor

between the EAC Secretariat and NMRAs for each Technical Working Group. These shortcomings contributed to subsequent inadequacies in coordinating project activities.

Monitoring ad evaluation (M&E) preparation constituted a notable shortcoming. The objective of harmonization of medicines registration systems in the EAC region was not realistic in a short period of three years and with a large variability of regulatory capacities in the region at appraisal. As noted in Section 9, harmonization can be achieved when all project countries adopt and utilize commonly agreed standard requirements (ICR, p. 14). Hence, limiting outcome indicators to a portion of NMRAs was not fully consistent with the stated harmonization objective. The NMRA situational assessment of 2009, which informed project preparation, had revealed that three of the six NMRAs (Burundi, Rwanda, and Zanzibar) had limited technical capacity and physical infrastructure, and lacked enabling laws that would allow them to carry out regulatory functions needed to approve market authorization for medicines. 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) in a short period of time. According to the ICR, this issue was raised in the internal project concept note review in May 2011, where the meeting recommended changing the objective from achieving a harmonized system to standardizing the protocols for medicines registration. Lessons learned that were highlighted by the PAD (p. 19) on realism and the consideration of the long time required to establish new institutional mechanisms were not actually applied, and the ICR noted that a similar harmonization undertaking by the Association of South East Asian Nations took over 10 years to materialize (ICR, p. 23). Also, the results framework was not properly prepared, and there were gaps in M&E focal points.

Quality-at-Entry Rating
Moderately Unsatisfactory

b. Quality of supervision
The task team conducted 11 supervision missions that included procurement and financial management staff, and that addressed implementation bottlenecks, procurement, and financial management. The missions were undertaken with the EAC Secretariat along with representation from WHO and NEPAD. Except for three missions in 2016 and 2017, NMRAs were not invited to the joint supervision missions, but several technical missions were carried out in project countries, thus providing opportunities to interact with NMRAs at the country level. Feedback from industry was obtained to improve regulatory processes. In addition, the task team participated with WHO and NEPAD in all Steering Committee meetings where implementation progress and challenges were discussed. According to the ICR (p. 26), Implementation Status Reports adequately tracked the indicators in the results framework and reported on issues for senior management actions. In addition, the mission Aides-Memoire tracked other indicators beyond the results framework, such as the number of medicines assessed and registered at national and regional levels, as these indicators were also used in assessing efficiency.

However, significant shortcomings were noted. The Bank team could have undertaken a corrective restructuring to address the harmonization objective. Ineffective coordination among regional and

country authorities and M&E gaps (Section 9) were not adequately pursued by the Bank team to facilitate resolution. The preparation of additional financing was delayed, and project implementation was interrupted. Also, according to the ICR (p.29), the task team lacked both a seasoned operations officer and an M&E specialist.

Quality of Supervision Rating
Moderately Unsatisfactory

Overall Bank Performance Rating
Moderately Unsatisfactory

9. M&E Design, Implementation, & Utilization

a. M&E Design
The objectives were clear and measurable, but the harmonization objective was very optimistic, as harmonization of medicines registration can be achieved only when all project countries adopt and utilize agreed standards and processes. The outcome targets limiting harmonization to some countries were inconsistent with the stated objective of harmonized systems in the region. Information about M&E arrangements was scant, and the PAD (p. 42) stated that data were planned to be collected from administrative records, information made available on the agencies' websites, documented reports such as ISO 9001 certification (Section 4), manufacturing industry records, and medicine registration by each NMRA.

b. M&E Implementation
The frequency of NMRAs' reporting to the EAC was inconsistent. Information on the number of medicines assessed and registered using the Common Technical Documents was also inconsistent. Annual reports were shared with partners, but data were not validated by WHO as planned at appraisal. Other gaps included the absence of reporting on M&E by NMRAs and a lack of M&E focal points at the EAC Secretariat (ICR, p. 26).

c. M&E Utilization
The ICR stated that data collected during implementation were used for project monitoring and assessment, and that data were used to inform corrective measures, but no further information was provided by the ICR (p. 26).

M&E Quality Rating
Modest

10. Other Issues

a. Safeguards
No environmental or social safeguard policies were triggered by the operation, which was classified as a Category C project.

b. Fiduciary Compliance
Financial Management. The EAC Secretariat was responsible for financial management aspects of the project through the Director of Finance and Budget, who was supported by six divisions: finance, expenditure control, accounts, payroll, budget, and funding. Fund flow arrangements and disbursements were transaction-based with supporting documentation. For small value services such as training, workshops, and individual consultants at the country level, the project adopted a virtual budget for disbursing funds to NMRAs to minimize delays in fund flows by allowing NMRAs to procure such services, but with payments made directly by the EAC Secretariat to vendors and consultants. For operational costs, the EAC directly reimbursed NMRA expenditures. By the Mid-Term Review, it became clear that the virtual budget arrangement was not adequate, as there was a lack of transparency on how project funds under virtual budgeting were spent (ICR, p. 28). The TTL (8/22/18) stated that virtual budgeting was a top-down approach fully controlled by the region at the EAC level. Also, some expenditures budgeted at the country level were shown as expenditures incurred at the regional level. The EAC Secretariat was requested to clarify the processes of virtual budgeting in the Operations Manual, but this was not done. Virtual budgeting was identified by NMRAs as a project challenge and weakness.

Apart from virtual budgeting, the ICR noted that, after initial delays, financial management was adequate, and by the Mid-Term Review, there were timely submissions of withdrawal applications, interim financial reports, and quality external audits. Financial issues raised by supervision missions and the comments provided by external audits were addressed in a timely manner. The ICR did not offer information about financial compliance and audit qualifications; however, the TTL (8/22/18) confirmed that all project audits were unqualified, and that there were occasional comments for further improving accounting and reporting.

Procurement. The main procurement for the project included information and communication technology hardware and software, and office equipment for the EAC and NMRAs. The EAC hired additional procurement staff. Procurement was undertaken according to Bank guidelines, and EAC procurement staff reportedly made regular recourse to the Bank Procurement Specialist. Procurement was completed for all planned packages, except for a contract for translating the compendium documents to French for Burundi's use.

c. Unintended impacts (Positive or Negative)

None reported.

d. Other

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11. Ratings

Ratings	ICR	IEG	Reason for Disagreements/Comment
Outcome	Moderately Unsatisfactory	Moderately Unsatisfactory	---
Bank Performance	Moderately Unsatisfactory	Moderately Unsatisfactory	---
Quality of M&E	Modest	Modest	---
Quality of ICR		High	---

12. Lessons

The ICR (pp. 31-33) offered several useful lessons, including the following lessons restated by IEG:

Harmonizing medicines registration regionally is a long and complex process, and its ultimate attainment can be facilitated by a phased approach. The project experience suggested that standardizing registration requirements, aligning them with national polices and legal frameworks, and building institutional capacity at the national level in all of the countries involved were pre-requisites to the actual attainment of regional harmonization of registration systems for medicines.

Bridging the gap between less-resourced NMRAs and stronger NMRAs facilitates the attainment of the collective regional objective for harmonizing medicines registration systems. The project twinned strong NMRAs with less resourced NMRAs, provided substantial training, and facilitated peer-to-peer learning through joint assessments and joint inspections. Project experience also suggested that further additional support was needed to bridge the gap, including for legal and political support, human resources, and infrastructure.

Defining concrete institutional roles, responsibilities, and division of labor for various agencies, and revisiting these during implementation, enhances effective coordination and implementation performance. Under the project, generic terms of reference were developed for various project actors, but

during implementation, the respective roles and division of labor became blurred, resulting in coordination shortcomings and duplication of efforts.

13. Assessment Recommended?

No

14. Comments on Quality of ICR

The ICR was fully aligned to development objectives and had a focused storyline. The weaving together of the project's storyline with the assessment of achievement of objectives was noteworthy. The ICR provided a candid overview of the project experience. It explained well the theories of change underlying the intended outcomes. The analysis was insightful, thorough, and of high quality. Lessons were derived from project experience and should prove useful to future similar operations in regional regulatory harmonization of medicines. The ICR was internally consistent with logical links between its various sections. The ICR followed guidelines, including in its performance narrative and ratings, except for a minor shortcoming concerning insufficient information about financial audits. Overall, the ICR provided a thorough and candid account of the operation, with accurate and substantiated conclusions and ratings.

a. Quality of ICR Rating
High