Global Medicines Regulatory Harmonization Initiative Trust Fund Agreement Providing for the Amendment and Restatement of the Grant Agreement (East African Community for Medicines Regulatory Harmonization Project)

between

EAST AFRICAN COMMUNITY

and

INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT and INTERNATIONAL DEVELOPMENT ASSOCIATION
Acting as Administrator of the Global Medicines Regulatory Harmonization Initiative Trust Fund

Dated March 21, 2012

As amended and restated on March 17th, 2016
GLOBAL MEDICINES REGULATORY HARMONIZATION INITIATIVE
GRANT AGREEMENT

AGREEMENT dated March 21, 2012, as amended and restated on ____, 2016, entered into between EAST AFRICAN COMMUNITY (“Recipient” or “EAC”) the regional intergovernmental organization of the Partner States (as they are hereinafter defined in the Appendix to this Agreement) and INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT and INTERNATIONAL DEVELOPMENT ASSOCIATION (collectively, the “World Bank”), acting as administrator of the Global Medicines Regulatory Harmonization Initiative.

WHEREAS (A) under an agreement, dated March 21, 2012, between the Recipient and the World Bank (“Original Grant Agreement”) in an amount equal to five million five hundred forty-nine thousand two hundred United States Dollars ($5,549,200) to assist in financing the project described in Schedule I to the Original Grant Agreement (“Original Project”);

(B) the Recipient has requested the World Bank to provide additional financial assistance in support of additional activities within the scope of the Original Project, by making available to the Recipient an additional grant (“Additional Grant”) in an amount equal to three million four hundred thousand United States Dollars ($3,400,000); and

WHEREAS the World Bank has agreed, on the basis, inter alia, of the foregoing to extend such additional assistance to the Recipient upon the terms and conditions set forth in this Agreement;

NOW THEREFORE the Recipient and the World Bank hereby agree to amend and restate the Original Grant Agreement, with effect as of the Effective Date of this Agreement, to read as follows:

Article I
Standard Conditions; Definitions

1.01. The Standard Conditions for Grants Made by the World Bank Out of Various Funds, dated July 31, 2010 (“Standard Conditions”), with the modifications set forth in Section II of the Appendix to this Agreement, constitute an integral part of this Agreement.

1.02. Unless the context requires otherwise, the capitalized terms used in this Agreement have the meanings ascribed to them in the Standard Conditions or in this Agreement.
Article II
The Project

2.01. The Recipient declares its commitment to the objectives of the Project. To this end, the Recipient shall carry out the Project through the Secretariat and shall cause the Partner States to carry out their respective activities to the Project in accordance with the provisions of Article II of the Standard Conditions and in accordance with pharmaceutical and ethical international best practices.

2.02. Without limitation upon the provisions of Section 2.01 of this Agreement, and except as the Recipient and the World Bank shall otherwise agree, the Recipient shall ensure that the Project is carried out in accordance with the provisions of Schedule 2 to this Agreement.

Article III
The Grant

3.01. The World Bank agrees to extend to the Recipient, on the terms and conditions set forth or referred to in this Agreement, a grant in an amount equal to eight million nine hundred forty-nine thousand two hundred United States Dollars ($8,949,200) (“Grant”) which consists of: (a) the Original Grant equal to five million five hundred forty-nine thousand two hundred United States Dollars ($5,549,200); and (b) the Additional Grant equal to three million four hundred thousand United States Dollars ($3,400,000), to assist in financing the project as described in Schedule 1 to this Agreement (“Project”).

3.02. The Recipient may withdraw the proceeds of the Grant in accordance with Section IV of Schedule 2 to this Agreement.

3.03. The Grant is funded out of the abovementioned trust fund for which the World Bank receives periodic contributions from the donors to the trust fund. In accordance with Section 3.02 of the Standard Conditions, the World Bank’s payment obligations in connection with this Agreement are limited to the amount of funds made available to it by the donors under the abovementioned trust fund, and the Recipient’s right to withdraw the Grant proceeds is subject to the availability of such funds. Accordingly, in the event that any donor cancels or fails to pay any contributions under the trust fund to the World Bank for any reason, or that as a result of currency exchange variations the amount of funds available in the trust fund is insufficient for the purposes of the Grant, the Recipient shall bear the risk of such funding shortfall and the World Bank shall not have any liability whatsoever to the Recipient or to any third parties in respect of any expenditures or liabilities incurred by the Recipient or any third parties in connection with this Agreement which exceed the amount of funds made available to the World Bank by the donors for the purposes of the Grant.
Article IV
Additional Remedies

4.01. The Additional Events of Suspension referred to in Section 4.02 (k) of the Standard Conditions consist of the following:

(a) The Treaty or the Protocol has been amended, suspended, abrogated, repealed or waived so as to affect materially and adversely the ability of the Recipient to carry out the Project.

(b) Any action has been taken for the dissolution, disestablishment or suspension of the operation of the Recipient.

(c) A Partner State has failed to: (i) meet the commitments towards the Project as set forth in the Letter of Comfort and/or pursuant to the decisions/instructions/resolutions made by the Recipient to ensure the effective implementation of their part of the Project; or (ii) make payment (notwithstanding the fact that such payment may have been made by a third party) of principal, interest, service charges or any other amount due to the Association or the World Bank: (A) under any agreement between such Partner State and the Association; or (B) under any agreement between such Partner State and the World Bank; or (C) in consequence of any guarantee extended or other financial obligation of any kind assumed by the Association or the World Bank to any third party with the agreement of such Partner State.

(d) (i) Subject to subparagraph (ii) of this paragraph, the right of the Recipient to withdraw the proceeds of any grant made to the Recipient for the financing of Part 2 of the Project shall have been suspended, canceled or terminated in whole or in part, pursuant to the terms of the WHO Co-financing Agreement.

(ii) Subparagraph (i) of this paragraph shall not apply if the Recipient establishes to the satisfaction of the World Bank that: (A) such suspension, cancellation or termination is not caused by the failure of the Recipient to perform any of its obligations under such agreement; and (B) adequate funds for Part 2 of the Project are available to the Recipient from other sources on terms and conditions consistent with the obligations of the Recipient under this Agreement.
AGREED at Arusha, Tanzania, as of the day and year first above written.

EAST AFRICAN COMMUNITY

By

Authorized Representative

Name: LIBERAT MFUMUKHE

Title: SECRETARY GENERAL

INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT AND INTERNATIONAL DEVELOPMENT ASSOCIATION acting as administrator of the Global Medicines Regulatory Harmonization Initiative

By

Authorized Representative

Name: Ahmedou Mansoura Ndiaye

Title: Country Director
Article V
Effectiveness; Termination

5.01. The Conditions of Effectiveness consist of the following, namely the Recipient has provided a legal opinion in form and substance satisfactory to the World Bank, of counsel acceptable to the World Bank, showing the following matters, namely, on behalf of the Recipient, that this Agreement has been duly authorized by, executed and delivered on behalf of, and is legally binding upon, the Recipient, in accordance with its terms.

Article VI
Recipient’s Representative; Addresses

6.01. The Recipient’s Representative referred to in Section 7.02 of the Standard Conditions is the Recipient’s Secretary General.

6.02. The Recipient’s Address referred to in Section 7.01 of the Standard Conditions is:

East African Community
EAC Close, Afrika Mashariki Road
P.O Box 1096
Arusha
United Republic of Tanzania

Facsimile:
+255 27 2162190

6.03. The World Bank’s Address referred to in Section 7.01 of the Standard Conditions is:

International Bank for Reconstruction and Development and International Development Association
1818 H Street, N.W.
Washington, D.C. 20433
United States of America

Facsimile:
1-202-477-6391
The objective of the Project is to harmonize medicines registration systems and to improve efficiency and enhance transparency in medicines registration among the East African Community Partner States.

The Project consists of the following parts:

Part 1. **Regional coordination and capacity building for medicines regulatory harmonization**

1. 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.

2. 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 the day to day operational support and reporting; and (c) six Regional Expert Working Groups which will respectively take technical lead in: (i) medicines registration, (ii) good manufacturing practices inspection, (iii) information management systems, (iv) pharmaceutical policy, legal and regulatory reforms; (v) pharmacovigilance; and (vi) quality management system.

3. Provision of support to undertake a comprehensive systems requirement study for online registration and to develop a national and regional web-based data information management system for the work sharing and sharing of medicines regulatory information across the East Africa region.

4. Provision of support to enhance pharmacovigilance capacity of the Recipient and the Partner States National Medicines Regulatory Agencies, by developing a strategic plan to monitor patient safety and strengthen management of adverse events following administration of medicines and vaccines.

Part 2. **Institutional development and strengthening of national medicines regulatory authorities**

1. Carrying out of capacity building activities to the Partner States’ NMRAs, including support to: (i) additional staff training in areas of project management; (ii) quality assessment and safety of medicines; and (iii) goods manufacturing practices inspections.

2. Provision of support for the twinning/mentoring of NMRAs in the region and implementation of quality management systems including internal and external audits.
SCHEDULE 2

Project Execution

Section I. Implementation Arrangements

A. Institutional Arrangements

1. Secretariat

The Secretariat of the East African Community shall be responsible for the overall implementation of the Project, in collaboration, as needed, with the structures within the Council of Ministers. For such purposes, the Recipient shall ensure the Secretariat is provided at all times the financial and human resources suitable to enable it to carry out its responsibilities under the Project. In particular, the Secretariat shall: (i) act as the operational link between the World Bank and each of the Partner States; (ii) be responsible for the procurement and financial management of the Project; and (iii) prepare and implement the AWP&Bs in accordance with the provisions of paragraph D of this Section I.

2. Project Coordination Team

The Recipient shall maintain, throughout the implementation of the Project, the Project Coordination Team (PCT) within the Health Department of the Secretariat, including financial management, procurement, accounting, and monitoring and evaluation and informatics specialists to assist the Secretariat to carry out its tasks in the Project, all with terms of reference and experience satisfactory to the World Bank.

3. Steering Committee

The Recipient shall maintain, throughout the implementation of the Project, the Steering Committee vested with the responsibility to provide overall guidance and oversight over Project preparation and implementation and to approve the AWP&Bs. The Steering Committee shall be composed of senior representatives from the Secretariat and from the Partner States' ministries responsible for health, finance and East African cooperation.

4. Council of Ministers

Following the approval of the AWP&Bs by the Steering Committee and prior to their implementation, the Recipient shall ensure that said plans are endorsed by the Council of Ministers.
(b) not later than April 30 immediately prior to each such Fiscal Year, furnish to the World Bank for its comments and approval, the draft AWP&B for such Fiscal Year and, promptly thereafter, finalize the AWP&B taking into account the World Bank's views and recommendations thereon; and

(c) adopt and sign the final version of the AWP&B in the form approved by the World Bank not later than June 30 immediately prior to each such Fiscal Year.

E. Training under the Project

For the purposes of the Training to be financed under the Project, the Recipient shall:

(a) furnish to the World Bank for its approval, not later than April 30 of each year, a training or workshop program including an explanation of how such training or workshop is consistent and conducive to the objectives of the Project and whether it offers the best price/quality ratio, as well as the schedule for its implementation;

(b) select the trainees or attendees in accordance with a transparent process and criteria satisfactory to the World Bank; and

(c) furnish to the World Bank a report of such scope and detail as the World Bank shall reasonably request, on the results of each training and workshop and the benefits to be derived there from.

F. Donor Visibility and Visit

1. The Recipient shall take or cause to be taken all such measures as the World Bank may reasonably request to identify publicly the Donor's support for the Project.

2. For the purposes of Section 2.09 of the Standard Conditions, the Recipient shall, upon the World Bank's request, take all measures required on its part to enable the representatives of the Donor(s) to visit any part of the Recipient's Partner States' territory for purposes related to the Project.

Section II. Project Monitoring, Reporting and Evaluation

A. Project Reports

1. The Recipient shall monitor and evaluate the progress of the Project and prepare Project Reports in accordance with the provisions of Section 2.06 of the Standard Conditions and on the basis of the Monitoring and Evaluation Indicators acceptable to the World Bank. Each Project Report shall cover the period of one calendar semester, and shall be furnished to the World Bank not later than one (1) month after the end of the period covered by such report.
5. **Regional Expert Working Group**

(a) The Recipient shall maintain, throughout the implementation of the Project, six Regional Expert Working Groups, in form and substance and qualified staff satisfactory to the World Bank, to respectively develop harmonized medicines related guidelines and supporting standard operating procedures in the following four areas: (i) medicines registration; (ii) good manufacturing practices inspection; (iii) information management systems, (iv) pharmaceutical policy; legal and regulatory reforms; (v) pharmacovigilance; and (vi) quality management system.

(b) Each Regional Expert Working Group shall comprise representatives of the national medicines regulatory authority of two or more Partner States and will function under the leadership of the national medicine regulatory authority of one of the Partner States, all as set forth in the Project Operations Manual.

**B. Anti-Corruption**

The Recipient shall ensure that the Project is carried out in accordance with the provisions of the Anti-Corruption Guidelines.

**C. Project Operational Manual**

The Recipient shall: (i) take all action required to carry out the Project in accordance with the provisions and requirements set forth or referred to in the Project Operational Manual; (ii) submit recommendations to the World Bank for its consideration for changes and updates of the Project Operational Manual as they may become necessary or advisable during the operation of the Project in order to achieve the objective of the Project; and (iii) not assign, amend, abrogate or waive the Project Operational Manual or any of its provisions without the World Bank’s prior agreement. Notwithstanding the foregoing, if any of the provisions of the Project Operation Manual is inconsistent with the provisions of this Agreement, the provisions of this Agreement shall prevail and govern.

**D. Annual Work Program and Budget (AWP&B)**

The Recipient shall:

(a) prepare a draft AWP&B for each Fiscal Year, setting forth, *inter alia*: (i) a detailed description of planned activities for Parts I and II of the Project for the Fiscal Year; (ii) the sources and uses of funds therefore; and (iii) responsibility for execution of said Project activities, budgets, start and completion date, outputs, and monitoring indicators to track progress of each activity;
2. The Recipient shall prepare the Completion Report in accordance with the provisions of Section 2.06 of the Standard Conditions. The Completion Report shall be furnished to the World Bank not later than six (6) months after the Closing Date.

B. Mid-Term Review

The Recipient, through the Project Coordination Team, shall:

(a) maintain policies and procedures adequate to enable it to monitor and evaluate on an ongoing basis, in accordance with the Monitoring and Evaluation Indicators, the carrying out of the Project and the achievement of the objective thereof;

(b) prepare, under terms of reference satisfactory to the World Bank, and furnish to the World Bank, by May 2014, a report integrating the results of the monitoring and evaluation activities and setting out the measures recommended to ensure the efficient carrying out of the Project and achievement of the objective thereof during the period following such date; and

(c) review with the World Bank, by June 2014, or such later date as the World Bank shall request, the report referred to in the preceding paragraph (b), and, thereafter, take all measures required to ensure the efficient completion of the Project and the achievement of the objective thereof, based on the conclusions and recommendations of the said report and the World Bank’s views on the matter.

C. Financial Management, Financial Reports and Audits

1. The Recipient shall ensure that a financial management system is maintained in accordance with the provisions of Section 2.07 of the Standard Conditions.

2. The Recipient shall ensure that interim unaudited financial reports for the Project are prepared and furnished to the World Bank not later than forty-five (45) days after the end of each calendar quarter, covering the quarter, in form and substance satisfactory to the World Bank.

3. The Recipient shall have its Financial Statements for the Project audited in accordance with the provisions of Section 2.07(b) of the Standard Conditions. Each such audit of the Financial Statements shall cover the period of one (1) fiscal year of the Recipient. The audited Financial Statements for each such period shall be furnished to the World Bank not later than six (6) months after the end of such period.
Section III.  Procurement

A.  General

1.  **Procurement and Consultant Guidelines.** All goods, non-consulting-services and consultants’ services required for the Project and to be financed out of the proceeds of the Grant shall be procured in accordance with the requirements set forth or referred to in:

   (a)  Section I of the Procurement Guidelines in the case of goods and non-consulting services, and Sections I and IV of the Consultant Guidelines in the case of consultants’ services; and

   (b)  the provisions of this Section III, as the same shall be elaborated in the procurement plan prepared and updated from time to time by the Recipient for the Project in accordance with paragraph 1.18 of the Procurement Guidelines and paragraph 1.25 of the Consultant Guidelines ("Procurement Plan").

2.  **Definitions.** The capitalized terms used below in this Section to describe particular procurement methods or methods of review by the World Bank of particular contracts, refer to the corresponding method described in Sections II and III of the Procurement Guidelines, or Sections II, III, IV and V of the Consultant Guidelines, as the case may be.

B.  Particular Methods of Procurement of Goods and Non-consulting Services

1.  **International Competitive Bidding.** Except as otherwise provided in paragraph 2 below, goods and non-consulting services shall be procured under contracts awarded on the basis of International Competitive Bidding.

2.  **Other Methods of Procurement of Goods and Non-consulting Services.** The following methods, other than International Competitive Bidding, may be used for procurement of goods and non-consulting services for those contracts specified in the Procurement Plan: (a) National Competitive Bidding; (b) Shopping; and (c) Direct Contracting.

3.  **Additional Provisions Governing National Competitive Bidding referred to in paragraph B.2 (a) of this Section.**

   National Competitive Bidding for goods and Non-consulting Services shall be subject to the following:

   (a)  In accordance with paragraph 1.16(e) of the Procurement Guidelines, each bidding document and contract financed out of the proceeds of the Grant shall provide that: (i) the bidders, suppliers, contractors and subcontractors shall
permit the World Bank, at its request, to inspect their accounts and records relating to the bid submission and performance of the contract, and to have said accounts and records audited by auditors appointed by the World Bank; and (ii) the deliberate and material violation by the bidder, supplier, contractor or subcontractor of such provision may amount to an obstructive practice as defined in paragraph 1.16(a)(v) of the Procurement Guidelines.

(b) There shall be no preference accorded to domestic suppliers and contractors.

C. Particular Methods of Procurement of Consultants' Services

1. Quality- and Cost-based Selection. Except as otherwise provided in paragraph 2 below, consultants' services shall be procured under contracts awarded on the basis of Quality- and Cost-based Selection.

2. Other Methods of Procurement of Consultants' Services. The following methods, other than Quality- and Cost-based Selection, may be used for procurement of consultants' services for those assignments which are specified in the Procurement Plan: (a) Quality-based Selection; (b) Selection under a Fixed Budget; (c) Least Cost Selection; (d) Selection based on Consultants' Qualifications; (e) Single-source Selection of consulting firms; (f) Selection of Individual Consultants; and (g) Single-source procedures for the Selection of Individual Consultants.

D. Review by the World Bank of Procurement Decisions

The Procurement Plan shall set forth those contracts which shall be subject to the World Bank's Prior Review. All other contracts shall be subject to Post Review by the World Bank.

Section IV. Withdrawal of Grant Proceeds

A. General

1. The Recipient may withdraw the proceeds of the Grant in accordance with the provisions of: (a) Article III of the Standard Conditions; (b) this Section; and (c) such additional instructions as the World Bank may specify by notice to the Recipient (including the “World Bank Disbursement Guidelines for Projects” dated May 2006, as revised from time to time by the World Bank and as made applicable to this Agreement pursuant to such instructions), to finance Eligible Expenditures as set forth in the table in paragraph 2 below.

2. The following table specifies the categories of Eligible Expenditures that may be financed out of the proceeds of the Grant (“Category”), the allocations of the amounts of the Grant to each Category, and the percentage of expenditures to be financed for Eligible Expenditures in each Category:
<table>
<thead>
<tr>
<th>Category</th>
<th>Amount of the Grant Allocated (expressed in USD) TF010846</th>
<th>Percentage of Expenditures to be Financed (inclusive of Taxes)</th>
<th>Amount of the Grant Allocated (expressed in USD) TF0A2289</th>
<th>Percentage of Expenditures to be Financed (inclusive of Taxes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Goods, non-consulting services, and consultants’ services, Operating Costs and Training under Part 1 of the Project</td>
<td>2,409,700</td>
<td>100%</td>
<td>1,924,936</td>
<td>100%</td>
</tr>
<tr>
<td>(2) Goods, non-consulting services, and consultants’ services, Operating Costs and Training under Part 2 of the Project</td>
<td>3,139,500</td>
<td>100%</td>
<td>1,475,064</td>
<td>100%</td>
</tr>
<tr>
<td>TOTAL AMOUNT</td>
<td>5,549,200</td>
<td></td>
<td>3,400,000</td>
<td></td>
</tr>
</tbody>
</table>

B. **Withdrawal Conditions; Withdrawal Period**

1. Notwithstanding the provisions of Part A of this Section no withdrawal shall be made for payments made prior to the date of this Agreement, except that withdrawals up to an aggregate amount not to exceed $150,000 equivalent may be made for payments made prior to this date on or after March 11, 2016, for Eligible Expenditures.

2. The Closing Date referred to in Section 3.06(c) of the Standard Conditions is June 30, 2017.

Section V. **Other Undertakings**

1. (a) To facilitate the carrying out of the Project, the Recipient shall make a portion of the Grant proceeds available on a grant basis to the Partner States under terms and conditions approved by the World Bank, which shall include, \textit{inter alia}: (a) the principal amount of the funds which will benefit each Partner State denominated in Dollars; (b) the Recipient’s right to suspend, terminate or obtain refund, of the funds that benefitted the Partner States individually or collectively, in the event a Partner State fails to perform its obligations under the Project pursuant to the instructions/decisions/resolution made by the Recipient to ensure the implementation of the Project; and (c) the obligation
of Partner States to abide by the terms of the Project Operations Manual and the Anti-Corruption Guidelines.

(b) The Recipient shall exercise its rights and carry out its obligations in such a manner as to protect the interests of the Recipient and the World Bank and to accomplish the purposes of the Grant.

2. The Recipient shall cause each Partner State to provide a Comfort Letter to the World Bank confirming the Partner State’s commitment to the objectives of the Project, and, that to this end each Partner State shall:

(a) respectively carry out the activities of Project at the local level with due diligence and efficiency and in conformity with appropriate administrative, financial, educational, technical, social, medical, ethical and environmental practices in collaboration with the Recipient;

(b) provide, promptly as needed, facilities, services and other resources required for the Project; and

(c) take all measures required on its part to enable the representatives of the World Bank and Donor(s) to visit any part of the Partner State’s territory for purposes related to the Project and provide any information as the World Bank shall reasonably request regarding the administration and operation of the activities carried out by said Partner State under the Project.

3. The Recipient shall have recruited, by July 1, 2013, the additional staff for the Secretariat and the National Focal Points in the National Medicines Regulatory Authorities of respective East African Community Partner States under terms of reference and with qualifications and experience satisfactory to the World Bank.

4. The Recipient and WHO shall, by July 19, 2012, enter into the WHO Co-financing Agreement.
APPENDIX

Section I. Definitions

1. "Annual Work Plan and Budget" and "AWP&B" mean the annual work plan and budget to be prepared on an annual basis by the Secretariat (as hereinafter defined).


3. "Category" means a category set forth in the table in Section IV of Schedule 2 to this Agreement.

4. "Co-financier" means the World Health Organization or WHO.

5. "Co-financing" means an amount of funds to be provided by the Co-financier to assist in financing the Project.

6. "Comfort Letter" means the letters referred to in Section V.2 of Schedule 2 of this Agreement provided by the Partner States to the World Bank.


8. "Council of Ministers" means the Recipient’s Council of Ministers referred to in paragraph 4 of Section I.A of Schedule 2 to this Agreement, which is the policy organ of the Recipient established and functioning pursuant to the provisions, respectively, of Articles 9.1(b) and 14 of the Treaty (as hereinafter defined).

9. "Fiscal Year" means the twelve (12) month period corresponding to any of the Recipient’s fiscal years, which period commences on July 1 and ends on June 30 in each calendar year.


11. "Monitoring and Evaluation Indicators" means the agreed monitoring and evaluation indicators set forth in the Project Operation Manual (as hereinafter defined) to be utilized by the Recipient to measure the progress in the implementation of the Project and the degree to which the objectives thereof is being achieved.

12. "National Medicines Regulatory Agencies" and "NMRAs", each means the agencies responsible for the regulation and control of medical products.
13. “Operating Costs” means the expenditures incurred to finance the cost of the administrative support to be provided under the Project, including: (i) office furniture and equipment; (ii) equipment maintenance and insurance; (iii) public utilities and communication technology (including, without limitation, internet and telephone); (iv) building security and maintenance; (v) translation services, photocopies and publications; and (vi) office supplies.

14. “Operational Manual” means the Recipient’s set of guidelines and procedures dated January 31, 2012, by the Recipient through the Secretariat (as hereinafter defined), as revised, applicable for the purpose of implementing the Project, including in the areas of monitoring and evaluation, coordination, financial management (including financial, administrative and accounting procedures, procurement, internal controls and audits), and other provisions related to the institutional organization of the Project, as such guidelines and procedures may be amended from time to time with the prior written agreement of the World Bank.

15. “Partner States” means the states of the Republic of Burundi, Republic of Kenya, Republic of Rwanda, United Republic of Tanzania and Republic of Uganda and with the prior agreement of the World Bank, any other state that might become a party to the Treaty following the date of this Agreement.


17. “Procurement Plan” means the Recipient’s procurement plan for the Project, dated February 13, 2012, and referred to in paragraph 1.18 of the Procurement Guidelines and paragraph 1.25 of the Consultant Guidelines, as the same shall be updated from time to time in accordance with the provisions of said paragraphs.

18. “Program” means the program designed to support countries increase the rapid availability of safe and effective medicines of assured quality, including life saving treatments for priority diseases (“ARMH”).

19. “Project Coordination Team” and “PCT” mean the group responsible for coordinating implementation of the Project activities and referred to in paragraph 2 of Section I.A of Schedule 2 to this Agreement.


22. “Secretariat” means the executive organ of the Recipient established pursuant to the provisions of Articles 9.1(g) and 66 of the Treaty (as hereinafter defined).

23. “Steering Committee” means the committee referred to in paragraph 3 of Section 1.A of Schedule 2 to this Agreement.

24. “Training” means the expenditures incurred to finance the cost of the meetings and the training and workshops to be provided and/or received under the Project, and including: (i) per diem and travel expenses of the attendees, training instructors (trainers) and/or training participants (trainees); (ii) educational equipment and materials for display (including, without limitation, television, projector); (iii) training and/or workshop fees and other reasonable and ancillary costs for attending the meetings, training and/or workshop; and (iv) organization and coordination, training facilities, and communication and marketing costs related to the meetings, training and/or workshop events.


27. “WHO Co-financing Agreement” (Memorandum of Understanding between the East African Community and World Health Organization) means an amount of approximately one million Dollars ($1,000,000) provided in kind by the WHO to assist in financing the Project out of the portion of the Global Medicines Regulatory Harmonization Initiative Trust Fund which the WHO shall receive from the Bank to support selected activities of the Project in accordance with the WHO’s own procedures and guidelines, including procurement guidelines.

Section II. Modifications to the Standard Conditions

The Standard Conditions are modified as follows:

1. (a) Paragraph 17 of the Appendix (Definitions) is modified to read as follows:

“17. “Member Country” means a member of the World Bank in whose territory the Project is carried out or any of such member’s political or administrative subdivisions, and refers separately to each such member.”

(b) A new definition 27 is added to read as follows:

“27. “Partner States” means collectively the states-parties signatories of the Arusha Treaty for the Establishment of the East African Community (1999), namely the Republic of Burundi, the Republic of Kenya, the United Republic of Tanzania, the Republic of Rwanda, and the Republic of Uganda, and in whose territories the Project is carried out; and “Partner State” refers separately and individually to each and any of such Partner States.”
2. Section 3.07 is modified to read as follows:

"Section 3.07. Financing Taxes

(a) The Grant Agreement may specify that the proceeds of the Grant may not be withdrawn to pay for Taxes levied by, or in the territory of, a Member Country on or in respect of Eligible Expenditures, or on their importation, manufacture, procurement or supply. In such case, if the amount of any such Taxes decreases or increases, the World Bank may, by notice to the Recipient, adjust the percentage of such Eligible Expenditures to be financed out of the proceeds of the Grant specified in the Grant Agreement, as required to ensure consistency with such limitation on withdrawals."

3. Section 4.02 is amended as follows:

(i) Paragraph (a) is amended to read as follows:

"(a) Interference. If the Grant has been made to a Recipient which is not the Member Country, a Member Country has: (i) taken or permitted to be taken any action which would prevent or interfere with the execution of the Project or the performance of the Recipient of its obligations under the Grant Agreement; or (ii) failed to afford a reasonable opportunity for representatives of the World Bank to visit any part of its territory for purposes related to the Grant or the Project."

(ii) Paragraphs (c) and (d) are amended to read as follows:

"(c) Fraud and Corruption. At any time, the World Bank determines that any representative of the Recipient (or any Member Country, if the Recipient is not the Member Country, or any other recipient of any of the proceeds of the Grant) has engaged in corrupt, fraudulent, coercive or collusive practices in connection with the use of the proceeds of the Grant, without the Recipient (or any such Member Country or any other such recipient) having taken timely and appropriate action satisfactory to the World Bank to address such practices when they occur.

(d) Cross Suspension. IBRD or IDA has suspended in whole or in part the right of the Recipient (or of any Member Country, if the Recipient is not the Member Country) to make withdrawals under any agreement with IBRD or with IDA because of a failure by the Recipient (or by any such Member Country) to perform any of its obligations under such agreement or any other agreement with IBRD or IDA."

(iii) Paragraph (h) is amended to read as follows:

"(h) Membership. A Member Country: (i) has been suspended from membership in or ceased to be a member of IBRD or of IDA; or (ii) has ceased to be a member of the International Monetary Fund."
(iv) The first sentence of paragraph (i) is amended to read as follows:

"(i) Condition of Recipient. If the Grant has been made to a Recipient which is not a Member Country:"

(v) Paragraph (j) is amended to read as follows:

"(j) Ineligibility. IBRD or IDA has declared the Recipient (other than a Member Country) ineligible to receive proceeds of any financing made by IBRD or IDA or otherwise to participate in the preparation or implementation of any project financed in whole or in part by IBRD or IDA, as a result of: (i) a determination by IBRD or IDA that the Recipient has engaged in fraudulent, corrupt, coercive or collusive practices in connection with the use of the proceeds of any financing made by IBRD or IDA; and/or (ii) a declaration by another financier that the Recipient is ineligible to receive proceeds of any financing made by such financier or otherwise to participate in the preparation or implementation of any project financed in whole or in part by such financier as a result of a determination by such financier that the Recipient has engaged in fraudulent, corrupt, coercive or collusive practices in connection with the use of the proceeds of any financing made by such financier."

4. Paragraph (c) of Section 4.03 is modified to read as follows:

"(c) Fraud and Corruption. At any time, the World Bank determines, with respect to any amount of the proceeds of the Grant, that corrupt, fraudulent, collusive or coercive practices were engaged in by representatives of the Recipient (or any Member Country, if the Recipient is not a Member Country, or any other recipient of the proceeds of the Grant), without the Recipient (or any such Member Country or other recipient of the proceeds of the Grant) having taken timely and appropriate action satisfactory to the World Bank to address such practices when they occur."

5. Paragraph (a)(ii) of Section 4.05 is modified to read as follows:

"(ii) (A) engaging in corrupt, fraudulent, collusive or coercive practices in connection with the use of such amount, or (B) use of such amount to finance a contract during the procurement or execution of which such practices were engaged in by representatives of the Recipient (or any Member Country, if the Recipient is not a Member Country, or other recipient of such amount of the Grant), in either case without the Recipient (or any such Member Country, or other such recipient) having taken timely and appropriate action satisfactory to the World Bank to address such practices when they occur."
6. Paragraph (j) of Section 5.03 is modified to read as follows:

"(j) If, within thirty days after counterparts of the award have been delivered to the parties, the award has not been complied with, any party may: (i) enter judgment upon, or institute a proceeding to enforce, the award in any court of competent jurisdiction against any other party; (ii) enforce such judgment by execution; or (iii) pursue any other appropriate remedy against such other party for the enforcement of the award and the provisions of the Grant Agreement. Notwithstanding the foregoing, if the Recipient is the Member Country, this Section shall not authorize any entry of judgment or enforcement of the award against the Recipient except as such procedure may be available otherwise than by reason of the provisions of this Section."