

Standard Terms and Conditions

Article 1. PURPOSE OF AGREEMENT

This Agreement between the Global Fund to Fight AIDS, Tuberculosis and Malaria, a non-profit foundation established under the laws of Switzerland (the “Global Fund”) and the United Nations Development Programme, a subsidiary organ of the United Nations, with its headquarters in New York, New York, United States of America, as represented by its Resident Representative in the country specified in the face sheet of this Agreement (the “Principal Recipient”) defines the terms and conditions under which the Global Fund will provide funding to the Principal Recipient to implement or oversee the implementation of the Program whose title is set forth in the face sheet of this Agreement (the “Program”) for the country specified in the face sheet of this Agreement (“Host Country”).

Article 2. THE PROGRAM

a. The Program is further described in Annex A of this Agreement, the “Program Implementation Abstract.” The Principal Recipient will implement or oversee the implementation of the Program in accordance with the terms of this Agreement, which the Principal Recipient will administer using its regulations, rules and procedures. The Principal Recipient will be responsible and accountable to the Global Fund for all resources it receives under this Agreement and for the results that are to be accomplished.

b. The Global Fund and the Principal Recipient may by agreement in writing from time to time modify Annex A of this Agreement during the implementation of the Program.

Article 3. FISCAL TERMS

a. For the current implementation period, as set forth in the face sheet of this Agreement, the Global Fund hereby grants to the Principal Recipient an amount not to exceed that stated in the face sheet of this Agreement, which shall be made available to the Principal Recipient under the terms of this Agreement. For the purpose of this Agreement, the “Grant” shall consist of funds as stated in the face sheet of this Agreement together with any funds previously granted by the Global Fund to the Principal Recipient for the Program. The Global Fund makes the Grant to the Principal Recipient in response to the Country Coordinating Mechanism’s request for financial assistance.

b. Any interest or other earnings on funds disbursed by the Global Fund to the Principal Recipient under this Agreement shall be used for Program purposes, unless the Global Fund agrees otherwise in writing.

c. (1) Total Global Fund funding for the Program is limited to the Grant. Each disbursement of Grant funds shall be subject to the availability of funds to the Global Fund for such purpose at the time of the disbursement. Unless the Global Fund agrees otherwise in writing, the Grant may be used for Program expenditures beginning from the “Program Starting Date”. If the Principal Recipient chooses to continue Program activities after the Global Fund funding has been exhausted, the Principal Recipient understands that the Global Fund makes no commitment beyond the amounts available under the terms of this Agreement.

(2) In making funds available for the Program, the Global Fund acknowledges that, in accordance with the Principal Recipient's Financial Regulations and Rules, disbursements to the Principal Recipient must be made in advance of the implementation of the activities to be financed. In the event funds are not available to the Global Fund, the Principal Recipient may reduce, suspend or terminate its support to the Program.

d. The Global Fund and the Principal Recipient estimate that the proposal described in Annex B, as designed and if fully funded and implemented, will be completed by the "Proposal Completion Date". Unless the Global Fund agrees otherwise in writing, the Global Fund will not authorize disbursement of the Grant after the "Program Ending Date" if the Global Fund determines in its sole discretion that satisfactory progress has not been made in implementing the Program before the Program Ending Date or that funds are not available for such disbursement.

e. Conditions Precedent to Disbursement.

(1) Annex A, the Program Implementation Abstract, may state conditions precedent to first disbursement of funds under the Grant or conditions precedent to disbursement of Grant funds for a particular purpose, in excess of a specified amount or after a certain time. Unless the Global Fund and the Principal Recipient agree otherwise in writing, the Principal Recipient must satisfy the stated conditions, in form and substance satisfactory to the Global Fund, before the Global Fund will authorize disbursement of the relevant funds.

(2) The terminal dates for meeting the conditions specified in Annex A are the dates (if any) specified in this Agreement, as indicated for the particular conditions. If the conditions precedent have not been met by the stated terminal date, the Global Fund, at any time, may terminate this Agreement by written notice to the Principal Recipient.

(3) Unless the Global Fund advises the Principal Recipient otherwise in writing, the Principal Recipient will furnish to the Global Fund all items required to satisfy the conditions precedent to disbursement stated in Annex A and shall ensure that members of the Country Coordinating Mechanism receive copies of the items. The Global Fund will promptly notify the Principal Recipient when the Global Fund has determined that a condition precedent has been met.

f. Consistent with numerous United Nations Security Council Resolutions, including S/RES/1269 (1999), S/RES/1368 (2001), and S/RES/1373 (2001), both the Global Fund and the Principal Recipient are firmly committed to the international fight against terrorism, and in particular, against the financing of terrorism. It is the policy of the Global Fund to seek to ensure that none of its funds are used, directly or indirectly, to provide support to individuals or entities associated with terrorism. In accordance with this policy, the Principal Recipient undertakes to use reasonable efforts to ensure that none of the Grant funds provided under this Agreement are used to provide support to individuals or entities associated with terrorism.

Article 4. TAXES AND DUTIES

a. The Principal Recipient shall try to ensure through coordination with the government of the Host Country and the Country Coordinating Mechanism and otherwise

that this Agreement and the assistance financed hereunder shall be free from taxes and duties imposed under laws in effect in the Host Country.

b. The Principal Recipient shall assert all exemptions from taxes and duties to which it believes it, the Global Fund or the Grant is entitled.

Article 5. THE TRUSTEE

The Global Fund and the International Bank for Reconstruction and Development (the "World Bank") have entered into an agreement as of May 31, 2002, by which the World Bank has agreed to establish the "Trust Fund for the Global Fund to Fight AIDS, Tuberculosis and Malaria" (the "Trust Fund") and to serve as the trustee of the Trust Fund (the "Trustee"). Grant funds made available to the Principal Recipient will be disbursed from the Trust Fund.

Article 6. DISBURSEMENTS

a. Approximately every three months, the Principal Recipient shall submit to the Global Fund requests for disbursements of funds from the Grant, in form and substance satisfactory to the Global Fund. Requests for disbursement shall be signed by the person or persons authorized by the Principal Recipient to do so. Upon the Global Fund's approval of a request for disbursement, the Global Fund will advise the Trustee to transfer the amount approved by the Global Fund into the account notified by the Principal Recipient to the Global Fund in writing.

b. The amount approved for disbursement will be based on achievement of Program milestones and the expected cash flow needs of the Principal Recipient. The Global Fund, at any time, may approve for disbursement an amount less than the disbursement request if the Global Fund concludes that the full disbursement request is not justified.

c. Each disbursement under the Grant is subject to the availability of funds to the Global Fund for such disbursement.

Article 7. AUDITS AND RECORDS

a. Books and Records of the Principal Recipient.

The Principal Recipient shall maintain Program accounts, books, records, and all other documents relating to the Program or maintained under the Agreement, adequate to show, without limitation, all costs incurred by the Principal Recipient under the Agreement and the overall progress toward completion of the Program ("Program books and records"). The Principal Recipient shall maintain Program books and records in accordance with United Nations Accounting Standards. Program books and records shall be maintained for at least three years after the date of last disbursement under this Agreement or for such longer period, if any, required to resolve any claims or audit findings.

b. Principal Recipient Audits.

(i) The Principal Recipient shall have annual financial audits conducted of Program expenditures. Subject to the approval of the Global Fund, which approval shall not be

unreasonably withheld, the Principal Recipient shall select an independent auditor to conduct the audits and set the terms of reference pursuant to which they shall be conducted. The cost of such special audit shall be borne by the Program.

(ii) Should the Global Fund have reason to request a special purpose audit on the use of Global Fund resources, UNDP agrees to be responsible for: (i) securing the appointment of a mutually agreed independent auditor; and (ii) preparing mutually agreed audit Terms of Reference which reflect, as necessary, circumstances giving rise to the Global Fund's request for said audit. The cost of such special audit shall be borne by the Program.

c. Certified Financial Statement.

Not later than June 30 of each year, the Principal Recipient shall submit to the Global Fund a statement, certified by the Comptroller of the Principal Recipient, of income and expenditure of the Program during the preceding year.

d. Sub-recipient Audits.

The Principal Recipient shall submit to the Global Fund a plan, acceptable to the Global Fund, for the audit of the expenditures of Sub-recipients under the Program. The Principal Recipient shall ensure that Sub-recipients are audited in accordance with the plan, unless the Global Fund and the Principal Recipient agree otherwise in writing. Upon request, the Principal Recipient shall furnish or cause to be furnished to the Global Fund a copy of reports of audits carried out under the plan.

e. Ad-hoc Site Visits

The Principal Recipient shall afford authorized representatives of the Global Fund and its agents or any third party of which the Global Fund notifies the Principal Recipient the opportunity at all reasonable times on an ad hoc basis to make visits related to operations financed by the Grant. The purpose of such ad hoc site visits is to allow the Global Fund to be in a position to report to its constituencies on the implementation of the Program and to determine whether value for money has been obtained. In connection with such visits, the Principal Recipient will make available to the Global Fund all relevant financial information drawn from the relevant accounts and records.

f. Notification.

The Principal Recipient shall notify the Global Fund promptly in writing of any audits of activities financed by this Agreement initiated by or at the request of an audit authority of the Government of the Host Country or of any other entity.

Article 8. REFUNDS

a. In the case of any disbursement of the Grant that is not made or used in accordance with this Agreement, or that finances goods or services that are not used in accordance with this Agreement, the Global Fund, notwithstanding the availability or exercise of any other remedies under this Agreement, may require the Principal Recipient to refund the amount of such disbursement in United States dollars to the Global Fund within sixty (60) days after the Principal Recipient receives the Global Fund's request for a refund.

b. If the Principal Recipient's failure to comply with any of its obligations under this Agreement has the result that goods or services financed or supported by the Grant are not used in accordance with this Agreement, the Global Fund may require the Principal Recipient to refund all or any part of the amount of the disbursements under this Agreement for or in connection with such goods or services in United States dollars to the Global Fund within sixty (60) days after receipt of a request therefor.

c. The right under paragraphs (a) or (b) of this Article to require a refund of a disbursement will continue, notwithstanding any other provision of this Agreement, for three years from the date of the last disbursement under this Agreement.

Article 9. ADDITIONALITY

In accordance with the criteria governing the selection and award of this Grant, the Global Fund has awarded the Grant to the Principal Recipient on the condition that the Grant is in addition to the normal and expected resources that the Host Country usually receives or budgets from external or domestic sources. In the event such other resources are reduced to an extent that it appears, in the sole judgment of the Global Fund, that the Grant is being used to substitute for such other resources, the Global Fund may terminate this Agreement in whole or in part under Article 21 of this Agreement.

Article 10. PROGRAM COOPERATION AND COORDINATION

a. The Country Coordinating Mechanism

(1) The Principal Recipient hereby acknowledges that:

(a) the Country Coordinating Mechanism (of which the Principal Recipient is a part) is the group that coordinates the submission of proposals to the Global Fund from the Host Country and monitors the implementation of activities under approved programs;

(b) the Country Coordinating Mechanism functions as a forum to promote true partnership development and participation of multiple constituencies, including Host Country governmental entities, donors, nongovernmental organizations, faith-based organizations and the private sector;

(c) the Country Coordinating Mechanism should encourage multisectoral program approaches and ensure linkages and consistency between Global Fund assistance and other development and health assistance programs, including but not limited to multilateral loans, bilateral grants, Poverty Reduction Strategy Programs, and sector-wide assistance programs; and

(d) the Country Coordinating Mechanism should encourage its partners to mobilize broadly to fight diseases of poverty, to seek increased financial resources and technical assistance for that purpose, and to ensure the sustainability of local programs, including those supported by the Global Fund.

(2) The Principal Recipient will cooperate with the Country Coordinating Mechanism and the Global Fund to assure that the purpose of this Agreement will be accomplished. To this end, the Principal Recipient and the Global Fund, at the request of either or of the Country Coordinating Mechanism, will exchange views on the progress of the Program, the performance of obligations under this Agreement, and the performance of any consultants, contractors, or suppliers engaged in the Program, and other matters relating to the Program.

(3) The Principal Recipient shall actively assist the Country Coordinating Mechanism to meet regularly to discuss plans, share information and communicate on Global Fund issues. The Principal Recipient shall keep the Country Coordinating Mechanism continuously informed about the Program and the Principal Recipient's management thereof and shall furnish to the Country Coordinating Mechanism such reports and information as the Country Coordinating Mechanism may reasonably request. The Principal Recipient understands that the Global Fund may, in its discretion, share information with the Country Coordinating Mechanism.

(4) The Principal Recipient shall coordinate its activities with the activities of related or substantially similar programs in the Host Country.

(5) The Global Fund and the Principal Recipient may agree in Implementation Letters, in accordance with Article 12 below, on additional responsibilities of the Principal Recipient with respect to the Country Coordinating Mechanism.

b. Sub-recipients

(1) From time to time, the Principal Recipient may, under this Agreement, provide funding to other entities to carry out activities contemplated under the Program ("Sub-recipients"). The Principal Recipient will be responsible for the results it and Sub-recipients (if any) are to accomplish. The Principal Recipient shall ensure that all agreements with Sub-recipients ("Sub-recipient Agreements") are consistent with this Agreement. Prior to any disbursement of Grant funds to a Sub-recipient, the Principal Recipient shall obtain and maintain in effect a certification from such Sub-recipient that such Sub-recipient shall (i) undertake best efforts to ensure that none of the Grant funds received by it are used to provide support to individuals or entities associated with terrorism and that the recipients of any amounts provided by the Principal Recipient under the Sub-recipient Agreement do not appear on the list maintained by the Security Council Committee established pursuant to resolution 1267 (1999); and (ii) ensure that the same undertaking is included in all sub-contracts or sub-agreements entered into under the Sub-recipient Agreement. The Principal Recipient shall furnish the Global Fund a copy of the form or forms of agreement, acceptable to the Global Fund, that the Principal Recipient will use with Sub-recipients.

(2) The Principal Recipient's accountability and reporting shall encompass the funds disbursed to all Sub-recipients and to the activities Sub-recipients carry out using Program funds. The Principal Recipient shall have systems in place to assess (before the Principal Recipient transfers any resources to a Sub-recipient) the capacity of Sub-recipients, monitor their performance, and assure regular reporting from them in accordance with this Agreement. The Principal Recipient shall comply with such systems to assess Sub-recipients and supervise and monitor their activities and reporting under the Program. If the Principal Recipient finds that a Sub-recipient does not possess the required capacity to carry out the

activities envisioned under the Program, the Principal Recipient will consult with the Country Coordinating Mechanism and the Global Fund about how the situation should most appropriately be addressed.

(3) With respect to Sub-recipients or other third parties that enter into agreements with the Principal Recipient, the Global Fund shall assume no responsibility for the actions of such Sub-recipients or other third parties.

c. Other Principal Recipients

In addition to the Principal Recipient, the Global Fund may from time to time award grants to other entities, as possibly proposed by the Country Coordinating Mechanism, to implement programs in the Host Country. The Principal Recipient will cooperate as appropriate with such other entities to realize the benefits of all programs financed by the Global Fund.

d. The LFA

(1) The Global Fund has entrusted an entity indicated in the face sheet of this Agreement (the “LFA”), to assist the Global Fund in its oversight role during the implementation of the Program.

(2) The Principal Recipient shall cooperate fully with the LFA to permit the LFA to carry out its functions. To this end, the Principal Recipient shall, inter alia, do the following, unless the Global Fund specifies otherwise in writing:

(a) submit all reports, disbursement requests and other communications required under this Agreement to the Global Fund through the LFA;

(b) submit to the LFA copies of all audit reports required under Article 7.d of this Agreement;

(c) permit the LFA to perform ad hoc site visits at the times and places decided by the LFA; and

(d) cooperate with the LFA in other ways that the Global Fund may specify in writing.

(3) For purposes of this Agreement, the principal representative of the LFA shall be the person named or acting in the position identified in the face sheet of this Agreement, unless the Global Fund notifies the Principal Recipient otherwise in writing.

Article 11. COMMUNICATIONS

Any notice, request, document, report, or other communication submitted by either the Principal Recipient or the Global Fund, unless this Agreement expressly provides otherwise or the Global Fund and the Principal Recipient agree otherwise in writing, will be sent to the other party’s Authorized Representative noted in the signature block of this Agreement, as

appropriate, and/or a representative noted in the “Name/Address for Notices” section of the face sheet of this Agreement, as appropriate, each as may be modified from time to time through written notice to the other party. In the case of communications to the Global Fund through the LFA, the Principal Recipient shall submit such communications to the LFA representative identified in the face sheet of this Agreement. All communications under this Agreement will be in English, unless the Global Fund and the Principal Recipient agree otherwise in writing.

Article 12. MANAGEMENT LETTERS AND IMPLEMENTATION LETTERS

To assist the Principal Recipient in the implementation of this Agreement, the Global Fund will from time to time issue Management Letters that will furnish additional information and guidance about matters stated in this Agreement. In addition, the Global Fund and the Principal Recipient may from time to time issue jointly signed Implementation Letters to confirm and record their mutual understanding on aspects of the implementation of this Agreement.

Article 13. REPORTS

a. Unless the Global Fund advises the Principal Recipient otherwise in writing, the Principal Recipient shall furnish to the Global Fund the reports specified in paragraph b below at the interval indicated or such other interval to which the Global Fund and the Principal Recipient may agree in writing. The reports shall cover all funds and activities financed under the Grant. In addition, the Principal Recipient shall furnish to the Global Fund such other information and reports at such times as the Global Fund may request. The Global Fund will from time to time specify in Implementation Letters the guidelines for the contents and formats of the reports. The Principal Recipient shall furnish to the Country Coordinating Mechanism a copy of all reports the Principal Recipient submits to the Global Fund.

b. Required Reports

(1) Quarterly Reports

Not later than 45 days after the close of each quarter of the Principal Recipient’s fiscal year, the Principal Recipient shall submit to the Global Fund, in form and substance satisfactory to the Global Fund, a periodic report on the Program. The report shall reflect (i) financial activity during the quarter in question and cumulatively from the beginning of the Program until the end of the reporting period; and (ii) a description of progress towards achieving the agreed-upon milestones set forth in Annex A. The Principal Recipient shall explain in the report any variance between planned and actual achievements for the period in question.

(2) Phase Two Reporting

The Principal Recipient shall cooperate with the Global Fund, the Country Coordinating Mechanism, and other actors as necessary and appropriate to provide for the timely filing of an application for the continuation of funding beyond the Program End Date.

Article 14. MONITORING

The Principal Recipient will follow a principle of results-based monitoring congruent with the Global Fund's results-based disbursement approach. Not later than 90 days after this Agreement enters into force, the Principal Recipient shall submit to the Global Fund, in form and substance satisfactory to the Global Fund, a detailed plan for monitoring the Program. The Global Fund will specify in Implementation Letters the guidelines for the plan.

Article 15. EVALUATION

The Global Fund, in its discretion, may conduct an independent evaluation of the Program. The Global Fund evaluation will conform to international best practice standards that include a focus on results, transparency and substantive accountability. The Global Fund will collaborate with the Evaluation Office of the Principal Recipient to specify, in consultation with the Country Coordinating Mechanism, the terms of reference for the evaluation and to plan, schedule and implement the evaluation. The Principal Recipient shall require all Sub-recipients to cooperate fully in the execution of the evaluation. The Global Fund will provide the Principal Recipient with a copy of the report of the evaluation.

Article 16. DISSEMINATION OF INFORMATION

The Global Fund and the Principal Recipient may make the information derived from the implementation of this Program available to the domestic and international community, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information. The Global Fund reserves the right to freely publish or disseminate information derived from the implementation of this Program.

Article 17. CONTRACTS FOR GOODS AND SERVICES.

a. Unless the Global Fund agrees otherwise in writing, the Principal Recipient shall disclose to the Global Fund the policies and practices that it will use to contract for goods and services under this Agreement. At a minimum, such policies and practices shall conform to requirements 1 through 5 listed below.

(1) Contracts shall be awarded, to the extent practical, on a competitive basis.

(2) Solicitations for goods and services shall be based upon a clear and accurate description of the goods or services to be acquired.

(3) Contracts shall be awarded only to responsible contractors that possess the potential ability to successfully perform the contracts.

(4) No more than a reasonable price (as determined, for example, by a comparison of price quotations and market prices) shall be paid to obtain goods and services.

(5) The Principal Recipient shall maintain records regarding the receipt and use of goods and services acquired under the Agreement by the Principal Recipient, the nature and extent of solicitations of prospective suppliers of goods and services acquired by the Principal Recipient, and the basis of award of Principal Recipient contracts and orders.

b. Title to goods or other property financed under this Agreement shall be in the name of the Principal Recipient or such other entity as the Principal Recipient may designate and shall be disposed of by the Principal Recipient during the life of the Program or at its completion in accordance with Article 19 below.

c. From time to time, the Global Fund will issue Implementation Letters to further advise the Principal Recipient regarding policies applicable to contracts for goods and services using Grant funds.

Article 18. PHARMACEUTICAL AND OTHER HEALTH PRODUCTS

a. Definitions. As used in this Article, the following terms shall have the meanings given to them below:

Available means that the manufacturer of the relevant product can supply the requested quantity of the product within 90 days of the requested delivery date.

Expert Review Panel (ERP) means a panel of independent experts which reviews the potential risks/benefits associated with the use of Finished Pharmaceutical Products and makes recommendations to the Global Fund as to whether such Finished Pharmaceutical Products may be procured with Grant funds. A Finished Pharmaceutical Product will be eligible for review by the Expert Review Panel if it has not yet been prequalified by the WHO or authorized for use by a Stringent Drug Regulatory Authority, but meets the following criteria:

- (a)
 - (i) the manufacturer of the Finished Pharmaceutical Product has submitted an application for prequalification of the product by the WHO Prequalification Programme and it has been accepted by WHO for review; or
 - (ii) the manufacturer of the Finished Pharmaceutical Product has submitted an application for marketing authorization to a Stringent Drug Regulatory Authority, and it has been accepted for review by the Stringent Drug Regulatory Authority, and
- (b) the Finished Pharmaceutical Products is manufactured at a site that is compliant with the GMP standards that apply for the relevant Product Formulation, as verified after inspection by:
 - (i) the WHO Prequalification Programme;
 - (ii) a Stringent Drug Regulatory Authority; or
 - (iii) a drug regulatory authority participating to the Pharmaceutical Inspection Cooperation Scheme.

ERP Recommendation Period means the period during which an Expert Review Panel recommendation for the use of a particular Finished Pharmaceutical Product remains in full force and effect. If the Expert Review Panel recommends the use of a Finished Pharmaceutical Product, the recommendation shall be valid for an initial period of no more than 12 months or until the Finished Pharmaceutical Product is prequalified by the WHO or authorized for use by a Stringent Drug Regulatory Authority, whichever is earlier. The Global Fund may, in its sole discretion, request the Expert Review Panel to consider extending the ERP Recommendation Period.

Finished Pharmaceutical Product means a medicine presented in its finished dosage form that has undergone all stages of production, including packaging in its final container and labeling.

Good Manufacturing Practices (GMP) means the practices, which ensure that Finished Pharmaceutical Products are consistently produced and controlled according to quality standards appropriate to their intended use, and as required by applicable marketing authorizations.

Health Products includes (i) Finished Pharmaceutical Products;(ii) durable health products (including but not limited to bednets, laboratory equipment, radiology equipment and supportive products); and (iii) consumable/single-use health products (including but not limited to condoms, rapid and non-rapid diagnostic tests, insecticides, aerial sprays against mosquitoes, breast milk substitute and injection syringes).

International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) is an initiative involving regulatory bodies and pharmaceutical industry experts that was established to make recommendations on ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration. ICH member countries are specified on its website: <http://www.ich.org> .

Medicine means an active pharmaceutical ingredient that is intended for human use.

National Drug Regulatory Authority (NDRA) means the official authority regulating Health Products in a country.

NDRA-Recognized Laboratories means Quality Control laboratories selected by NDRA's according to their standards to conduct their Quality Control testing for Finished Pharmaceutical Products.

Pharmaceutical Inspection Cooperation Scheme (PIC/S) means the Swiss association of inspectorates which provides a forum for GMP training. The PIC/S is not subject to any international or domestic regulations. PIC/S member countries are specified on its website: www.picscheme.org .

Product Formulation means an active pharmaceutical ingredient (or combination of ingredients), dosage form and strength.

Quality Control means all measures taken, including the setting of specification sampling, testing and analytical clearance, to ensure that starting material, intermediate, packaging material and Finished Pharmaceutical Products conform with established specifications for identity, strength, purity and other characteristics.

Stringent Drug Regulatory Authority means a regulatory authority which is (a) a member of the ICH (as specified on its website:); or (b) an ICH Observer, being the European Free Trade

Association (EFTA), Health Canada and WHO (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally binding mutual recognition agreement.

WHO Prequalification Programme means the programme managed by WHO which prequalifies (a) Medicines that are considered to be acceptable for procurement by the United Nations and specialized agencies; and (b) Quality Control laboratories for Medicines.

b. Health Product Management Assessment and PSM plan. Due to the complexity and significant risks of the procurement of Health Products, no Grant funds may be used to finance such procurement until:

- (1). the Global Fund has assessed the Principal Recipient's capability to manage such procurement; and
- (2). the Principal Recipient has submitted to the Global Fund, in form and substance satisfactory to the Global Fund, a plan for the procurement, use and supply management of Health Products that is consistent with this Article, (the "PSM Plan").

The Global Fund shall advise the Principal Recipient in writing whether it has approved the PSM Plan. The Principal Recipient shall ensure that the procurement and supply management of Health Product under the Program is carried out in accordance with the approved PSM Plan. The Principal Recipient must submit any proposed changes to the approved PSM Plan to the Global Fund for approval.

c. List of Medicines to be Procured. Grant funds may only be used to procure a Medicine that appears in the current Standard Treatment Guidelines (STG) or Essential Medicines Lists (EML) of the WHO, the Host Country government or an institution in the Host Country recognized by the Global Fund. The PSM Plan shall include the STG/EML that will apply to the Program.

The Principal Recipient shall submit a technical justification to the Global Fund if it intends to procure a Medicine that (i) was not specified in the grant proposal approved by the Global Fund; and (ii) is included in the relevant STG/EML of the Host Country government or an institution in the Host Country recognized by the Global Fund, but not included in the STG/EML of the WHO, or vice versa.

d. Procurement Responsibilities. In circumstances where the Global Fund has determined that the Principal Recipient possesses the requisite procurement capacity, the Principal Recipient shall be responsible for all procurement under the Agreement, and at its discretion, may use, or permit its Sub-recipients to use, contracted local, regional or international procurement agents to conduct procurements. If the Global Fund has determined that the Principal Recipient does not possess the requisite procurement capacity, the Principal Recipient shall use established regional or international procurement agents or other mechanisms acceptable to the Global Fund, but shall remain responsible for compliance of all procurement with the terms of this Agreement.

When a Sub-recipient carries out procurement of Health Products, the Principal Recipient shall ensure that such procurement is carried out in compliance with this Agreement.

In all cases, the Principal Recipient is encouraged to use, or cause Sub-recipients to use, capable regional and global procurement mechanisms wherever pooling of demand reduces prices for products and improves procurement efficiency.

e. Procurement Practices. The Principal Recipient shall ensure that the procurement of Finished Pharmaceutical Products under this Agreement adheres to the Interagency Operational Principles for Good Pharmaceutical Procurement. In cases where actual practices differ from these principles, the Principal Recipient shall demonstrate to the Global Fund that it has established a comparable system of competitive, transparent and accountable procurement using a group of pre-qualified suppliers and the application of necessary quality assurance mechanisms.

In addition, Principal Recipients shall ensure that the procurement of Finished Pharmaceutical Products under this Agreement complies with the principles set forth in the Interagency Guidelines: A Model Quality Assurance System for Procurement Agencies (as amended from time to time).

f. Lowest Possible Price. The Principal Recipient shall use good procurement practices when procuring Health Products, including competitive purchasing from prequalified manufacturers and suppliers, as outlined in sub-section (e) above, to attain the lowest possible price of products that comply with the quality assurance standards specified in this Agreement. In determining what constitutes the “lowest possible price”, the Principal Recipient may take into account the unit price for the products, product registration, the delivery and insurance costs, and the delivery timeframe and method. With respect to durable products, the lowest possible price shall take into account the total cost of ownership, including the cost of reagents and other consumables as well as costs for annual maintenance.

g. Quality Standards for all Finished Pharmaceutical Products. Grant funds may only be used to procure Finished Pharmaceutical Products that have been authorized for use by the National Drug Regulatory Authority in the Host Country where the products will be used.

h. Additional Quality Standards for Antiretroviral, Antimalarial and/or Antituberculosis Finished Pharmaceutical Products. In addition to the quality standards specified in sub-section (g) above, Grant funds may only be used to procure antiretroviral, antimalarial and/or antituberculosis Finished Pharmaceutical Products that meet one of the following quality standards:

- (1). the product is prequalified under the WHO Prequalification Program or authorized for use by a Stringent Drug Regulatory Authority; or
- (2). the product has been recommended for use by the Expert Review Panel, as described in paragraph i of sub-section (i) below.

Such products may only be procured with Grant funds in accordance with the selection process specified in sub-section (i) below.

i. Selection Process for Procuring Antiretroviral, Antimalarial and/or Antituberculosis Finished Pharmaceutical Products.

- (1) If there are two or more Finished Pharmaceutical Products Available for the same Product Formulation that are either prequalified by the WHO or authorized for use by a Stringent Drug Regulatory Authority, the Principal Recipient may only

use Grant funds to procure a Finished Pharmaceutical Product that meets either of those standards.

- (2). If a Principal Recipient determines that there is only one or no Finished Pharmaceutical Product Available that is prequalified by the WHO or authorized for use by a Stringent Drug Regulatory Authority and it wishes to use Grant funds to procure an alternate Finished Pharmaceutical Product, it must request confirmation from the Global Fund that the Principal Recipient's determination is accurate and that the alternate Finished Pharmaceutical Product is currently recommended for use by the Expert Review Panel. If the Global Fund provides this confirmation, the Principal Recipient may enter into a contract with a supplier for the procurement of the alternate Finished Pharmaceutical Product that has been recommended for use by the Expert Review Panel at any time until the end of the ERP Recommendation Period, but the duration of the contract shall not exceed 12 months. That is, the Principal Recipient may not place an order for that Finished Pharmaceutical Product under the contract more than 12 months after the contract is signed.

j. Quality Standards for Long-Lasting Insecticidal Mosquito Nets. Grant funds may only be used to procure long-lasting insecticidal mosquito nets that are recommended for use by the WHO Pesticide Evaluation Scheme.

k. Quality Standards for All Other Health Products. Grant funds may only be used to procure Health Products other than Finished Pharmaceutical Products or long-lasting insecticidal mosquito nets, if they are selected from lists of pre-qualified products, if any, and comply with quality standards applicable in the Host Country where such products will be use, if any.

l. Monitoring Supplier Performance. The Principal Recipient shall monitor the performance of suppliers with respect to the quality of the goods and services they supply and shall submit the information gathered to the Global Fund electronically for publication over the Internet through the Price and Quality Reporting mechanism referred to in sub-section (r).

m. Monitoring Product Quality. The Principal Recipient shall have systems in place to monitor the quality of Health Products financed under this Agreement that are acceptable to the Global Fund.

n. Quality Control Tests of Finished Pharmaceutical Products

- (1). Subject to paragraph ii below, the Principal Recipient shall ensure that random samples of Finished Pharmaceutical Products financed under the Agreement are obtained at different points in the supply chain, from initial receipt of the products in the Host Country to the delivery of those products to patients. Such samples shall be sent to one of the following laboratories for Quality Control testing:

(a) a laboratory prequalified by the WHO Prequalification Programme;

(b) an NDRA or NDRA-Recognized Laboratory that meets one of the following criteria:

(i) Prequalified by WHO Prequalification Programme, or

(ii) Accredited in accordance with ISO17025; or

- (c) a laboratory contracted by the Global Fund.

Such Quality Control testing may be conducted in accordance with protocols and standard operating procedures prescribed by the Global Fund, as may be amended from time to time.

The Principal Recipient shall submit the results of the Quality Control tests to the Global Fund, which may be made available to the public.

- (2). If a Principal Recipient procures a Finished Pharmaceutical Product that has been recommended for use by the Expert Review Panel, the Global Fund will make the necessary arrangements for randomly selected samples of the Finished Pharmaceutical Product to be tested for Quality Control purposes, in accordance with advice provided by the Expert Review Panel, prior to the shipment and delivery of that product by the manufacturer to the Principal Recipient or other designated recipient. The Principal Recipient shall ensure that its contract with the manufacturer affords the Global Fund right to (i) obtain the manufacturer's specifications; (ii) remove samples of products and conduct random Quality Control testing while the products are within the possession of the manufacturer; and (iii) make the results of such testing available to the public. The cost of any such sampling and testing of the Finished Pharmaceutical Product shall be borne by the Global Fund.

o. Supply Chain and Inventory Management. With regard to the supply chain for Health Products financed under the Program, the Principal Recipient shall seek to ensure optimal reliability, efficiency and security.

The Principal Recipient shall comply with, and shall ensure that its Sub-Recipients comply with the WHO Guidelines for Good Storage Practices and Good Distribution Practices for Pharmaceutical Products. The Global Fund may approve deviations from such guidelines if the Principal Recipient can demonstrate to the Global Fund that comparable systems have been implemented to manage the storage and distribution of Finished Pharmaceutical Products procured with Grant funds.

p. Avoidance of Diversion. The Principal Recipient shall implement and ensure that Sub-recipients implement procedures that will avoid the diversion of Program financed health products from their intended and agreed-upon purpose. The procedures should include the establishment and maintenance of reliable inventory management, first-in first-out stock control systems, internal audit systems, and good governance structures to ensure the sound operation of these systems.

q. Adherence to Treatment Protocols, Drug Resistance and Adverse Effects. The Principal Recipient shall implement mechanisms to:

- (1)i. encourage patients to adhere to their prescribed treatments (which mechanisms shall include but not be limited to fixed-dose combinations, once-a-day formulations, blister packs, and peer education and support);
- (2). ensure prescribers' adherence to agreed treatment guidelines;
- (3). monitor and contain drug resistance; and

- (4) monitor adverse drug reactions according to existing international guidelines.

To help limit resistance to second-line tuberculosis Medicines and to be consistent with the policies of other international funding sources, all procurement of Medicines to treat multi-drug resistant tuberculosis financed under the Agreement must be conducted through the Green Light Committee of the Global Stop TB Partnership.

r. Price and Quality Reporting. Upon receipt in the country of Health Products purchased with Grant funds, the Principal Recipient shall promptly report to the Global Fund the prices it has paid for such Health Products and other information related to the quality of the Health Products, as specified in, and using the form of, the Price and Quality Reporting mechanism available on the website of the Global Fund.

Article 19. UTILIZATION OF GOODS AND SERVICES

All goods and services financed with Grant funds will, unless otherwise agreed in writing by the Global Fund, be devoted to the Program until the completion or termination of this Agreement, and thereafter unless the Principal Recipient and the Global Fund agree otherwise, any remaining property shall be transferred to the Global Fund. The Global Fund shall deal directly with the local authorities as necessary and appropriate regarding any such transfer.

Article 20. AMENDMENT

No modification of this Agreement shall be valid unless in writing and signed by an authorized representative of the Global Fund and the Principal Recipient.

Article 21. TERMINATION; SUSPENSION

a. Either the Global Fund or the Principal Recipient may terminate this Agreement in whole or in part upon giving the other party 60 days written notice. Either the Global Fund or the Principal Recipient may suspend this Agreement in whole or in part upon giving the other party seven days written notice. Any portion of this Agreement that is not terminated or suspended shall remain in full force and effect.

b. In the event that the Principal Recipient terminates this Agreement, it shall, if requested by the Global Fund, do its utmost to help to identify a suitable new entity to assume the responsibilities of implementing the Program.

c. Notwithstanding the termination of this Agreement, the Principal Recipient may use portions of the Grant that have already been disbursed to it to satisfy commitments and expenditures already incurred in the implementation of the Program before the date of termination. After the Principal Recipient has satisfied such commitments and liabilities, it will return all remaining Grant funds to the Global Fund or dispose of such funds as directed by the Global Fund.

d. In addition, upon full or partial termination or suspension of this Agreement, the Global Fund may, at the Global Fund's expense, direct that title to goods financed under the Grant, be transferred to the Global Fund if the goods are in a deliverable state.

Article 22. NOVATION; TRANSFER OF PRINCIPAL RECIPIENT RESPONSIBILITIES UNDER THIS AGREEMENT

If at any time, either the Principal Recipient or the Global Fund concludes that the Principal Recipient is not able to perform the role of Principal Recipient and to carry out its responsibilities under this Agreement or if, for whatever reason, the Global Fund and the Principal Recipient wish to transfer some or all of the responsibilities of the Principal Recipient to another entity that is able and willing to accept those responsibilities, then the Global Fund and the Principal Recipient may agree that the other entity (“New Principal Recipient”), may be substituted for the Principal Recipient in this Agreement. The substitution shall occur on such terms and conditions as the Global Fund and the New Principal Recipient agree, in consultation with the Country Coordinating Mechanism. The Principal Recipient hereby agrees to cooperate fully to make the transfer as smooth as possible.

Article 23. NONWAIVER OF REMEDIES.

No delay in exercising any right or remedy under this Agreement will be construed as a waiver of such right or remedy.

Article 24. SUCCESSORS AND ASSIGNEES

This Agreement shall be binding on the successors and assignees of the Principal Recipient and the Agreement shall be deemed to include the Principal Recipient’s successors and assignees. However, nothing in this Agreement shall permit any assignment without the prior written approval of the Global Fund.

Article 25. LIMITS OF GLOBAL FUND LIABILITY

a. The Global Fund shall be responsible only for performing the obligations specifically set forth in this Agreement. Except for those obligations, the Global Fund shall have no liability to the Country Coordinating Mechanism, the Principal Recipient, Sub-recipients or any other person or entity as a result of this Agreement or the implementation of the Program.

b. The Principal Recipient undertakes the Program on its own behalf and not on behalf of the Global Fund. This Agreement and the Grant shall in no way be construed as creating the relationship of principal and agent, of partnership in law or of joint venture as between the Global Fund and the Principal Recipient or any other person involved in the Program. The Global Fund assumes no liability for any loss or damage to any person or property arising from the Program.

Article 26. ARBITRATION

a. Any dispute between the Global Fund and the Principal Recipient arising out of or relating to this Agreement that is not settled amicably shall be submitted to arbitration at the request of either Party. The arbitration shall be conducted in accordance with UNCITRAL Arbitration Rules as at present in force. The Global Fund and the Principal Recipient agree to be bound by the arbitration award rendered in accordance with such arbitration, as the final adjudication of any such dispute, controversy, or claim.

b. For any dispute for which the amount at issue is 100,000 United States dollars or less, there shall be one arbitrator.

c. For any dispute for which the amount at issue is greater than 100,000 United States dollars, there shall be three arbitrators appointed as follows: The Global Fund and the Principal Recipient shall each appoint one arbitrator, and the two arbitrators so appointed shall jointly appoint a third who shall be the chairperson.

Article 27. CONFLICTS OF INTEREST; ANTI-CORRUPTION

a. The Parties agree that it is important to take all necessary precautions to avoid conflicts of interest and corrupt practices. To this end, the Principal Recipient shall maintain standards of conduct that govern the performance of its staff, including the prohibition of conflicts of interest and corrupt practices in connection with the award and administration of contracts, grants, or other benefits, as set forth in the Staff Regulations and Rules of the United Nations, the UNDP Financial Regulations and Rules, and the UNDP Procurement Manual.

b. No person affiliated with the Principal Recipient (staff, individual contractors, counterpart government officials) shall participate in the selection, award or administration of a contract, grant or other benefit or transaction funded by the Grant, in which the person, members of the person's immediate family or his or her business partners, or organizations controlled by or substantially involving such person, has or have a financial interest. No person affiliated with the Principal Recipient (staff, individual contractors, counterpart government officials) shall participate in such transactions involving organizations or entities with which or whom that person is negotiating or has any arrangement concerning prospective employment. Persons affiliated with the Principal Recipient (staff, individual contractors, counterpart government officials) shall not solicit gratuities, favors or gifts from contractors or potential contractors.

c. If the Principal Recipient has knowledge or becomes aware of any actual, apparent or potential conflict between the financial interests of any person affiliated with the Principal Recipient, the Country Coordinating Mechanism, the LFA, or the Global Fund and that person's duties with respect to the implementation of the Program, the Principal Recipient shall immediately disclose the actual, apparent or potential conflict of interest directly to the Global Fund.

d. The Global Fund and the Principal Recipient shall neither offer a third person nor seek, accept or be promised directly or indirectly for themselves or for another person or entity any gift or benefit that would or could be construed as an illegal or corrupt practice

Article 28. PRIVILEGES AND IMMUNITIES

Nothing in or related to this Agreement may be construed as a waiver, express or implied of:

a. the privileges and immunities of the Principal Recipient pursuant to the Convention on the Privileges and Immunities of the United Nations, approved by the General Assembly of the United Nations on February 13, 1946 or otherwise under any international or national law, convention or agreement; or

b. the privileges and immunities accorded to the Global Fund under (i) international law including international customary law, any international conventions or agreements, (ii) under any national laws including but not limited to the to the United States of America's International Organizations Immunities Act (22 United States Code 288), or (iii) under the Headquarters Agreement between the Global Fund and the Swiss Federal Council dated 13 December 2004.