Investing in our future
The Global Fund
To Fight AIDS, Tuberculosis and Malaria

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19 June 2009
Our ref: EECA/NC/107-19/06/2009

Dr. Victor Volovei
Executive Director
Project Coordination Implementation and
Monitoring Unit of the Ministry of Health
of the Republic of Moldova
36/1 Ciuflea street, of. 23-25
MD2001 Chisinau
Republic of Moldova

Subject: **Program Grant Agreements for Grant Number MOL-607-G02-T (the "Grant Agreement")**
Implementation Letter 3
Quality Assurance of Pharmaceutical Products

Dear Dr Volovei,

In February 2009, we informed you that the Global Fund Board approved a revised Quality Assurance Policy for Pharmaceutical Products (QA Policy). The revised QA Policy will come into effect on 1 July 2009. The Principal Recipient must comply with this policy, and ensure that its Sub-recipients comply with it from that date onwards.

Information explaining the QA Policy is set out on the Global Fund's website: http://www.theglobalfund.org/en/procurement/policy. This site will be updated on a regular basis.

As a result of the introduction of the revised QA Policy, the Grant Agreement specified above needs to be amended by:

(a) replacing Article 19 of the Standard Terms and Conditions with the new section entitled "Pharmaceutical and Other Health Products" set out in Attachment 1 to this letter;

(b) updating Block 4A of the Face Sheet of the Grant Agreement as follows:

MOL-607-G02-T	Modification Number 3(Implementation Letter 3 dated 19 June 2009).

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Please confirm your agreement with these amendments by signing the enclosed copy of this letter and returning it to us. These amendments come into effect on 1 July 2009, irrespective of whether this letter is signed before or after this date.

All other terms and conditions remain the same. Please do not hesitate to contact your Fund Portfolio Manager if you have any questions about the QA Policy.

Sincerely,

William Paton
Director of Country Programs

Agreed and signed:

For: **THE PROJECT COORDINATION IMPLEMENTATION AND MONITORING UNIT OF THE MINISTRY OF HEALTH OF THE REPUBLIC OF MOLDOVA**

By: _____

Authorized Representative:

Date: _____

Enc: Attachment 1: Article 19 of the Standard Terms and Conditions
Face Sheet for Grant Agreement MOL-607-G02-T

cc: Dr. Larisa Catrinici, Chair of the Country Coordinating Mechanism
Ms. Viorelia Gutu, Assistant Manager, PriceWaterhouseCoopers Audit S.R.L. Moldova, Local Fund Agent

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PROGRAM GRANT AGREEMENT

1. Country: Republic of Moldova

2. Principal Recipient Name and address: Project Coordination, Implementation, and Monitoring Unit, Ministry of Health of the Republic of Moldova, 101 Sciusev street, MD2012, Chisinau, Republic of Moldova

3. Program Title: Strengthening Tuberculosis Control in the Republic of Moldova

4. Grant Number: MOL-607-G02-T		4A. Modification Number: 3 (Implementation Letter 3 dated 19 June 2009)
5. Phase 1 Starting Date: 1 October 2007	6. Phase 1 Ending Date: 30 September 2009	7. Phase 2 Ending Date: 30 September 2012
7A. Condition Precedent Terminal Date: 1 December 2007	7B. Condition Precedent Terminal Date: 30 June 2008	7C. Condition Precedent Terminal Date: 1 December 2007
7D. Condition Precedent Terminal Date: 30 June 2008	7E. Condition Precedent Terminal Date:	7F. Condition Precedent Terminal Date:

8. Grant Funds: US$ 5,675,507 (Five Million, Six Hundred Seventy-Five Thousand, Five Hundred and Seven United States Dollars)

9. Program Coverage: Tuberculosis

10. Information for Principal Recipient Bank Account into Which Grant Funds Will Be Disbursed:

Owner of Bank Account:	The Project Coordination, Implementation and Monitoring Unit of the Ministry of Health of the Republic of Moldova
Account Title:	Special Account (USD)
Account number:	2271880125
Bank name:	BC Moldova-Agroindbank SA Chisinau-Centru Branch
Bank address:	182 Stefan cel Mare str., MD 2004, Chisinau, Moldova
Bank SWIFT Code:	AGRN MD2X
Bank Code: IBAN:	AGRNMD2X723

Routing instructions for disbursements: Citibank, N.A., New York, NY, acc.No.36126158, swift code: CITIUS 33

11. The fiscal year of the Principal Recipient is from 1 January to 31 December.

12. Local Fund Agent ("LFA")
Name: PricewaterhouseCoopers Audit SRL
Address: 37 Maria Cibotari Street, Chisinau 2012, Republic of Moldova
Tel: +373 22 238122 Fax: +373 22 238120
Attention: Mr. Dan Popov
E-mail: dan.popov@ro.pwcglobal.com

13. Name/Address for Notices to Principal Recipient	14. Name/Address for Notices to Global Fund:
Dr. Victor Burinschi TB/AIDS Project Coordinator Project Coordination, Implementation and Monitoring Unit, Ministry of Health of the Republic of Moldova 101 Sciusev Street MD2012 Chisinau Republic of Moldova Tel.: +373 22 238751 Fax: +373 22 202437 E-mail: vburinschi@ucimp.md	Dr Urban Weber Regional Team Leader, Eastern Europe and Central Asia Team Chemin de Blandonnet 8 1214 Vernier-Geneva, Switzerland Tel.: +41 22 791 1700; Fax: +41 22 791 1701

This Agreement consists of the two pages of this face sheet and the following:
Standard Terms and Conditions **Annex A – Program Implementation Description**

Article 19 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 Prequalification Programme or authorized for use by a Stringent Drug Regulatory Authority, but meets the following criteria:

i.

a. 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

b. 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

ii. 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:

a. the WHO Prequalification Programme;

b. a Stringent Drug Regulatory Authority;

c. or a drug regulatory authority participating in 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 Prequalification Programme 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 mosquito nets, 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 NDRAs 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, Grant funds may not be used to finance such procurement until:

i. the Global Fund has assessed the Principal Recipient's capability to manage such procurement; and

ii. 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 Products 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 pre-qualified 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:

i. the product is prequalified under the WHO Prequalification Program or authorized for use by a Stringent Drug Regulatory Authority; or

ii. 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.

i. If there are two or more Finished Pharmaceutical Products Available for the same Product Formulation that are either prequalified by the WHO Prequalification Programme 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.

ii. If a Principal Recipient determines that there is only one or no Finished Pharmaceutical Product Available that is prequalified by the WHO Prequalification Programme 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 used, 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

i. 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.

ii. 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 (a) obtain the manufacturer's specifications; (b) remove samples of products and conduct random Quality Control testing while the products are within the possession of the manufacturer; and (c) make the results of such testing 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 shall 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:

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);

ii. ensure prescribers' adherence to agreed treatment guidelines;

iii. monitor and contain drug resistance; and

iv. 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.

(s) Amendments to this Article. The Global Fund may, from time to time, change all or part of its policy for procurement of Health Products. Notwithstanding Article 31, these policy changes will be reflected through amendments to this Article which shall apply as of the date specified by the Global Fund. The Global Fund shall provide the Principal Recipient with reasonable notice of these policy changes.