



Investing in our future

The Global Fund

To Fight AIDS, Tuberculosis and Malaria

28 April 2005

Mr. Milo Stanojevich
CARE Perú
Av. Gral. Santa Cruz 659
Jesús Maria
Lima
Peru

Re: Program Grant Agreement between The Global Fund to Fight AIDS, Tuberculosis and Malaria and CARE Perú for Grant Number PER-202-G01-H-00 with respect to the program entitled "Strengthening of the Prevention and Control of AIDS in Peru" (the "Grant Agreement")
Implementation Letter Number 2
Quality Assurance of Limited and Single Source Pharmaceutical Products

Dear Mr. Stanojevich,

We are referring to the above-captioned Grant Agreement.

The Global Fund has recently amended its policy with respect to quality assurance for single source pharmaceutical products. As a result of this policy change, the section entitled "Pharmaceutical and Other Health Products" in the Grant Agreement, if any, is out of date.

This letter amends the Grant agreement by replacing the section entitled "Pharmaceutical and Other Health Products" in the Grant Agreement (or, if applicable, adding this section to the Grant Agreement) with the section which is attached to this letter. Please note that we have attached the entire new section and highlighted the changes made to the quality assurance provisions contained in it.

Except as modified herein, the Grant Agreement remains in full force and effect.

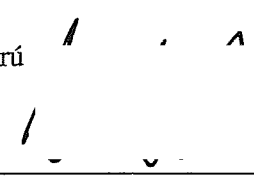
A document explaining the new Global Fund quality assurance policy will be sent to you in due course. In the meantime, please confirm your agreement with the foregoing by signing the enclosed copies of this letter and return one to us, retaining one copy for your records.

Sincerely,

Wm. Bradford Herbert
Chief of Operations
The Global Fund to Fight AIDS, Tuberculosis and Malaria

Agreed and signed:

For: CARE Perú



Authorized Representative:
Mr. Milo Stanojevich – Country Director

Date: _____

cc: Dr. Pilar Mazzetti Soler – Country Coordinating Mechanism Chairperson
Mr. Oscar de la Torre – Local Fund Agent – PriceWaterhouseCoopers

Article 18. PHARMACEUTICAL AND OTHER HEALTH PRODUCTS

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

“WHO” means the World Health Organization.

The terms “medicines,” “multisource pharmaceutical product,” and “pharmaceutical products” have the meanings used by the WHO in the “Glossary” of its “Marketing Authorization of Pharmaceutical Products with Special Reference to Multisource (Generic) Products: A Manual for Drug Regulatory Authorities.”

The term “health products” includes pharmaceutical products, diagnostic technologies and supplies, bed nets, insecticides, aerial sprays against mosquitoes, other products for prevention (e.g., condoms), or laboratory equipment and supportive products (e.g., microscopes and reagents).

The term “stringent regulatory authority” means the regulatory authority of (a) a member of the Pharmaceutical Inspection Convention or an entity participating in the Pharmaceutical Inspection Cooperation Scheme; or (b) a member of the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use.

The term “WHO Prequalification Program” means the United Nations Pilot Procurement, Quality and Sourcing Project initiated by the WHO.

The term “GMP” means Good Manufacturing Practice as such term is used by the WHO in its “Marketing Authorization of Pharmaceutical Products with Special Reference to Multisource (Generic) Products: A Manual for Drug Regulatory Authorities.”

With respect to a Host Country, the term “National Drug Regulatory Authority” means the cognizant national drug regulatory authority in such Host Country.

With respect to sub-section g(c) of this Article, a product is “unavailable” when its manufacturer is unable to supply a sufficient quantity of the finished product within 90 days of the date of order.

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

a. Procurement assessment and procurement 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 approved an assessment of 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 and use of the health products that will be procured that is consistent with this Article, (the “Procurement Plan”). The Procurement Plan shall include a plan to procure and use diagnostic technologies and supplies and other major categories of supplies related to the provision of the medicines.

The Global Fund shall advise the Principal Recipient in writing when it has approved the procurement plan. The Principal Recipient shall ensure that procurement under the Program is carried out in accordance with the procurement plan.

b. List of medicines to be procured

The Principal Recipient shall ensure that Grant funds are not used to procure medicines that do not appear in current standard treatment guidelines or essential medicines lists of the World Health Organization, the Host Country government, or the Recipient or Sub-recipient. The procurement plan shall include a listing of the standard treatment guidelines and essential medicines lists that will apply to the Program.

c. Forecasting and inventory management

The Principal Recipient shall:

(1) systematically and regularly update forecasts of the quantities of pharmaceutical and other health products needed for the Program. Initial forecasts for new activities shall be based on morbidity, adjusting the potential demand in light of realistic estimates of the anticipated capacity to deliver services. Forecasts for ongoing activities shall be based on consumption;

(2) monitor forecasts and regularly compare estimated needs for pharmaceutical and other health products under the Program with actual consumption of such products and report this information to the Global Fund;

(3) develop a plan and information system to minimize the risk that products will be out of stock;

(4) not less frequently than semi-annually, report to the Global Fund how often products are out of stock; and

(5) establish (or ensure the establishment of) product-specific levels of local buffer stocks and closely monitor them.

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 not determined that the Principal Recipient possesses 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 the Article.

In all cases, the Principal Recipient is encouraged to use, or cause Sub-recipients to use, capable regional and global procurement services wherever pooling of demand lowers prices for products of assured quality.

e. Procurement practices

The Principal Recipient shall ensure that the procurement of pharmaceutical products under this Agreement adheres to the Interagency Operational Principles for Good Pharmaceutical Procurement, unless, in cases where actual practices differ from the Interagency Operational Principles for Good Pharmaceutical Procurement, the Principal Recipient demonstrates, in form and substance satisfactory to the Global Fund, a comparable system of competitive procurement by a group of pre-qualified suppliers, transparency and accountability to their practices, and the application of necessary quality assurance mechanisms.

f. Lowest possible price

The Principal Recipient shall use good procurement practices, including competitive purchasing from qualified manufacturers and suppliers, as outlined in item e above, to attain the lowest price of products, consistent with quality assurance.

g. Compliance with quality standards

Pharmaceutical products may be financed by Grant funds under the Agreement only if the quality standards of such pharmaceutical products can be assured.

For multisource, off-patent products with available dosage from published pharmacopoeial quality standards, the Principal Recipient may verify compliance with applicable standards in accordance with existing national procedures of the Host Country.

Grant funds may be used to procure a single- or limited-source pharmaceutical product (that is, a pharmaceutical product for which there are not publicly available quality assurance standards, analytic methods, and reference standards) provided that such product meets one of the following standards:

- (1) such product is acceptable under the WHO Prequalification Program; or
- (2) such product has been authorized for use by a stringent regulatory authority; or
- (3) such product has been authorized for use by the National Drug Regulatory Authority; provided that this clause shall only apply until April 30, 2005.

After April 30, 2005, Grant funds may only be used to procure single- or limited-source pharmaceutical products that meet the requirements of either (1) or (2) of this sub-section g, provided that:

(a) Contracts entered into by the Principal Recipient on or before April 30, 2005 with suppliers for products that qualified for purchase under clause (3) of this sub-section g may be honored until such contracts expire or otherwise terminate.

(b) After April 30, 2005, the Principal Recipient may not enter into any new contracts, nor extend any existing contracts, for the supply of products that would have qualified for purchase under clause (3) of this sub-section g prior to April 30, 2005.

(c) If the Principal Recipient determines that there is only one or no equivalent pharmaceutical product that meets the standards of either (1) or (2) of this sub-section g, or if the Principal Recipient determines that the products that meet these standards are unavailable and represents the same to the Global Fund, and the Global Fund does not object, then Grant funds may be used to procure another equivalent pharmaceutical product, provided that such product is selected in accordance with the following, in order of priority:

- (i) the manufacturer has submitted an application for approval of such product to the WHO Prequalification Program or a stringent regulatory authority and such product is manufactured at a site that is compliant with the standards of GMP, as certified (after inspection) by the WHO or a stringent regulatory authority; or
- (ii) if the manufacturer of such product has not submitted an application for approval of such product to the WHO Prequalification Program or a stringent regulatory authority, such product is manufactured at a GMP-compliant manufacturing site, as certified (after inspection) by the WHO or a stringent regulatory authority.

The Principal Recipient shall promptly notify the Global Fund in writing if it procures any products pursuant to the criteria in clause (i) or (ii) above.

(d) The Global Fund shall contract an independent third-party to conduct random quality analysis of products being procured pursuant to the criteria in clause (c)(i) or (ii) above to ensure the quality of such products. The Principal Recipient shall permit (and shall ensure that Sub-recipients permit) such third party (and/or its agents) to access its storage sites and to remove samples of products procured pursuant to the criteria in clause (c)(i) or (ii) above for such analysis.

(e) With respect to a product procured pursuant to the criteria in clause (c)(i) or (ii) above, in the event that: (i) the application submitted by a manufacturer to the WHO Prequalification Program or a stringent regulatory authority for approval of such product is no longer under consideration; or (ii) an independent third party contracted by the Global Fund determines that the quality of such product is unacceptable, then the Principal Recipient shall promptly terminate the contract with the supplying manufacturer for such product.

(f) Procurement of products according to criteria in clause (c)(i) or (ii) above should be time-limited and the Principal Recipient should procure products meeting the criteria in clauses (1) or (2) of this sub-section g as soon as possible.

In all cases, pharmaceutical products financed by Grant funds under the Agreement shall satisfy quality standards prescribed from time to time by the Global Fund.

h. National drug registration

If pharmaceutical products intended for use under the Program require approval by the National Drug Regulatory Authority in the Host Country, such pharmaceutical products may be financed under this Agreement only if they have been granted such approval.

i. 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 a mechanism to be established or specified by the Global Fund.

j. Monitoring product quality

The Principal Recipient shall systematically ensure that random samples of pharmaceutical products financed under the Agreement are tested for compliance with applicable quality standards. The Principal Recipient shall have appropriate monitoring systems in place that are acceptable to the Global Fund or provide for the use of international procurement agencies acceptable to the Global Fund.

k. Supply chain

With regard to the supply chain for pharmaceutical and other health products financed under the Program, the Principal Recipient shall seek to ensure optimal reliability, efficiency and security.

l. 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.

m. Adherence to treatment protocols, drug resistance and adverse effects

The Principal Recipient shall implement mechanisms to:

- (1) 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) monitor and contain drug resistance; and
- (3) monitor adverse drug reactions according to existing international guidelines.

To help limit resistance to second-line tuberculosis drugs 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.