PROGRAM GRANT AGREEMENT
BETWEEN
THE GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS AND MALARIA
("Global Fund")
AND THE UNITED NATIONS DEVELOPMENT PROGRAMME
("Principal Recipient")

<table>
<tr><td colspan="3">1. Country: Sao Tome e Principe</td></tr>
<tr><td colspan="3">2. Program Title: Malaria Control in Sao Tome e Principe</td></tr>
<tr><td colspan="2">3. Grant Number: STP-405-G01-M</td><td>3A. Modification Number: 3
(Phase 2 Amendment)</td></tr>
<tr><td>4. Program Starting Date:
1 March 2005</td><td>5. Program Ending Date:
28 February 2010</td><td>6. Proposal Completion Date:
28 February 2010</td></tr>
<tr><td>6A. Condition Precedent Terminal Date: 1 March 2005</td><td>6B. Condition Precedent Terminal Date: 1 July 2005</td><td>6C. Condition Precedent Terminal Date: 1 February 2006</td></tr>
<tr><td>6D. Condition Precedent Terminal Date: 30 November 2007</td><td>6E. Condition Precedent Terminal Date:</td><td>6F. Condition Precedent Terminal Date:</td></tr>
<tr><td colspan="3">7. Global Fund Grant: US$3,484,859 (Three Million Four Hundred Eighty Four Thousand Eight Hundred and Fifty Nine United States Dollars)</td></tr>
<tr><td colspan="3">8. Program Coverage: ___ HIV/AIDS ___ Tuberculosis __X_ Malaria ___ HIV/AIDS/Tuberculosis</td></tr>
<tr><td colspan="3">9. Information for Principal Recipient Bank Account into Which Grant Funds Will Be Disbursed:
Beneficiary: United Nations Development Programme (UNDP)
Account name: UNDP Contributions Account
Account number: Account Number: 015-002284
Bank name: CHASE Manhattan Bank
Bank address: United Nations Branch, New-York, NY 10017, USA
Bank SWIFT Code: CHASUS33
Bank Code: 0210-00021
Routing instructions for disbursements: For STP Global Fund Malaria Project</td></tr>
<tr><td colspan="3">10. The fiscal year of the Principal Recipient runs from 1 January to 31 December.</td></tr>
<tr><td colspan="3">11. LFA Swiss Tropical Institute, Swiss Centre for International Health
Address B. O. Box, Socinstrasse 57,
CH – 4002 Basel, Switzerland
Tel.: +41 61 284 81 31
Fax: +41 61 284 81 03
Attention: Mr. João Conceição, Manager
E-mail: joao.costa@unibas.ch</td></tr>
<tr><td colspan="2">12. Principal Recipient Additional Representative

Name Mr. Antonio Viegas
Title Assistant Resident Representative
Address BP 109 Sao Tomé, Sao Tome & Principe
Tel.: 239 22 11 22 / 23 Fax: 239 22 21 98
E-mail: antonio.viegas@undp.org</td><td>13. Global Fund Additional Representative:

Nosa Orobaton, MD, DrPH, MBA
Director of Operations
Chemin de Blandonnet 8
1214 Vernier, Switzerland
Tel.: +41 22 791 1700
Fax: +41-22-791-1701</td></tr>
<tr><td colspan="3">14. This Agreement consists of the two pages of this face sheet and the following:
Standard Terms and Conditions Annex A – Program Implementation Abstract</td></tr>
</table>

AMENDMENT TO

PROGRAM GRANT AGREEMENT
(the "Grant Agreement")

BETWEEN

THE GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS AND MALARIA
(the "Global Fund")

AND

UNITED NATIONS DEVELOPMENT PROGRAMME
(the "Principal Recipient")

WHEREAS,

1. the Global Fund entered into the Grant Agreement for Grant Number STP-405-G01-M with the Principal Recipient on 17 February 2005 for the purpose of providing funds to implement a malaria program in Sao Tome e Principe described more fully in the Grant Agreement as "Malaria Control in Sao Tome et Principe" (the "Program");

2. In accordance with Article 12 and 20 of the Standard Terms and Conditions of the Grant Agreement, the Grant Agreement was amended by an implementation letter dated 6 July 2006;

3. Article 3.d of the Standard Terms and Conditions" of the Grant Agreement states that "[u]nless the Global Fund agrees otherwise in writing, the Global Fund will not authorize disbursement of the Grant after the 'Program Ending Date' (specified in block 5 of the face sheet of this Agreement)";

4. The "Program Ending Date" specified in block 5 of the face sheet of the Grant Agreement is 28 February 2007; and

5. Subject to certain conditions, the Global Fund wishes to increase the amount of the Grant, to continue disbursement of funds under the Grant and to extend the Program Ending Date,

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein and intending to be legally bound, the parties hereby agree to amend the Grant Agreement as follows:

1. The existing face sheet of the Grant Agreement is replaced by the face sheet attached hereto.

2. Article 26.a of the Standard Terms and Conditions of the Grant Agreement entitled "ARBITRATION" is amended by adding the following words to end: "The language of the arbitration shall be English."

3. Annex A of the Grant Agreement, (exclusive of any attachments that have formerly been attached to such Annex A) is replaced with the revised Annex A attached hereto entitled "Annex A: Program Implementation Abstract"; and

4. The document entitled "Attachment 3: Indicators, Targets and Periods" attached hereto is attached to Annex A of the Grant Agreement, as revised by this Amendment.

All other provisions of the Grant Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, the parties have executed this Amendment on the date as stated below.

UNITED NATIONS DEVELOPMENT PROGRAMME

By: _____

Name: António Vieyra

Title: O.I.C.

Date: 03/04/07

THE GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS AND MALARIA

By: _____

Name: Helen Evans

Title: Interim Executive Director

Date: 4/4/07

ANNEX A to the PROGRAM GRANT AGREEMENT

Program Implementation Abstract

Country:	São Tome e Príncipe
Proposal Name:	Project proposal for Tuberculosis, HIV/AIDS and Malaria control for Sao Tome e Principe
Proposal Number:	STP-404-003
Program Title:	Malaria Control in Sao Tome e Principe
Grant Number:	STP-405-G01-M
Disease:	Malaria
Principal Recipient:	United Nations Development Programme (UNDP)

A. PROGRAM DESCRIPTION

1. Background and Summary:

Malaria is a major public health problem on the islands of Sao Tome e Principe. As of the date of the signing of this agreement, malaria accounted for 68% of hospitalizations and 48% of hospital deaths. The incidence of morbidity is usually greater than one case per person per year in children under five years old. Mortality due to severe anemia is around 11% and malaria is the single most contributing risk factor. According to Ministry of Health data, the proportional hospital mortality of malaria in children under five during 1995-2001 was in the range of 48% to 75%. The Program will attack malaria by scaling up existing anti-malaria interventions and introducing new strategies with the goal of substantially reducing morbidity and mortality due to malaria. Existing programs to be scaled up include the free distribution of Insecticide-bed nets, community-based management of malaria and the provision of information, education and communication (IEC) about malaria to the community. Interventions which are new to this country and necessary to combat malaria include intermittent preventive treatment (IPT), which will help prevent the complications of malaria in pregnancy, and artemisinin-based combination therapies (ACT) that will restore the efficacy of first line anti-malarial drugs, lost due to resistance. In order to ensure proper implementation of these new or intensified efforts, the overall capacity of the health infrastructure and its human resources will be strengthened through a comprehensive program of health worker and manager training and through the provision and maintenance of essential equipment.

2. Goal: To reduce the burden of malaria in Sao Tome & Principe

3. Target Group/Beneficiaries:

- Children under five
- Pregnant women
- Youth and students
- General population

4. **Strategies:**

- To improve the management of severe malaria in health services up to 95% by 2009.
- To improve management of uncomplicated malaria cases in health facilities to 95% by 2009
- To improve management of uncomplicated malaria at community level to 50% by 2009
- To have at least about 80% of the total population sleeping under ITNs by 2009
- To increase awareness of malaria and its prevention to 80% by 2009 in the community and especially among school students
- To strengthen the human and institutional capacity of the National Malaria Program

5. **Planned Activities:**

- Provision of medical and non-medical equipments, including bed nets, re-treatment kits, drugs, reagents, consumable, vehicles and motorcycles
- Training and retraining health worker and community actors
- Strengthening of capacities of the National Malaria Control Program by providing technical assistance in the areas of entomology, monitoring and evaluation and surveillance.
- information, education and communication targeting school students and communities.

B. CONDITIONS PRECEDENT TO DISBURSEMENT

1. Conditions Precedent to First Disbursement (Terminal Date as stated in block 6A of the Face Sheet)

Before first disbursement under the Grant, the Principal Recipient shall, except as the Global Fund and the Principal Recipient may otherwise agree in writing, furnish to the Global Fund, in form and substance satisfactory to the Global Fund, evidence that the Principal Recipient has appointed, under terms of reference acceptable to the Global Fund, one person with appropriate experience and expertise to fill the position of Program Coordinator with responsibility for proper management of this grant.

2. Conditions Precedent to Second Disbursement (Terminal Date as stated in block 6B of the Face Sheet)

Before second disbursement under the Grant, the Principal Recipient shall, except as the Global Fund and the Principal Recipient may otherwise agree in writing, furnish to the Global Fund, in form and substance satisfactory to the Global Fund, evidence of the appointment, under terms of reference acceptable to the Global Fund, one person with appropriate experience and expertise to fill each of the following positions:

i. Internal auditor, with responsibility for Global Fund grants and terms of reference and reporting lines acceptable to the Global Fund that include, but are not limited to, (a) compliance with applicable UNDP finance, procurement and administration rules and regulations, and (b) monitoring of Sub-recipient operations to ensure that Grant funds and goods and services purchased with Grant funds are employed for Program purposes consistently with the terms of this Agreement;

ii. Procurement specialist in charge of management and monitoring of pharmaceuticals in the health districts within the FNM (National Drug Fund); and

iii. Monitoring and Evaluation Expert to reinforce the team in charge of tracking program achievements.

3. Conditions Precedent to Third Disbursement (Terminal Date as stated in block 6C of the Face Sheet)

Before Third disbursement under the Grant, the Principal Recipient shall, except as the Global Fund and the Principal Recipient may otherwise agree in writing, furnish to the Global Fund, in form and substance satisfactory to the Global Fund, Attachment 2 to this Annex A stating intended Program results for year 2 of the grant and a detailed budget for that year 2.

4. Condition Precedent to Fourth Disbursement in Phase 2 (Terminal Date as stated in block 6D of the Face Sheet)

The fourth disbursement of Grant funds after signing the Amended and Restated Program Grant Agreement is subject to the delivery by the Principal Recipient to the Global Fund of a revised version of each of the following documents covering the fourth and fifth years of the Program:

(a) work plan;
(b) budget; and
(c) performance targets as detailed in Attachment 4 and 5 to this Annex A,

Each of the above-noted documents must be consistent with the forecast of the requirements of the Program for ACT drugs for the period covered, based upon the epidemiological changes in the country.

C. SPECIAL TERMS AND CONDITIONS FOR THIS AGREEMENT

The Principal Recipient shall, by the end of the eighteenth month after the Program Starting Date, provide to the Global Fund and in form and substance acceptable to the Global Fund, evidence that the Country Coordinating Mechanism of the Republic of Sao Tome and Principe has nominated a national institution to take over the Principal Recipient's Program responsibilities as well as a draft plan for transferring such responsibilities.

D. FORMS APPLICABLE TO THIS AGREEMENT

For purposes of Article 13b(1) of the Standard Terms and Conditions of this Agreement entitled "Periodic Reports," the Principal Recipient shall use the "On-going Progress Update and Disbursement Request", available from the Global Fund upon request.

E. ANTICIPATED DISBURSEMENT SCHEDULE

For the purposes of Article 6a. of the Standard Terms and Conditions of this Agreement, the anticipated disbursement schedule for the Program shall be quarterly starting from the Phase 1 Starting Date.

F. PROGRAM BUDGET

The budget contained in Attachment 3 to this Annex A sets out the anticipated expenditures for the third year of the Program.

Attachment 3 to Annex A: Indicators, Targets, and Periods Covered

Program Details

Country:	Democratic Republic of Sao Tome et Principe
Disease:	Malaria
Grant number:	STP-405-G01-M
Principal Recipient:	UNDP

A. Periods covered and dates for disbursement requests and progress updates

	Period 9	Period 10	Period 11	Period 12
Period Covered	1 March -31 May 2007	1 June-31 August 2007	1 September-30 November 2007	1 December 2007 -29 February 2008
Date Disbursement Request/Progress Update due	15-Jul-07	15-Oct-07	15-Jan-08	15-Apr-08

Annual Report Due Date:	30-Mar-08
Audit Report Due Date:	30-Jun-08

B. Program Objectives, Service Delivery Areas and Indicators

Objective Number	Program Objectives
1	To improve the management of severe malaria in health services up to 95% by 2009.
2	To improve management of uncomplicated malaria cases in health facilities to 95% by 2009
3	To improve management of uncomplicated malaria at community level to 50% by 2009
4	To have at least about 80% of the total population sleeping under ITNs by 2009
5	To increase awareness of malaria and its prevention to 80% by 2009 in the community and especially among school students

Impact / outcome Indicator	Indicator formulation	Baseline			Targets					Comments
		value	Year	Source	Year 1	Year 2	Year 3	Year 4	Year 5	
% of malaria related mortality in children under five years old*	Total number of malaria mortality in children under five years old /total number of mortality in children under five years old (all causes)	26.9% (53/197)	2005	Statistic NMCP-CNE	42%	26.90%	22%	11%	10%	
Under 5 mortality rate (all causes)	Mortality rate in under 5 children (all causes)	115/1000	2005	WHO Country profile 2006				to be communicated at the end of Q14 for Y4 and Y5		STP MDG target in relation to <5 mortality: in 2002 101/1000 live births, in 2015 should be 40/1000. Source: Republic of STP. Coordination of UN programs in STP. MDGs. First National Report. April 2004
Malaria related mortality at hospital	Total number of malaria mortality in children under five years old at hospital (in-patient mortality) /total number of mortality in children under five years old (all causes) at hospital	38.6%(45/117)	2005	Statistic NMCP-CNE	64%	38.60%	28,6%	15%	10%	
% of malaria related morbidity in children under five	Total number of malaria cases in children under five years old (in-patient+ external consultation) /total number of cases (all diseases) in children under five years old (in-patient and external consultation)	34.5% (11274/32635)	2005	Statistic NMCP-CNE	52%	34.50%	30.90%	13%	10%	
Percentage of children under five sleeping under bed net the previous night	% of children under five years sleeping under bednets the previous night	57.90%	2006	KAP survey report		65%	65%	70%	80%	
Percentage of women sleeping under bednets the previous night	% and number of pregnant women sleeping under bednets the previous night	56.30%	2006	KAP survey report		65%	67.50%	70%	80%	

Objective Number	Service Delivery Area*	Nr.	Indicator formulation	Directly tied (Y/N)1	Baseline (if applicable)			Year 2		Quarterly targets for year 3 (cumulative over the quarters and excluding baselines)				Cumulative year 1-3	Comments
					Value	Year	Source	Target	Results**	Q9	Q10	Q11	Q12		
1	Treatment: Prompt, effective anti-malarial treatment	1	Number of health workers trained /retrained in proper management of malaria cases in the health facilities (including lab technicians)	Y	421	2006	SR report	411	421			651	841	841	
1	Treatment: Prompt, effective anti-malarial treatment	2	Number and percentage of district health facilities supplied with drugs and consumables with no reported stock out	Y	65% (13/21)	2006	Supervision report	95%	73%		95% (20/21)		95% (20/21)	95% (20/21)	

1	Treatment: Prompt, effective anti-malarial treatment	3	Percentage of children under 5 years of age receiving prompt and effective treatment	Y	87%	2006	Supervision report	95%			95%		95%	95%	Data from the sup report. Denominato. on the sample of health facilities supervised. This is the reason it has not been included in this indicater.
2	Treatment: Prompt, effective anti-malarial treatment	4	Number of children under five with uncomplicated malaria treated with ACT in health facilities.	Y	11546	2006	Supervision report	13,290	13,857	917	1,399	1,615	1,874	15,731	Quarterly targets are not cumulative from Phase 1. Targets are reduced due to changes in the epidemiology given the effect of indoor residual spraying. The forecast is reviewed monthly.
2	Treatment: Prompt, effective anti-malarial treatment	5	Number of persons with uncomplicated malaria treated in health facilities	Y	12720	2006	Supervision report	19,476	16,711	1,880	3,118	3,763	4,535	24,011	Target set annually, not cumulative with year 1 and 2.
2	Treatment: Prompt, effective anti-malarial treatment	6	Number of health worker trained on use of the rapid diagnostic kits	Y	56	2006	Training report	56	56	-	-	84		84	
3	Treatment: Home based management of malaria	7	Number of community health workers retrained in management of uncomplicated malaria cases	Y	240	2006	Training report			60	120	180	240	240	
4	Prevention: Insecticide treated nets (ITNs)	8	Number of long lasting bed nets and insecticide treated nets distributed	Y	18664	2006	SR report	58,000	42,101	0	0	0	63,648		Bednets will be bought in Y3 but expected to arrive in Y4.
5	Prevention: BCC - community outreach	9	Number of BCC session organized in the community (awareness/education sessions, leaflets, posters, booklets, etc)	Y	236	2006	SR report	528	409	-	-	-	-	528	No activities in Y3. Number of people to be reached in Y4 is 16,000 & Y5 would be 13,000.
5	Prevention: BCC - community outreach	10	Number of school children reached with BCC services (awareness sessions, plays, leaflets, cartoon-booklets, etc)	Y	25,272	2,006	SR report	54,000	36,384	-	-	-	-	54000	Material for BCC to be produced in Y3 but distributed in Y4.
1	Supportive environment: Diagnosis	11	Number of delivery points (district health centre) properly equipped for diagnosis & treatment of malaria	Y	7	2006	Supervision report	7	7	7	7	7	7	7	Properly equipped for effective measurement means: a health service point with capacity to do microscopy and/or malaria test, that disposes lab materials glucosemeter, thermometer, scale, timer, haematocrit & related medical materials.

1.The default assumption is that targets described for an SDA reflect results that are directly tied to Global Fund financing, i.e., "Y" is checked by default. If targets described for a particular SDA reflect results of a broader national, regional or institutional programme to which Global Fund resources contribute, please check the box "N".
* For other SDA's than listed in the drop down boxes please use the last line where you can input a text. To place the specified SDA under the respective objective, please copy and insert the last line where appropriate.
**This comment is applicable to all indicator: The results reported for year 2 are until month 21.

C. Program Budget

Summary period budget	Year 3 budget break-down ***				Year 3 budget	Indicative budgets***		Budget***
	Q9	Q10	Q11	Q12		Year 4	Year 5	Y3+Y4+Y5
Human resources	26,350	26,350	26,350	26,350	105,399			
Infrastructure and equipment	73,952	400	-	-	74,352			
Training	29,797	21,711	22,954	19,772	94,234			
Commodities and products	127,443	30,611	3,036	3,036	164,126			
Drugs	-	725	8,421	9,146	18,292			
Planning and administration	28,292	23,352	28,104	23,714	103,463			
Other (KAP surveys)	-	8,000	-	-	8,000			
GMS UNDP	14,292	5,557	4,443	4,101	28,393			
TOTAL	300,126	116,707	93,308	86,119	**596,260**	**591,432**	**482,478**	**1,670,170**

*** Budget includes left over funds from phase 1

PROGRAM GRANT AGREEMENT
BETWEEN
THE GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS AND MALARIA ("Global Fund")
AND THE UNITED NATIONS DEVELOPMENT PROGRAMME
("Principal Recipient")

1A. Country: Sao Tome Et Principe		
1B. Program Title: Malaria control in Sao Tome et Principe		
2. Grant Number: STP-405-G01-M	3. Modification Number: 5 (Implementation letter 4 dated 10 July 2008)	
4. Program Starting Date: 1 March 2005	5. Program Ending Date: 28 February 2010	6. Proposal Completion Date: 28 February 2010
6A. Condition Precedent Terminal Date: 1 March 2005	6B. Condition Precedent Terminal Date: 1 July 2005	6C. Condition Precedent Terminal Date: 1 February 2006
7. Global Fund Grant: US$ 3,484,859 (Three Million Four Hundred Eighty Four Thousand Eight Hundred and Fifty Nine United States Dollars)		
8. Program Coverage: ___ HIV/AIDS ___ Tuberculosis _X_ Malaria ___ HIV/AIDS/Tuberculosis		
9. Information for Principal Recipient Bank Account into Which Grant Funds Will Be Disbursed: Beneficiary: United Nations Development Programme (UNDP) Account name: UNDP Contributions Account Account number: 015-002284 Bank name: CHASE Manhattan Bank Bank address: United Nations Branch, New-York, NY 10017, USA Bank SWIFT Code: CHASUS33 Bank Code: 0210-00021 Routing instructions for disbursements: For STP Global Fund Malaria Project		
10. The fiscal year of the Principal Recipient runs from 1 January to 31 December.		
11.LFA Swiss Tropical Institute, Swiss Centre for International Health P. O. Box, Socinstrasse 57, CH – 4002 Basel, Switzerland Tel.: + 41 61 284 81 31 Fax: + 41 61 284 81 03 Attention: Ms. Charlotte Kristiansson E-mail: charlotte.kristiansson@unibas.ch		
12. Principal Recipient Additional Representative: Name: Mr. Antonio Viegas Title: Assistant Resident Representative Address: BP 109 Sao Tomé, Sao Tome & Principe Tel.: +239 22 11 22 / 23 Fax: +239 22 21 98 E-mail: antonio.viegas@undp.org	13. Global Fund Additional Representative: Name : William Paton Title : Director of Country Programs. Address: Chemin de Blandonnet 8 1214 Vernier, Switzerland Tel.: +41-22-791-1700 Fax: +41-22-791-1701	
14. This Agreement consists of the two pages of this face sheet and the following: Standard Terms and Conditions Annex A – Program Implementation Abstract		

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

Ref: AFRIII/08/VHL/113

10 July 2008

Mr. Gana Fofang
UNDP Resident Representative (OIC)
UNDP, Av. Des Nations
Unies – S. Tome
PO Box 109
S. Tome e Principe

Subject: **Program Grant Agreement Number STP-405-G01-M**
Implementation Letter 4

Dear Mr. Fofang,

Interim Amendment to Quality Assurance Policy for Pharmaceutical Products

We are writing to inform you that the Global Fund Board has decided to make a temporary amendment to the Global Fund Quality Assurance Policy for Pharmaceutical Products (the "QA Policy").

As you are aware, the Global Fund currently classifies pharmaceutical products under its QA Policy as follows:

(1) Single and Limited-Source Pharmaceutical Products – these are pharmaceutical products for which there are no publicly available quality assurance standards, analytic methods, and reference standards; and

(2) Multi-Source Pharmaceutical Products – these are pharmaceutical products for which the monographs of the finished dosage forms are publicly available in one or more pharmacopoeias (i.e. technical reference standards).

To address concerns raised about the risk of quality assurance problems with products that have recently been classified as Multi-Source Pharmaceutical Products, the Global Fund Board decided on 12 November 2007 that any drugs for the treatment of HIV/AIDS, tuberculosis and malaria for which the monograph of the finished dosage has been published in the International, US or UK Pharmacopeia (i.e. technical reference standards) after 10 October 2002, shall be subject to the QA Policy for Single and Limited-Source Pharmaceutical Products.

This change to the QA Policy will take effect immediately and will apply until the Board considers the issue again in November 2008 following a full review of the Global Fund's QA Policy.

This means that the QA Policy for Single and Limited-Source Pharmaceutical Products (as set out in Attachment 1 to this letter) now applies also to all future procurement of products that are listed in the table set out in Attachment 2 to this letter.

Chemin de Blandonnet 8, 1214 Vernier – Geneva, Switzerland
tel +41 22 791 1700 fax +41 22 791 1701

This also means that any product that is currently classified as Single or Limited-Source Products, but for which the monograph of the finished dosage is subsequently published in the International, US or UK Pharmacopeia after the date of this letter, will remain subject to the QA Policy for Single and Limited-Source Pharmaceutical Products.

Further information about the QA Policy for Single and Limited-Source Pharmaceutical Products is posted on the Global Fund website:
http://www.theglobalfund.org/en/about/procurement/quality/.

Next Steps

You are requested to take the following steps:

1. Please confirm your agreement with the foregoing and the proposed amendments to the Grant Agreement between you and the Global Fund (as set out below) by signing both copies of this letter where indicated, returning one copy to us and retaining one copy for your records.

2. Please check whether any of the products that you are currently procuring or that you intend to procure are listed in the table set out in Attachment 2 to this letter. If they are, please check that the products comply with the QA Policy for Single and Limited-Source Products according to the following:

    a. If you are procuring or plan to procure any products listed in Attachment 2 to this letter that are not prequalified by WHO or approved by a stringent regulatory authority, you should promptly complete the notification form contained in Attachment 3 to this letter and submit it to your Fund Portfolio Manager.

    b. If you are currently procuring any product listed in the Attachment 2 to this letter that does not comply with the QA Policy for Single and Limited-Source Pharmaceutical Products, please inform your Fund Portfolio Manager immediately by email and copy all correspondence on the matter to Joelle Daviaud at Joelle.daviaud@theglobalfund.org.

    If you have entered into contracts **before** receiving this letter to procure products listed in Attachment 2 that do not comply with the QA Policy for Single and Limited-Source Pharmaceutical Products, the Global Fund will work with you to find a solution to this problem that ensures that patients continue to receive treatment with drugs of acceptable quality.

    However, please be advised that if you do enter into a contract **after** receiving this letter to procure products that do not comply with the QA Policy for Single and Limited-Source Pharmaceutical Products, the Global Fund will apply the enforcement measures specified in Attachment 4 to this letter.

Amendments to the Grant Agreement

As a consequence of this Board decision, we need to amend the Standard Terms and Conditions of the Grant Agreement between you and the Global Fund for the program

entitled "Malaria control in Sao Tome et Principe" effective 17 February 2005 and amended by implementation letters dated 2 May 2005, 6 July 2006, and 14 May 2007, and a Phase 2 Amendment effective 4 April 2007 (the "Grant Agreement").

We are also taking this opportunity to update the face sheet of the Grant Agreement and add the Attachment 4 & 5 to Annex A.

By signing this implementation letter, the Global Fund and the Principal Recipient agree to amend the Grant Agreement as follows:

(1) by replacing the second and third paragraphs in Article 18(g) of the Standard Terms and Conditions with the following paragraphs respectively:

"For any pharmaceutical product for which the monograph of the finished dosage form was published in the International, U.S. or U.K pharmacopoeias before 10 October 2002, the Principal Recipient may verify compliance with applicable quality standards in accordance with existing national procedures of the Host Country."

"Single or Limited-Source Pharmaceutical Products and Other Pharmaceutical Products: Grant funds may be used to procure a single- or limited-source pharmaceutical product (that is, a pharmaceutical product for which there are no publicly available quality assurance standards, analytic methods, and reference standards) or a pharmaceutical product for which the monograph of the finished dosage form was published in the International, U.S. or U.K. pharmacopoeias on or after 10 October 2002, provided that such product meets one of the following standards:.."; and

(2) by amending the following blocks of the face sheet of the Grant Agreement as follows:.

Block 3. Modification Number: 5 (Implementation Letter 4 dated 10 July 2008);

Block 11. LFA Swiss Tropical Institute, Swiss Centre for International Health
P. O. Box, Socinstrasse 57,
CH – 4002 Basel, Switzerland
Tel.: + 41 61 284 81 31
Fax: + 41 61 284 81 03
Attention: Ms. Charlotte Kristiansson
E-mail: charlotte.kristiansson@unibas.ch

Block 13. Global Fund Additional Representative:
Name: William Paton
Title: Director of Country Programs
Address: Chemin de Blandonnet 8
1214 Vernier, Switzerland
Tel.: +41-22-791-1700 Fax: +41-22-791-1701

(3) by attaching to Annex A of the Grant Agreement the document entitled "Attachment 4 & 5 to Annex A: Indicators, Targets, and Periods Covered" attached to this letter.

The face sheet of the Grant Agreement, as amended, is attached. Except as modified herein, the Grant Agreement remains in full force and effect.

Please do not hesitate to contact your Fund Portfolio Manager if you have any queries or need any further clarifications in relation to the above.

As stated above, the Global Fund's primary concern in handling matters related to this Board decision is to ensure that patients continue to receive treatment with drugs of acceptable quality.

Yours sincerely,

William Paton

William Paton
Director of Country Programs

Agreed and Signed:

For: **THE UNITED NATIONS DEVELOPMENT PROGRAMME**

By: _____
Authorized Representative Mr. Gana Fofang, UNDP Resident Representative

Date: 24 July 2008

cc: S.E. Martinho Lopes do Nascimento, CCM Chair
Charlotte Kristiansson, LFA – Swiss Tropical Institute

Enclosures: Face sheet of the Grant Agreement, as amended
Attachment 4 & 5 to Annex A: Indicators, Targets, and Periods Covered
Attachment 1 - Quality Assurance Policy for Single and Limited-Source Pharmaceutical Products
Attachment 2 - Table of products affected by the Interim Amendment to the QA Policy
Attachment 3 - Notification Form
Attachment 4 - Enforcement of Quality Assurance Policy for Single and Limited-Source Pharmaceutical Products

Attachment 1

Quality Assurance Policy for Single and Limited-Source Pharmaceutical Products.

Grant funds may be used to procure a single- or limited-source pharmaceutical products (that is, a pharmaceutical product for which there are no 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.

If the Principal Recipient determines that there is only one or no equivalent pharmaceutical product that meets the standards of either (1) or (2), 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.

* 'Unavailable' is defined as the inability of the manufacturer to supply a sufficient quantity a of finished product within 90 days from the date of the order (12th Board Meeting).

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Attachment 2

List of Multi-Source Products that are subject to the Global Fund's Quality Assurance Policy for Single and Limited-Sourced Pharmaceutical Products (as of 12 November 2007

Antiretrovirals (ARVs)

Non proprietary name (INN)	Dosage Form
Nelfinavir	*Powder for oral solution*
Nelfinavir	*Tablet*
Stavudine	*Powder for oral solution*
Stavudine	*Capsule*
Abacavir	*Tablet*
Didanosine	*Powder for solution*
Lamivudine / Zidovudine	*Tablet*
Lamivudine / Zidovudine / Abacavir	*Tablet*

Anti Malaria pharmaceuticals products

Non proprietary name (INN)	*Dosage form*
Artesunate + Amodiaquine Co-Blistered	*Tablet*
Artesunate +(Sulfadoxine + Pyrimethamine)	*Tablet*
Artemether	*Solution for Injection*
Artemotil	*Solution for Injection*

Anti-TB pharmaceuticals products

Non proprietary name (INN)	*Dosage form*
Capreomycin*	*Powder for injection*
Ethambutol/ Isoniazid	*Tablet*

* The Global Fund requirement for 2nd line TB drugs procurement is that the procurement , using Global Fund grants, must be conducted through the Green Light Committee (GLC) of the Stop TB initiative.

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Attachment 3

To: Dr. Marguerite Samba-Maliavo
Cc: GF Procurement and Supply Management Team

PR's Notification to the Global Fund of intent to procure Single- and Limited-Source Pharmaceutical product(s) or Other Pharmaceutical Products pursuant to Article18g.(c)(i) or (c)(ii) of the Grant Agreement

Please find below the required information regarding the following single- and limited-source pharmaceutical product(s) classified according to criteria Ci and/or Cii that we, The United Nations Development Programme, intend to procure:

Date of notification:	
Country:	
Grant Number:	

(If there is more than one pharmaceutical product to be notified, please provide information for each product in separate table, as follows)

INN†/ Generic product name	**Strength**	**Dosage form**	**Manufacturer/Supplier** (Please indicate manufacturing site)
Main Reason for selecting this Manufacturer/supplier			

INN*/ Generic product name	**Strength**	**Dosage form**	**Manufacturer/Supplier** (Please indicate manufacturing site)
Main Reason for selecting this Manufacturer/supplier			

† INN : International Nonproprietary Name

We look forward to receiving the Global Fund response, in order for us to finalize the selection process of the above listed products.

Sincerely,

Mr. Gana Fofang
UNDP Resident Representative (OIC)
UNDP, Av. Des Nations
Unies – S. Tome
PO Box 109
S. Tome e Principe
Tel + 229 221122
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Attachment 4

Enforcement of Quality Assurance Policy for Single and Limited-So8rce Pharmaceutical Products

Quality Assurance Policy

The Global Fund Board approved the Quality Assurance Policy for the procurement of Single- and Limited-Source Pharmaceutical Products in April 2005 in order to ensure that Global Fund resources are used to procure quality-assured pharmaceutical products.

According to the Quality Assurance policy, Single- and Limited-Source Pharmaceutical Products have been classified into three categories: A, B and C.

Category A products are products that have been found to be acceptable by the WHO UN Pilot Procurement Quality and Sourcing Project.

Category B products have been authorized for consumption in their country by a stringent regulatory authority.‡

Category C products are sub-divided into two sub-categories, Ci and Cii. A Ci pharmaceutical product is (1) produced by a manufacturer that has submitted an application for product pre-qualification to the WHO Prequalification Program and/or for product approval by a stringent regulatory authority and (2) the manufacturing site for this product is compliant with Good Manufacturing Practice (GMP) standards as certified by WHO or by one of the stringent regulatory authorities. A Cii pharmaceutical product is manufactured according to GMP standards as certified by WHO or by one of the stringent regulatory authorities. The manufacturer of a Cii pharmaceutical product has not submitted an application for product prequalification to the WHO Prequalification Program and/or for product approval by a stringent regulatory authority.

Pursuant to the Quality Assurance Policy, Category C products may only be purchased if the Principle Recipient determines that there is only one or no equivalent pharmaceutical product that meets Category A or B or if the Principal Recipient determines that such products are unavailable within 90 days. In addition, Cii products can only be purchased if Ci products are unavailable.

Procuring inappropriately under Category C could result in the distribution of products that are not safe for consumption. In particular, failure by PRs to notify the Global Fund that they are purchasing under this category makes it impossible for the Global Fund to conduct random testing of the quality of the products, thereby increasing the risk that patients will be put at risk. To prevent that from occurring, the Global Fund will enforce the corrective measures that are outlined in this document.

Levels of Non-Compliance

The Global Fund has defined two levels of non-compliance as described below.

Level 1 – "No-notification but compliant procurement": A Principal Recipient did not inform the Global Fund of its intent to procure a "C" product before it procured such product(s) and the quality control testing has not been conducted by the Global Fund.

‡ For the purposes of this policy, a "stringent drug regulatory authority" is defined as a regulatory authority participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and/or the International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use.

However, the selection of the product(s) procured is compliant with the Quality Assurance policy.

Level 2 – "No-notification and non-compliant procurement": A Principal Recipient did not inform the Global Fund of its intent to procure a "C" product before it procured such product(s), the quality control testing has not been conducted by the Global Fund and the selection of the product(s) is not in compliance with the Quality Assurance policy.

Enforcement of Non-Compliance

In the event of non-compliance with the Quality Assurance Policy, the Global Fund will enforce the following corrective measures, depending on the level of non-compliance.

Level 1 – "No-notification but compliant procurement":

First Instance of no-notification but compliant procurement – The Global Fund will inform the Principal Recipient that it has received information that the Principal Recipient has procured "C" products using grant funds without notifying the Fund Portfolio Manager of its intent to procure such "C" product(s) and will request the Principal Recipient to urgently send written notification to the GF. (To facilitate this notification, a template letter of notification for use by Principle Recipients is contained in Attachment 3 and available on the Global Fund website.)

Once the Principal Recipient sends written notification to the Global Fund, compliance of the procurement with the Quality Assurance policy will be verified before the Global Fund releases any further disbursements related to procurement of pharmaceutical products.

Additionally, the Global Fund will send a warning letter to the Principal Recipient stating that should the Principle Recipient fail to comply a second time, the Global Fund will only disburse funds for procurement of pharmaceutical products directly to a procurement agent or to the supplier.

Second Instance of no-notification but compliant procurement – The Global Fund will inform the Principal Recipient that it has received information that the Principal Recipient has procured "C" products for a second time without notifying the Fund Portfolio Manager of its intent to procure such "C" product(s). The Global Fund will request the Principal Recipient to urgently send written notification (template letter of notification contained in Attachment 3) and will advise the Principal Recipient that all further disbursement of funds for procurement will be made directly to a procurement agent or to the supplier.

Once the Global Fund receives written notification from the Principal Recipient, compliance of the procurement with the Quality Assurance policy will be verified. The Global Fund will only disburse funds for pharmaceutical products directly to a procurement agent or the supplier for the remaining period of the Grant Agreement.

Level 2 – "No-notification and Non-compliant Procurement":

First Instance of no-notification and non-compliant procurement – The Global Fund will inform the Principal Recipient that it has received information that the Principal Recipient has used grant funds to procure "C" products without notifying the Fund Portfolio Manager of its intent to procure such "C" product(s) and that these products are not compliant with the Quality Assurance policy as per the Grant Agreement.

To verify the compliance of this procurement, the Global Fund will request the Principal Recipient to urgently send written notification with all documentation justifying the choice of the product(s).

When the non-compliant procurement is confirmed, the amount paid by the Principal Recipient for the non-compliant products will be deducted from future disbursements and the Global Fund will only disburse funds for pharmaceutical products directly to a procurement agent or a supplier for the remaining period of the Grant Agreement.

Further, non-compliance with this policy may have repercussions on the Country Coordinating Mechanism's (CCM) Request for Continued Funding (also known as the "Phase 2 Request"). For example, if the Global Fund confirms the non-compliant procurement after submission of the Request for Continued Funding, the amount paid by the Principal Recipient for the non-compliant pharmaceutical products will be deducted from the recommended Phase 2 amount, with notification to the Global Fund Board. In addition, the Phase 2 Panel may recommend a "Conditional Go" with conditions attached to compliance with the Quality Assurance Policy. In cases of repeated non-compliance, the Phase 2 Panel may consider recommending no further funding for Phase 2 on that basis.

In cases of repeated non-compliant procurement by Principal Recipients the Global Fund may suspend or terminate a grant and/or replace the Principal Recipient.

Communication about Compliance

As is existing practice, Principal Recipients are reminded that all formal communications with the Global Fund must be sent directly to the Fund Portfolio Manager responsible for the portfolio of grants. The Fund Portfolio Manager will answer any queries or direct the Principal Recipient to in-house technical expertise as needed.

Principal Recipients should be aware that the CCM and the Local Fund Agent (LFA) will be copied on all correspondence in relation to the Quality Assurance Policy and the compliance measures as described in this letter.

The Global Fund is ready to assist with any queries or clarifications regarding the Quality Assurance Policy, its implementation and the enforcement of the policy. I encourage you to be in touch with your Fund Portfolio Manager who can provide guidance and further information.

Attachment 4&5 to Annex A: Indicators, Targets, and Periods Covered

Malaria

Date of draft version: _____
Date of final version: _____
Approved by: _____

Program Details

Country:	Sao Tome et Principe
Disease:	Malaria
Grant number:	STP-405-G01-M
Principal Recipient:	United Nations Development Programme

A. Periods covered and dates for disbursement requests and progress updates

	Period 13	Period 14	Period 15	Period 16	Period 17	Period 18	Period 19	Period 20
Period Covered: from	1-Apr-08	1-Jul-08	1-Oct-08	1-Jan-09	1-Apr-09	1-Jul-09	1-Oct-09	1-Jan-10
Period Covered: to	30-Jun-08	30-Sep-08	31-Dec-08	31-Mar-09	30-Jun-09	30-Sep-09	31-Dec-09	28-Feb-10
Date Progress Update due (typically 45 days after end of period)	14-Aug-08	14-Nov-08	14-Feb-09	15-May-09	14-Aug-09	14-Nov-09	14-Feb-10	14-Apr-10
Disbursement Request ? (Y,N)	-	-	-	-	-	-	-	-

Annual Report Due Date:	14-Feb-08	16-Feb-09
Audit Report Due Date:	30-Jun-08	30-Jun-09

B. Program Goal, Impact and Outcome Indicators

Goals:	
1	To reduce burden of malaria in Sao Tome & Principe
2	

Impact / Outcome Indicator	Indicator	Baseline			Targets					Comments*
		value	Year	Source	Year 1	Year 2	Year 3	Year 4	Year 5	
Impact	Total number of malaria mortality in under five years children /total number of mortality in under five years old children (all causes)	26.9% (53/197)	2005	Statistic NMCP-CNE	42.0%	28.9%	22.0%	11.0%	10.0%	The NMCP (statistic unity) goes, at least, quarterly to the field to verify the deaths at health service (i) and to the civil registration (ii) to collect the all deaths ocurred in the specific period
Impact	Mortality rate in under 5 children (all causes)	116/1000	2005	WHO Country Profile 2006 & (INE folowing years)				TBD in Q14		Regarging the following years, this data, as it is periodicaly produced by National Statistical Institute (INE), the M&E personnel will collect this information in there
Impact	Total number of malaria mortality in under five years children at hospital (in-patient mortality) /total number of mortality in under five years old children (all causes) at hospital.	38.6% (45/117)	2005	Statistic NMCP-CNE	64.0%	38.6%	28.6%	15.0%	10.0%	The NMCP (statistic unity) goes, at least, quarterly to the field to verify the deaths at health service (i) and to the civil registration (ii) to collect the all deaths ocurred in the specific period
Impact	Total number of malaria cases in under five years children (in-patient+ external consultation) /total number of cases (all diseases) in under five years old children (in-patient and external consultation)	34.5% (11274/32635)	2005	Statistic NMCP-CNE	52.0%	34.5%	30.9%	13.0%	10.0%	The NMCP (statistic unity) goes, at least, quarterly to the field to verify the reported (from district) data in the external consultation and in-patient and laboratory record(Health service records).
Outcome	% of children sleeping under bednet	53.5% (460/860)	2006	KAP survey report		53.5%	55.0%	56.0%	60.0%	IDEM, as the last indicator but, with the U5 children
Outcome	% of pregnant women sleeping under bednet	41.3% (38/92)	2006	KAP survey report		41.3%	50.0%	52.0%	56.0%	Through a survey a radom sample will be done and X households will be defined to be interviewed. Each pregnant women (PW) among all household will be investigated. The indicator is the PW slepet last night under bed net divided by the all pregnant women encontered in these households
please select...	please select...			please select...						

* please specify source of measurement for indicator in case different to baseline source

C. Program Objectives, Service Delivery Areas and Indicators

Objective Number	Objective description
1	To improve the management of severe malaria in health services up to 95% by 2009
2	To improve management of uncomplicated malaria cases in health facilities to 95% by 2009
3	To improve management of uncomplicated malaria at community level to 50% by 2009
4	To have at least about 60% of the total population sleeping under ITNs by 2009
5	To increase awareness of malaria and its prevention to 80% by 2009 among school students

Objective / Indicator Number	Service Delivery Area	Indicator	Baseline (if applicable)			Targets		Periodical targets for year 4 & 5								Directly Used (Y/N)	Baselines included in targets (Y/N)	Targets cumulative (Y over program term / Y, cumulative annually / N - not cumulative)	Comments
			Value	Year	Source	Year4	Year5	P13	P14	P15	P16	P17	P18	P19	P20				
1	Treatment: Prompt, effective anti-malarial treatment	Number of health workers trained in management of malaria cases	421	2006	Training report from SR NMCP	993	1'193	993		1'193	1'193				1'193	Y	Y	Y - over program term	
1	Treatment: Prompt, effective anti-malarial treatment	Number of health facilities supplied with drugs with not reported stock out of ACT (artesunate+amodiaquine), lasting at least 15 days, in the last	13/21; 65%	2006	Supervision Report (SR-FNM)	96%	96%		96%		96%		96%		96%	Y	N	N - not cumulative	

Objective / Indicator Number	Service Delivery Area	Indicator	Baseline (if applicable)			Targets		Periodical targets for years 4 & 5								Directly linked (Y/N)	Baselines included in targets (Y/N)	Targets cumulative (Y - over program term / Y - cumulative annually / N - not cumulative)	Comments
			Value	Year	Source	Year4	Year5	P13	P14	P15	P16	P17	P18	P19	P20				
1	Treatment: Prompt, effective anti-malarial treatment	Percentage of children under five years old with access to prompt effective treatment	87.0%	2006	NMCP-Supervision Report	94%	95%		93%		94%		94%		95%	N	N	N - not cumulative	
2	Treatment: Prompt, effective anti-malarial treatment	Number of children under five years old with uncomplicated malaria treated in health facilities	11'546	2006	Supervision Report (SR-FNM)	17'026	17'111	16'809	16'891	16'945	17'026	17'062	17'083	17'097	17'111	Y	Y	Y - over program term	
2	Treatment: Prompt, effective anti-malarial treatment	Number of persons over five years old with uncomplicated malaria treated in health facilities	12'720	2006	Supervision Report (SR-FNM)	23'017	23'416	22'305	22'598	22'806	23'017	23'109	23'270	23'352	23'416	Y	Y	Y - over program term	
3	Treatment: Prompt, effective anti-malarial treatment	Number of community health workers retrained in management of uncomplicated malaria cases	240	2006	Training Report from SR Zatona ADIL	480				420	480				480	Y	Y	Y - over program term	
4	Prevention: Insecticide treated nets (ITNs)	Number of long lasting bednets and insecticide treated nets distributed	16'064	2006	Reproductive health & community NGO ADRA report	85'762	107'076				85'762				107'076	Y	Y	Y - over program term	
5	Prevention: BCC - community outreach	Number of school children reached with BCC services (awareness/education sessions, leaflets, posters, booklets,etc)	36'690	2006	SR-NGO Zatona ADIL supervision report	86'861	107'861	57'861		71'316	86'861			104'316	107'861	Y	Y	Y - over program term	
	Treatment: Diagnosis	Number and % of malaria cases confirmed (RDT or microscopy)	69,7% (2965/3306)	2007	NMCP report-CNE	92%	95%				92%				95%	N	N	N - not cumulative	
	Treatment: Home based management of malaria	% of carelakers who know the cause, symptoms preventive measures and treatment of malaria	NA	NA	KAP Survey	NA	NA									N	N	N - not cumulative	Baseline to be determined through planed KAP surveys and targets to be set up accordingly. 5% increase after the baseline in Year 4; and 15% increase since the baseline by Year 5.