

# AMENDMENT OF GRANT

<b>1. AMENDMENT NUMBER: 22</b>	<b>2. EFFECTIVE DATE OF MODIFICATION:</b> See Block 15	<b>3. GRANT NUMBER:</b> AAG-G-00-99-00005-22	<b>4. EFFECTIVE DATE OF GRANT</b> 09/24/99
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<b>5. GRANTEE:</b>  Dr. Anders Nordström Assistant Director-General General Management World Health Organization 1211 Geneva 27 Switzerland	<b>6. ADMINISTERED BY:</b>  U.S. Agency for International Development (USAID) Bureau for Global Health Washington, DC 20523-3700
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<b>7. FISCAL DATA:</b>  See page 2	<b>8. TECHNICAL/PROJECT OFFICE:</b>  GH/HIDN/ID
	<b>9. PAYMENT OFFICE:</b>  M/FM/CMP/GIB, Room 7.07-107

<b>10. FUNDING SUMMARY:</b>	<u>Obligated Amount</u>	<u>Total Est. Amt.</u>
Amount Prior to this Modification:	\$176,614,201.87	\$200,000,000.00
Change Made by this Modification:	1,895,000.00	0
New/Current Total:	\$178,509,201.87	\$200,000,000.00

**11. DESCRIPTION OF AMENDMENT:**

The purpose of this amendment is to provide \$1,895,000 of core funding to procure antimalarial drugs (ACTs) for the President's Malaria Initiative activities.

All other terms and conditions remain the same.

12. THIS AMENDMENT IS ENTERED INTO PURSUANT TO THE AUTHORITY OF THE FAA OF 1961, AS AMENDED, AND THE FG&CAA OF 1977. EXCEPT AS SPECIFICALLY HEREIN AMENDED, ALL TERMS AND CONDITIONS OF THE GRANT REFERENCED IN BLOCK #3 ABOVE, AS IT MAY HAVE HERETOFORE BEEN AMENDED, REMAIN UNCHANGED AND IN FULL FORCE AND EFFECT.

13. GRANTEE  IS  IS NOT REQUIRED TO SIGN THIS DOCUMENT TO RECONFIRM ITS AGREEMENT WITH THE CHANGES EFFECTED HEREIN.

<b>14. GRANTEE: World Health Organization</b>	<b>15. THE UNITED STATES OF AMERICA U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT</b>
<b>BY:</b> _____  Dr. Anders Nordström _____ (Name Typed or Printed)	<b>BY:</b> _____  Gloria D. Steele _____ (Name Typed or Printed) Senior Deputy Assistant Administrator,
<b>TITLE:</b> Assistant Director-General	<b>TITLE:</b> Bureau for Global Health
<b>DATE:</b> _____	<b>DATE:</b> _____

## ACTION MEMORANDUM

TO: SDAA/GH, Gloria D. Steele

FROM: GH/HIDN, Richard Greene

SUBJECT: Amendment No. 22 of Grant No. AAG-G-00-99-00005 with the World Health Organization (WHO)

### ISSUE FOR DECISION

Whether to approve an amendment to subject Grant between USAID and WHO to add \$1,895,000 of core funding.

### ESSENTIAL FACTORS

Background: On June 30, 2005, President Bush challenged the world to reduce the burden of malaria dramatically as a major killer of children in sub-Saharan Africa and pledged to increase funding of malaria prevention and treatment by more than \$1.2 billion over five years. The goal of this effort is to reduce malaria deaths by 50 percent in each of the target countries after three years of full implementation.

One of the key strategies to meet these ambitious goals is the scale up of treatment through antimalarial drugs in target countries. At the present time, the artemether-lumefantrine combination (ACTs) is the first line treatment in several African countries including the first three President's Malaria Initiative (PMI) focus countries. Novartis is currently the only World Health Organization (WHO)

prequalified manufacturer of the artemether-lumefantrine combination, marketed under the trade name Coartem®.

This amendment provides funding to WHO for the purchase of ACTs in Angola, Tanzania, and Uganda. WHO has an institutional procurement arrangement with Novartis (manufacturer of Coartem®) with preferential public sector pricing. The Roll Back Malaria Partnership Secretariat's Malaria Medicines and Supply Services (MMSS) coordinates delivery and purchase orders with Novartis for Roll Back Malaria, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and individual country orders.

Discussion: The WHO Umbrella Grant was effective and obligation was made on September 24, 1999. The grant is scheduled to expire on September 30, 2009. The total estimated cost of the agreement is \$200,000,000. The total obligations to date are \$176,614,201.87. The amount to be obligated with this action is \$1,895,000.00, making the total amount obligated, including this action \$178,509,201.87. This amount consists of FY 2006 early malaria funds requested by GH/HIDN on behalf of the initial three PMI countries for activities. These funds will be used to procure ACTs in Angola, Tanzania, and Uganda: \$860,000 will be obligated for ACTs in Angola; \$700,000 will be obligated for ACTs in Tanzania, and \$335,000 will be obligated for ACTs in Uganda, making the total funds provided \$1,895,000. Representatives from USAID will monitor these activities and agree to any necessary changes or adjustments to the activities, outcomes, indicators, or budget line items.

Authority: In accordance with Automated Directives System (ADS) 103.3.8.2, Assistant Administrators (AAs) have the authority to negotiate, execute, amend, and supplement grants to Public International Organizations. Pursuant to GH Delegations of Authority, under ADS 103.3.16.1, paragraph (i) delegates that authority to the Senior Deputy Assistant Administrator.

## RECOMMENDATION

That you approve by signing five original face sheets of the attached Amendment No. 22 to the WHO Umbrella Grant (AAG-G-00-99-00005) to add \$1,895,000.00 provided in FY 2006 early Malaria funding on behalf of the three PMI countries.

Attachments:

Grantee Face Sheet and Appropriation Data Sheet

Attachment 1, Amendment to Schedule

Attachment 2, Supplemental Financial Plan and Budget

Attachment 3, Program Description

Appendix 1, Submission form for Country Applying to WHO for Coartem

Appendix 2, WHO Reimbursable procurement of Coartem at cost price for use in the public sector in disease endemic developing countries

CLEARANCE PAGE FOR Amendment No. 22 to the WHO Umbrella Grant,  
Award Number AAG-G-00-99-00005.

Clearances:

GH/HIDN/ID, DGibb _____	Date _____
GH/HIDN, IKoek _____	Date _____
GH/HIDN, JIce _____	Date _____
M/OP/TC/COM, RCameron _____	Date _____
GH/HIDN, EFox _____	Date _____
DAA/GH, MMiller _____	Date _____
GH/SPBO LWhite _____	Date _____

Drafted MO'Keefe 1/20/06

Location: P:\GH.SHARED\HIDN Program Staff docs & guidance\Meaghan's  
folder (pre clearance)\WHO\WHO 22

## ACCOUNTING AND APPROPRIATION DATA SHEET

### Grant to World Health Organization Award No. AAG-G-00-99-00005-22

#### A. General

1.	Total Estimated Amount:	\$200,000,000.00
2.	Total Amount Obligated prior to this Action:	\$176,614,201.87
3.	Total Amount obligated this Action:	\$ 1,895,000.00
4.	Total Amount Obligated:	\$178,509,201.87
5.	Activity Approval Documents:	Various

6. USAID Project Office: Dale Gibb  
GH/HIDN/ID  
RRB 3.07-066  
Office of Health,  
Infectious Diseases, and Nutrition  
U.S. Agency for International Development  
Washington, DC 20523-3700

#### B. Specific

1.	Phoenix/NMS Request Number:	01538
2.	Organization Symbol:	GH/HIDN/ID
3.	Resource Category Code:	
4.	Activity Name:	WHO Umbrella Grant
5.	Fund Account/Allotment Symbols:	SO5 Core (PMI Funding)
6.	Total Obligation Amount:	\$ 1,895,000.00

## **ATTACHMENT 1: AMENDMENT TO SCHEDULE**

C. Amount of Grant and Payment

2. USAID hereby obligates the amount of US \$1,895,000.00 for program expenditures during the period set forth in B.1. and as shown in the Grant Budget below.

D. Grant Budget

The Supplemental Budget is included in Attachment 2 to Grant Amendment No. 22. In the event of conflict between the budget as described in the Program Description and the budget described in Attachment 2 to Grant Amendment No. 22, Attachment 2 shall control.

(End of Provision)

**Attachment 2**  
**WHO Umbrella Grant (AAG-G-00-99-00005)**  
**BUDGET (AMENDMENT #22)**  
Summary by Activity Area and Implementing Unit

<u>Activity</u>	<u>Implementing Unit</u>	<u>Funding</u>
Procurement of Coartem	RBM/MMSS*	\$1,895,000.00
	<b>TOTAL</b>	<b>\$1,895,000.00</b>

\*Malaria Medicines and Supplies Service



**Attachment 3: Program Description**  
**WHO Umbrella Grant (AAG-G-00-99-00005)**  
**BUDGET (AMENDMENT #22)**

Collaborative ACT Program Objectives: USAID and WHO have agreed to implement a collaborative program, beginning December 15, 2005 until September 20, 2007, with shared program objectives. The Collaborative ACT Program will be governed under the existing USAID/WHO umbrella grant no. AAG-G-00-99-00005. Joint program objectives include the following:

1. Scaling up coverage of ACT treatment according to countries' drug policies, most likely with Coartem® when relevant, in PMI focus countries;
2. Coordination of orders, shipments and deliveries of ACT treatments to avoid stock-outs or oversupply in PMI focus countries;
3. Strengthening of the global ACT supply chain through collaboration on industry demand forecasts, information sharing, and technical consultations.

Roles and Responsibilities: Under the Collaborative ACT Program, USAID and WHO will assume joint responsibility for achieving the shared program objectives. Specifically, USAID will be responsible for the following, in consultation with country partners and MMSS:

1. Provision of indicative annual budget allocation by country;
2. Provision of annual purchase forecasts for Coartem® funded by the PMI or for other USAID funded countries;
3. Submission of country orders (most likely annual) for ACTs according to the RBM/MMSS process with written concurrence from the Ministry of Health;
4. Coordination of delivery schedules to avoid oversupply or stock-outs.

WHO's RBM and MMSS will be responsible for the following:

1. Processing PMI country orders for ACTs according to MMSS procedures. This includes placing firm orders and transferring USAID funds to supplier, arranging shipments, freight transport, insurance, and consignment to the Ministry of Health or other pre-determined consignees;

2. Coordinating technical assistance and providing guidance on the delivery, timing, logistics, and management of ACT orders in country;
3. Providing quarterly reporting on expenditures and delivery status, cost/budget estimates, and expenditures using established MMSS reporting procedures;
4. Collaboration and information sharing on global and country-level ACT supply issues including financing, pipelines, partnerships with suppliers, and other strategic issues.

Funding/Budget: The total budget ceiling for the Collaborative ACT Program until September 30, 2007 is \$25 million, inclusive of a 6% overhead, mutually agreed upon. USAID will provide an annual budget allocation per country, per year. The estimated total 2006 budget obligation by country is stated in **Table 1** below. Budget details will be filled in by WHO based on the individual country budgets.

Table 1 Estimated Budget Obligation for Purchase of Antimalarial Drugs by Country							
Country	Coartem and treatment regimen (1-4) see footnote*	a. Cost of Goods/tablet	b. Total number of tablets needed	c. Total cost of tablets	d. Customs, Freight, Insurance, Storage	e. Program Support Costs (PSC) % (c+d)	Total Budget** (c+d+e)
<b>Angola</b>	1						
	2						
	3						
	4						
<b>Subtotal</b>							860,000
<b>Tanzania</b>	1						
	2						
	3						
	4						
<b>Subtotal</b>							700,000**
<b>Uganda</b>	1						
	2						
	3						
	4						
<b>Subtotal</b>							335,000
<b>Total</b>							1,895,000

\*The four regimens utilized include: 1: 20mg Artemether+ 120 mg Lumefantrine, 2: 40

mg A + 240 M, 3: 60 mg A + 360 L,4: 80 mg A + 480 mg L. Totals will have to be adjusted to provide for PSC.

\*\* Includes \$ 300,000 for ADDOS and \$400,000 for ACTs for camps.

Expenditures on this budget will be authorized upon submission of the joint USAID/Ministry of Health country order for Coartem® or other ACTs and USAID receipt of the MMSS proforma invoice for shipment.

Order Process: The process for ordering Coartem® or other ACTs will include the following steps:

1. USAID will determine the 2006 initial order estimates for Coartem® based on the scheduled PMI planning visits for the three focus countries. The needs assessments will be based on extensive consultation with the Ministries of Health, the WHO country offices, Global Fund for AIDS, TB, Malaria and other stakeholders in countries.
2. USAID will review the initial projections of PMI Coartem® orders with MMSS to determine optimal timing of deliveries, logistics issues, country absorptive capacity, and order size.
3. USAID and the Ministries of Health will jointly submit the country's order form to MMSS (**see Appendix 1 for form**). MMSS will confirm official receipt of the order form and transmit it to the RBM focal person for follow up and review by the ACT Technical Advisory Group (TAG).
4. MMSS will advise USAID once the TAG review has been completed and send the proforma invoice which authorizes the expenditure and transfer of USG funds for the purchase of Coartem®. MMSS will advise USAID on the expected shipment deliveries, funds transferred, and order placed with Novartis.

Special Provisions:

- a. Technical Advisory Group (TAG) - The TAG is a Group of independent experts established by WHO, responsible for advising WHO on requests for supplies of Coartem® for Public Sector Agencies, for distribution through the public sector of disease endemic countries, based on a set of criteria (**please see Appendix 2**). In rare instances, the TAG may determine that a USAID-funded order needs be delayed so that available drugs can be directed to another country to address a malaria epidemic or malaria emergency situation. In this case, WHO will advise USAID of the delay and provide written notification that will include the following: technical justification for the delay, country that to which the shipment is

being diverted, and dates when USAID-funded shipment will be delivered.

- b. Consignment—Coartem®/ACT shipments will be consigned to the Ministry of Health in each country. In instances where USAID requests consignment to a different party or organization, USAID will obtain written concurrence from the corresponding Ministry of Health.
- c. Reporting—MMSS will report quarterly on orders passed, cost/budget estimates, delivery times and production pipeline. MMSS will provide the following reports:

<b>Report/Document Name</b>	<b>Frequency</b>
1. Proforma Invoice	Upon receipt of USAID/MOH submission of Coartem® order form.
2. Status of Coartem® Order Report	Quarterly
3. Report/documentation certifying consignment of shipment in country	45 days after shipment delivery