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The Global Fund
To Fight AIDS, Tuberculosis and Malaria

APPLICATION FORM

AFFORDABLE MEDICINES FACILITY – MALARIA (AMFM) PHASE 1*F

Country	**Nigeria**			
Applicant Name	**Country Coordinating Mechanism (CCM)**			
Application Type	**Affordable Medicines for Malaria (AMFm) Phase 1**			
Duration	**Start***(month and year):*	**February 2010**	**End** *(month and year):*	**February 2012**

Deadlineforsubmission of application: **1 July 2009**
12 noon (Central European Time)

IMPORTANT: Applicants are strongly encouraged to read the Guidelines for AMFm Phase 1 Applications before completing this Application Form and refer to the guidelines as they respond to each section.

***"AMFm Phase 1" refers to the initial operational period of AMFm and should not be confused with the "Phase 1" of standard Global Fund grants. The Global Fund Board decided that AMFm will be launched in a small group of countries (AMFm Phase 1) and assessed through an independent evaluation. The results of this evaluation will be used by the Board to decide whether to proceed to a global roll-out of AMFm.**

1. Contact and summary information

(1a) Applicant contact details

Clarified Section 1a.

	Primary contact	Secondary contact
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Title	Chairman	Executive Secretary
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E-mail address	johnhelpng@yahoo.com.	fwbello@ccmnigeria.org
Alternate e-mail address	johnhelpng@yahoo.com.	fwbello@yahoo.com

(1b) Currency

('Tick' (✓) which currency is used throughout the application)	☒ USD	Or	☐ EURO

(1c) List of abbreviations and acronyms used by the applicant

Acronym/ Abbreviation	Meaning
AA	Artesunate + Amodiaquine Combination
ABUTH	Ahmadu Bello University Teaching Hospital
ACHPN	Association of Community Health Practitioners of Nigeria
ACOMIN	Association of Civil Society Organizations in Malaria Immunization and Nutrition
ACT	Artemisinin-based Combination Therapies
ADR	Adverse Drug Reaction
AHE	Association of Health Educators
AL	Artemether + Lumefantrine Combination
AMFm	Affordable Medicines Facility for Malaria
AMLSN	Association of Medical Laboratory Scientists of Nigeria
APIN	Association of Pharmaceutical Importers of Nigeria

1. Contact and summary information

AQ	Artesunate + Mefloquine combination
BBC	British Broadcasting Corporation
BCC	Behavioral Change Communication
CAC	Corporate Affairs Commission
CAN	Christian Association of Nigeria
CCM	Country Coordinating Mechanism
CDC	Community Development Committee
CDTI	Community Directed Treatment with Ivermectin
CEM	Cohort Event Monitoring
cGMP	Current Good Manufacturing Practice
CIMCI	Community Integrated Management of Childhood Illness
CMFS	Certificate of Manufacture and Free Sale
CMS	Central Medical Store
COPP	Certificate of Pharmaceutical Product
CORPs	Community Oriented Resource Persons
CQ	Chloroquine
CSO	Civil Society Organizations
DSNO	Disease Surveillance and Notification Officers
DTET	Drug Therapeutic Efficacy Test
DRF	Drug Revolving Fund
ECWA	Evangelical Church of West Africa
EID	Establishment Inspection Directorate of NAFDAC
FBO	Faith Based Organization
FDS	Food & Drug Services
FGD	Focus Group Discussion
FMC	Federal Medical Centre
FMoH	Federal Ministry of Health
GFR4	Global Fund Round 4
GFR8	Global Fund Round 8
HMIS	Health Management Information Systems
HMM	Home Management of Malaria
HMO	Health Management Organization
HSS	Health System Strengthening

1. Contact and summary information

ICB	International Competitive Bidding
IEC	Information, Education, Communication
IMNCH	Integrated Maternal and Newborn Childhood Health
INN	International Non Propriety Name
IPC	Interpersonal Communication
IPIMN	Indian Pharmaceutical Manufacturers and Importers of Nigeria
IRS	Indoor Residual Spraying
ITN	Insecticide Treated Nets
LCB	Local Competitive Bidding
LGA	Local Government Area
LLIN	Long Lasting InsecticideNets
LMIS	Logistics Management Information System
LQAS	Lot Quality Assurance Sampling
MAMA	Mothers Against Malaria Attack
MAPS	Malaria Treatment at Point of Service
MDA	Ministries, Departments and Agencies
MDCN	Medical and Dental Council of Nigeria
MDG	Millennium Development Goal
MICS	Multiple Indicator Cluster Survey
MoH	Ministry of Health
M2S2	Malaria Medicines Supply Services
NAFDAC	National Agency for Food & Drug Administration & Control
NANNM	National Association of Nigeria Nurses & Midwives
NAPPMED	National Association of Patent and Proprietary Medicine Dealers
NASFAT	Nasrul-Lahi-ilFathi Society of Nigeria
NASS	National Assembly
NATP	National Anti-Malaria Treatment Policy
NDLEA	National Drug Law Enforcement Agency
NDHS	National Demographic Health Survey
NIFAA	Nigeria Inter Faith Agency Action
HDSAC	National Drug Safety Advisory Committee
NGO	Non Governmental Organization
NHIS	National Health Insurance Scheme

1. Contact and summary information

NIPRD	National Institute for Pharmaceutical Research & Development
NIROPHARM	Nigerian Representatives of Overseas Pharmaceutical Manufacturers
NMA	Nigeria Medical Association
NMSP	National Malaria Strategic Plan
NMCP	National Malaria Control Program
NPC	National Pharmacovigilance Centre
NRN	NAFDAC Registration Number
NPHCDA	National Primary Health Care Development Agency
NUT	Nigeria Union of Teachers
OTC	Over The Counter
3PL	Third Party Logistics Provider
PCN	Pharmacists Council of Nigeria
PHC	Primary Health Care
PID	Ports Inspection Directorate of NAFDAC
PLWHA	People Living With HIV and AIDS
POM	Prescription Only Medicine
PPMV	Patent and Proprietary Medicine Vendors
PPP	Public-Private Partnership
PQ	Pre-Qualification
PR	Principle Recipient
PSN	Pharmaceutical Society of Nigeria
PSM	Procurement and Supply Management
QA	Quality Assurance
RBM	Roll Back Malaria
RDT	Rapid Diagnostic Test
RMM	Role Model Mother
SFH	Society for Family Health
SOP	Standard Operating Procedure
SP	Sulfadoxine-Pyrimethamine
SR	Sub-Recipient
SRP	Suggested Retail Price
STG	Standard Treatment Guidelines
TVC	Television Commercials

1. Contact and summary information

UCH	University College Hospital, Ibadan
UMC	Uppsala Monitoring Center
UNTH	University of Nigeria Teaching Hospital, Enugu
USAID	United States Agency for International Development
UUTH	University of Uyo Teaching Hospital, Uyo
VHW	Village Health Worker
WADRAN	West African Drug Regulatory Authorities Network
WDC	Ward Development Committee
WHO	World Health Organization
YGC	Yakubu Gowon Centre for International Cooperation

2. Applicant summary

(2a) AMFm 'host' grant

Funding for AMFm supporting interventions will be disbursed through an **existing Global Fund malaria grant**. This "**host grant**" will be amended to include the budget and performance indicators for AMFm supporting interventions. Applicants are recommended to nominate a "host" grant with an ACT procurement component; however, this is not compulsory. Refer to the Guidelines for AMFm Phase 1 Applicationsfor further information and also see Section 7 of this application form.

In the table below, nominate an existing Global Fund malaria grant through which funding for AMFm supporting interventions can be disbursed. Provide the name of the **current** Principal Recipient for this grant.

Clarified Section 2a.

	Details
AMFm 'host' grant number	**Not yet assigned (Round 8)**
Name of current Principal Recipient	1. Yakubu Gown Centre for International Cooperation (YGC) 2. Society for Family Health (SFH)

(2b) Principal Recipient(s) for AMFm Phase 1

Applicants may choose to nominate the **existing Principal Recipient** for the 'host' grant to receive and manage funds for AMFm Phase 1 supporting interventions. Alternatively, applicants may choose to nominate a **different Principal Recipient**.

Applicants must ensure that the nominated Principal Recipient(s) has the capacity for responsible management of Global Fund for finances and grant management ***and*** is capable of leading rapid implementation of supporting interventions.

i. Is the Principal Recipient nominated for AMFm Phase 1 the same as the existing Principal Recipient for the AMFm 'host' grant?	☐ **Yes** Proceed to Section 2c ☐ No Complete Sections 2bii and 2biii
ii. Describe the process used to make a transparent selection of the Principal Recipient(s) for AMFm Phase 1 [1/2 page maximum]. Attach the signed and dated minutes of the meeting(s) at which this Principal Recipient(s) was selected.	***Annex 1, Annex 2, Annex 3***

In order to ensure a transparent and inclusive Principal Recipient (PR) selection process by the Country Coordinating Mechanism (CCM), key briefings and interactions took place prior to the CCM meeting where the PR decision was made:

- Briefing of the Honorable Minister of Health Professor Babatunde Osotimehin and CCM Chairperson Dr. Jerome Mafeni on 13.03.09 at the Federal Ministry of Health (FMoH) in

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Abuja.

- Briefing of the CCM Executive Committee on AMFm progress on 04.03.09 in Abuja.
- CCM Communications Officer Emma Cousin has actively participated in the core application writing team. Also, the CCM chair, secretary and some executive committee members have contributed as members of the advisory group to the core team.
- CCM vote on the AMFm took place on 18.05.09 in Abuja where it was decided that YGC would remain PR, and that SFH would become the second PR. It was agreed that the PRs, supported by the SRs already selected under the Global Fund Round 8 (GFR8) grant, would work with the CCM under a transparent and inclusive process to select additional SRs required who are capable of rapidly and effectively implementing supporting interventions (Annex 2).

The assessment of existing and any additional SRs will follow approximately the process outlined below and is subject to finalization by the CCM:

- Establish Terms of Reference (ToR) with clear deliverables and mechanisms for Monitoring & Evaluation (M&E) for each of the activities that will require an SR for its implementation.
- Launch an Expression Of Interest (EoI).
- Ask organizations that responded to fill in a standard proposal form including:
  - Background on the organization.
  - Explain capacity to implement and report; important for Local Funding Agent (LFA) assessment.
  - Description of how the activity will be implemented including a detailed budget.
- Set-up of an independent committee to evaluate the proposal and make recommendations to the CCM.
- Follow CCM procedures to select based on the recommendations made, ensuring that no conflicts of interest exist (Annex 3).

In addition there will be need to engage specialized centers and institutions for specific services as sub-recipients or contractors e.g. National Pharmacovigilance Centre.

iii. Provide the name and contact details of the **Principal Recipient(s) nominated for AMFm Phase 1**, if different from the existing Principal Recipient for the nominated 'host' grant.

	Principal Recipient nominated for AMFm Phase 1	**Principal Recipient nominated for AMFm Phase 1**
Name	Yakubu Gowon Center for International Cooperation (Ambassador Maurice Ekpang)	Society For Family Health (Mr. Bright Ekweremadu) (Dr. OlaronkeLadipo)
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Other E-mail		oladipo@sfhnigeria.org

2. Applicant summary

[Add columns as necessary if nominating more than one Principal Recipient]

(2c) CCM endorsement of AMFm Phase 1 application

1. Have all CCM members completed and signed Attachment C to indicate their endorsement of this AMFm Phase 1 application?	☒	**Yes**
	☐	No

Executive Summary

Provide a summary of the AMFm application. This summary should address - why is the country applying for the AMFm and how does it complement other efforts (with an emphasis on Global Fund-supported efforts) to increase access to ACTs? What will be achieved with the AMFm? How will the objectives and goals be achieved? What are the risks? How will the AMFm be monitored? What is the total funding request?[1 page maximum].

Background

With an estimated 120 million cases per year, Nigeria contributes about a quarter to the total African malaria morbidity and mortality burden. One of the key components of the Nigerian National Malaria Control Strategic Plan for 2009-2013 is Scaling Up For Impact (SUFI) malaria case management with ACTs (Annex 4). Although significant resources are being mobilized from partners including Global Fund, World Bank, USAID and DFID to achieve the country targets, the overall national access to ACTs remains low, with only 2.4% of children under 5 years receiving ACTs within 24 hours of the onset of symptoms. There is clear evidence, however, that concerted interventions can overcome this challenge: an increase to 43.3% use of ACTs among children under five was observed in 18 Global Fund assisted states in 2008 (Annex 5). Key issues that prevent replication and expansion of this success across other areas and drives continued widespread use of inappropriate monotherapies include:

- High cost of ACTs, which prohibits increased use in the private sector where 60% of the suspected malaria cases are treated.
- Insufficient quantities of ACTs in the public sector where ACTs are to be provided free of charge to patients.

Current resources from the Nigerian Government, Global Fund, World Bank, and UK Department For International Development (DFID) will provide a total of 124,708,417 million of the 181,000,272 million doses of ACTs needed by 2011 to achieve Nigeria's goal of universal coverage (>80% of patients using ACTs within 24 hours of the onset of symptoms). The AMFm provides a timely opportunity to make significant progress towards filling this gap by dramatically reducing the price for the three tiers of government that are authorized to purchase essential medicines and by rapidly increasing use of ACTs in the private sector. As a result, Nigeria expects to make significant gains towards achieving the SUFI targets for malaria treatment in the public sector.

Strategies and Interventions

The AMFm in Nigeria would facilitate more rapid achievement of universal access to high quality, affordable ACTs in all sectors. As described in the GFR8 proposal, Nigeria is committed to expanding access to treatment through the many private outlets in the country, including pharmacies and patent medicine vendors, which serve as an important source of treatment for many patients. This approach has been included in the national malaria strategic plan and is facilitated by the fact that ACTs have been reclassified as over-the-counter drugs (OTCs).

2. Applicant summary

To achieve the objectives of broad access to and responsible use of highly subsidized ACTs, a range of key supporting interventions will be implemented throughout the country:

- Strengthen the national distribution of ACTs through private, public, and not-for-profit supply chains;
- Increase the range and intensity of activities to promote ACT use and other key treatment-related behaviors, including mass media and community outreach
- Expand training, supervision, and ongoing support of health providers in the public and private sectors to ensure responsible stocking and dispensing of ACTs;
- Expand national drug monitoring, including pharmacovigilance and resistance monitoring
- Improve the regulatory environment for ACTs
- Scale up home based management through Role Model Mothers distributing ACTs in remote, underserved areas;

Risks and Mitigation Strategies
Capacity to implement the targeted interventions has been identified as a potential risk that may result in slower than anticipated achievement of targets. This includes the capacity of the two PRs that will also be managing significant funds under the GFR8 grant. Steps have been taken to address this challenge, including:

- Rapidly increasing the capacity of the existing PRs through the addition of staff;
- Appointment of a third PR with strong capacity through a transparent process;
- Increase in partner capacity to provide greater support to the program, notably the appointment of six additional WHO-National Program Officers in the six geo-political zones;
- Subcontracting of key supporting interventions to additional SRs with expertise and capacity through a transparent process;
- Retaining KPMG to provide detailed analysis and guidance to improve the management capacity of the National Malaria Control Program (NMCP);

A second key risk that Nigeria faces is inappropriate and or inadequate private sector engagement leading to the continued sale of high priced ACTs and inappropriate alternatives. To mitigate this risk, cooperation among public and private sector organizations will be intensified through engagement of relevant associations, national stakeholder meetings to inform the private sector about the benefits of the subsidy, and the convening of a national AMFm Task Force that will ensure regular information flow between the public and private sectors. It is also expected that the comprehensive public awareness and behavior change campaigns will generate strong demand for ACTs and thereby incentivize wholesalers to distribute the products.

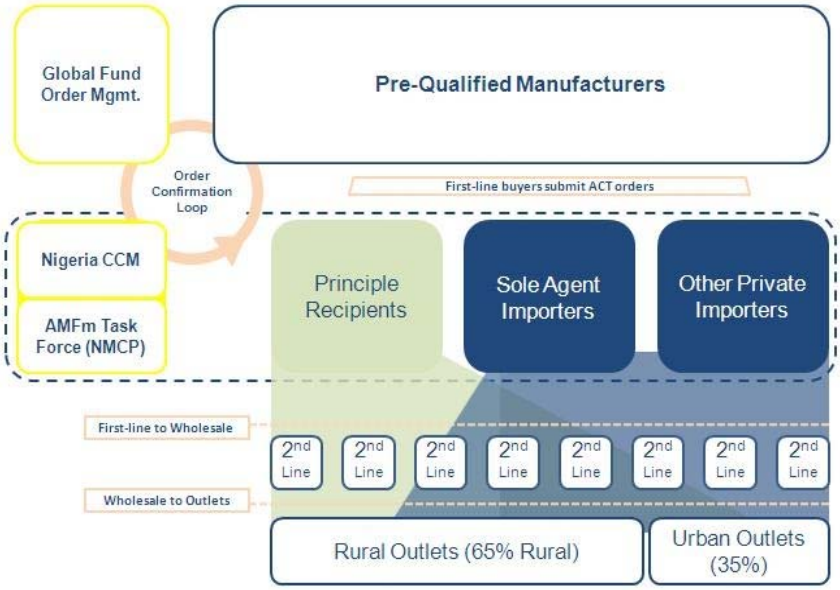
A final risk is that subsidized ACTs will not reach the most remote and poor areas of the country. This will be overcome by expanding the RMM program, which enables ACTs to be distributed at the community level and by having the PRs complement the normal private supply chain through distribution of low priced ACTs to areas typically underserved (see Figure 1).

Monitoring and Evaluation
Nigeria's approach to monitoring Phase I of the AMFm involves three key activities: the creation of the AMFm Task Force for the overall coordination of AMFm initiative, expanded M&E activities to correspond with the scaling up of interventions, and operational research projects to explore improved malaria diagnosis in public and private sectors and to measure the impact of packaging designs on consumer comprehension and adherence. Figure 1 shows a schematic summary of the AMFm coordination model as it relates specifically to private sector distribution and oversight. In addition to the complementary distribution of ACTs in the private sector by the PRs, a critical

2. Applicant summary

component of this model will be the regular tracking of subsidized ACT orders ("order confirmation loop") by the AMFm Task Force to identify and address bottlenecks and appropriately target supporting interventions.

Figure 1: AMFm Private Sector Coordination in Nigeria



Total Funding Request

The total savings under the AMFm are projected at **$50,885,584 USD**. The total funding requested for expanded and new AMFm supporting interventions is **$ $46,450,469 USD**. No net additional funding is being requested for this application.

3. AMFm in the national malaria context

Malaria Disease Profile

(3a) Provide a *brief* overview any characteristics of the malaria profile in your country (including patterns of incidence or mortality) that have changed significantly since your last application to the Global Fund [1/2 page maximum].

The malaria profile regarding patterns of incidence and mortality in the country, as described in the GFR8 grant, is still essentially the same.

Malaria is endemic in Nigeria with 97% of the population at risk of infection, excluding the high mountainous area of the plateau. Transmission of malaria is stable and perennial in all parts of the country. The Health Management Information System (HMIS) reports a total of approximately 300,000 malaria deaths annually. Malaria in pregnancy accounts for 11% of maternal mortality in Nigeria. Malaria is responsible for 25% of all infant-related mortality and 30% of mortality in children under five years of age. A decrease in early childhood mortality has been seen in under-five mortality, which has reduced from 201 in the 2003 National Demographic Health Survey (NDHS) to 157 deaths per 1000 live births in 2008 (NDHS Annex 6). Given the massive impact that malaria has on early childhood death, the progress demonstrated since 2003 can be expedited by increasing appropriate malaria treatment for this target group by implementing the AMFm in Nigeria.

National Supply and Distribution of ACTs

(3b) What is the current estimated population coverage of ACTs, with a breakdown by sector (public, private and the not-for-profit, if known)?

Population coverage of ACTs: The revised National Malaria Strategic Plan for 2009-2013 amended the focus of malaria control activities from the targeting of vulnerable groups such as children under five years of age and pregnant women to universal coverage of the whole population with preventative and curative interventions. As such, existing data on population utilization of anti-malarial drugs and of ACTs in particular is mostly confined to the vulnerable groups of children under five years of age. In 2008, 33.3% of children under five years with fever within the last 2 weeks took an anti-malarial drug (NDHS 2008), of which 15.5% received anti-malarials within 24 hours of fever onset. In a 2007 MICS survey, ACT use in children under 5 years of age was 2.4%. However, in 18 states with focused support from the GFR4 grant, the use of ACTs in children under five years of age within 24 hours of the onset of fever was 43.3%.

Although over 6 million doses of ACTs were distributed in the public sector in 2008, this – in combination with private sector distribution – still only covers 19.6% of estimated national need (Table 1).

Table 1: Summary of ACT Sector Distribution in Nigeria

Period	ACT need for total population coverage	ACTs distributed in public sector	ACTs distributed in private sector	Proportion of 2008 ACT need covered by all sectors
2008	89,464,024[1]	6,021,834[2]	11,500,000[3]	19.6%

[1]Base on updated GFR8 Gap Analysis
[2]Based on government and partner reports
[3]Based on reports from PMGMAN

Although specific data on ACT coverage among populations is currently unavailable, the recent ACTwatch Outlet Survey provides insight into the availability of ACTs at key outlets throughout the country. The 2008 ACTwatch survey monitored the availability, price and volumes of anti-malarials at

3. AMFm in the national malaria context

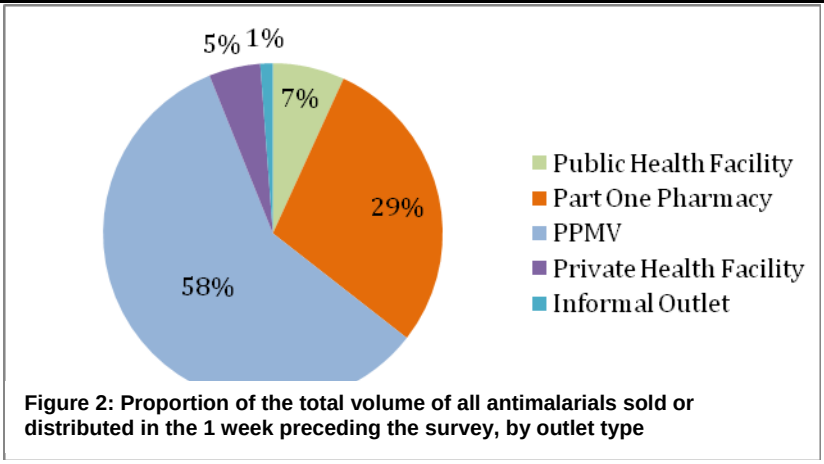


Figure 2: Proportion of the total volume of all antimalarials sold or distributed in the 1 week preceding the survey, by outlet type

607 different outlets (public, private and not-for-profit) across the various geographical zones of the country (Annex 7). Critically, it was observed that in Nigeria, PPMVs are the largest and most frequently accessed channel for anti-malarials

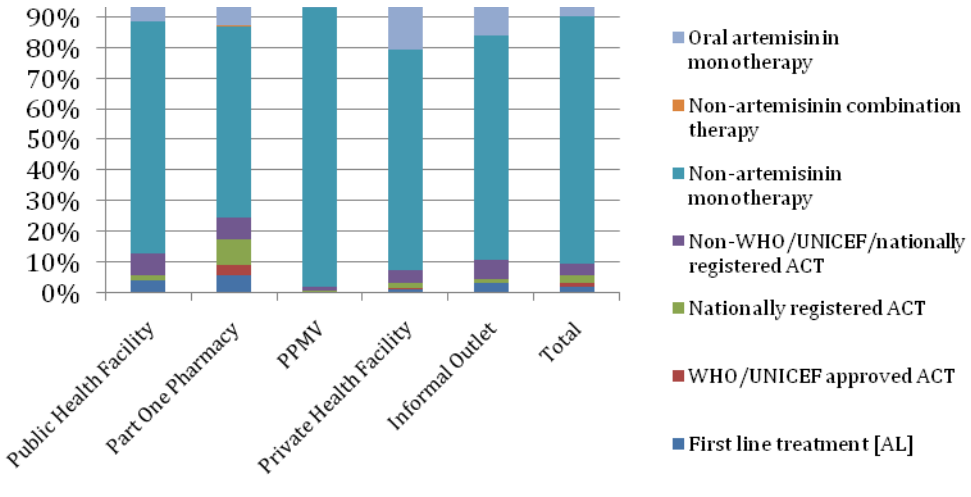
Sources of anti-malarials: Overall,the survey found that 58% of all adult full anti-malarial treatment courses were provided through PPMVs, while Part One Pharmacies were the second largest source of anti-malarials (29% of adult treatment courses). Only 7% of all full adult treatment courses distributed or sold were provided through public health facilities (Figure 2; Annex 8). Although the public sector has invested significantly in ACT distribution since the change in national treatment policy, population-wide ACT access remains limited because PPMVs, the primary source of anti-malarial treatment for Nigerians, vend predominantly non-artemisinin monotherapies.

Stocking of anti-malarials: According to the nationwide survey, 94.9% of all outlets had anti-malarials in stock. Of these, 16.7% stocked Artemether-Lumefantrine (AL), the recommended first line treatment for uncomplicated malaria in Nigeria (Annex 8i). It was found that 73.3% of public health facilities and 97.4% of registered pharmacies had the recommended first line treatment (AL) in stock while only 15.6% of private health facilities and 7.5% of PPMVs stocked the drug. In comparison, 92.5% of outlets stocked non-artemisinin monotherapies and 47.4% stocked oral artemisinin monotherapies, with private pharmacies stocking oral artemisinin monotherapies most frequently (92.3%).

The not-for-profit sector has become increasingly relevant in terms of health care service delivery in Nigeria. However, limited data on availability of ACTs through this sector is currently available (ACTwatch does not disaggregate data by this sector), which will be addressed through later surveys.

Volume of anti-malarials dispensed: The survey revealed that non-artemisinin monotherapies continue to dominate the volumes dispensed (83.6% of all anti-malarials dispensed were non-artemisinin monotherapies). This pattern was consistently observed across all outlet types, even among public health facilities where one would expect recommended treatment guidelines to be more strictly observed. In line with the low availability

Figure 3: Volume of anti-malarial type dispensed by outlet type



observed, ACTs constituted less than 2% of the volume sold through PPMVs (Figure 3).

(3c) Describe the **current supply chain for anti-malarials** (including ACTs) within the **public, private and not-for-profit sectors** in your country [2 pages maximum]. This description should address:

i. First-line buyer purchase from manufacturers

ii. Supply to outlets

iii. Sale or provision to patients

Applicants should also identify any points in the supply chain that may inhibit widespread availability of ACTs under AMFm. Refer to the Guidelines on AMFm Phase 1 Applications for detailed guidance.

1. **Public Sector**

i. First-line buyer purchase from manufacturers

Procurement*:* The Procurement and Supply Management (PSM) department of the FMoH and procurement agencies acting on behalf of partners such as the U.S. Agency for International Development (USAID) and the Department for International Development (DFID) are the primary first line buyers for the public sector.

The process of procurement of anti-malarial medicines, like any other health sector commodities, starts with product selection and quantification by the health program or division. The Tenders Unit of the Procurement and Supply department of the FMoH advertises for bids through Local Competitive Bidding (LCB) or International Competitive Bidding (ICB). Bids are then reviewed and contracts awarded by the Tenders Board. Depending on the funding source, the commodities are delivered to the Central Medical Store (CMS), State and Local Government Area (LGA) warehouses, or third party agents as appropriate.

For ACTs that are procured with GF resources for the public sector, the PR selects a procurement agent through competitive bidding. The procurement agent then procures ACTs through competitive bidding in line with the GF Procurement and Supply Management (PSM) guidelines. Storage at the port, port clearing, and distribution to the national central warehouse are the responsibility of the procurement agent. All imported commodities are batch tested by the National Agency for Food & Drug Administration & Control (NAFDAC) to ensure compliance with quality standards and suitability for distribution. The commodities are then transferred to PR storage facilities, from which point commodities are then delivered to the State Medical Stores (SMS).

ii. **Supply To Outlets**

Medicines are delivered to tertiary, secondary and primary health facilities either from the Federal CMS or SMSs via the LGAs. In theory, pharmaceutical commodity distribution in Nigeria is based on a push system from CMS down through health facilities, with LGA facilities resupplied through a consumption-based pull system. However, unpredictable resource availability restricts the effectiveness of this model, and often available drugs are distributed to all levels according to prioritized need. As a result, deliveries often do not follow a coordinated schedule or accurately match the needs of facilities. For GF-assisted states, commodities are delivered straight to selected tertiary, secondary, and primary health facilities from SMSs by third party logistic agents on a quarterly basis.

iii. **Sale Or Provision To Patients**

In public health facilities, ACTs that are supplied by the Federal Government are made

available for all age groups free of charge. However, this Federal supply does not cover national need. Therefore, where state resources are available, state governments augment this supply by purchasing and providing ACTs for patients. These ACTs may be provided to patients under and over five years at a highly subsidized cost (roughly 200-300 Naira; USD 1.43-2.14). Furthermore, in a few states, the Drug Revolving Fund makes ACTs available at a reduced cost to patients in vulnerable groups.

In addition to the cost of ACTs, patients may face consultation or other miscellaneous fees depending on the level of facility that they are accessing. Public facilities that distribute ACTs and other essential medicines to patients in Nigeria include:

- *Tertiary* (53) – Teaching hospitals and federal medical centers that are capable of providing complex care and that are staffed with specialists who provide specialized care.
- *Secondary* (855) – General hospitals that are staffed with medical doctors and outfitted with laboratory services.
- *Primary* (13,000) – Primary health centers that have limited facilities and staff who provide basic care.

Through the Home Management of Malaria (HMM) strategy, community based care providers also provide anti-malarial medicines to children under 5 at no cost in two of the thirty seven states. These care providers receive their stock from the closest public health facilities and replenish their supply upon submission of their stock management data.

2. **Private Sector**

i. First-line buyer purchase from manufacturers

Procurement: Anti-malarial procurement by the private sector is informed by government treatment guidelines, but is predominantly driven by consumer demand. It is common practice for international manufacturers to use a sole agent to import all of their products into the country. In total, there are 286 importers registered to bring in pharmaceutical products. There are 12 in-country manufacturers of anti-malarials, which are a key source of anti-malarials for wholesalers and distributors.

The first line buyer is responsible for the importation, shipping and marketing of the product. Importers determine their volumes based on the season and forecasted monthly sales. Imported commodities undergo quality assurance testing at the port of entry as already described above and in Section 4f. Given the existence of exclusivity agreements, and in order to access the benefits of these distributorship agreements, some smaller local importers and distributors have in the past pooled their purchases to ensure that one of them might qualify to procure directly from a preferred manufacturer. In addition, there are cases of sales between importers (“horizontal distribution”) in order to prepare the optimal package of products for distribution.

Supply To Outlets

The private sector is very heterogeneous in Nigeria. The importers deliver the commodities to their warehouses and depots, which are located primarily in key distribution hubs across the country. These commodities are then sold through a network of approximately 616 distributors and wholesalers, from where they are further distributed to private sector outlets. Without stringent price regulation for pharmaceutical products in Nigeria, price mark-ups vary

throughout the country from the distributor to wholesalers to retail outlets, from 1-3% on average to 5-10% for those wholesalers that deliver drugs over a wider area, and up to 15% if the product is scarce (Annex 8).

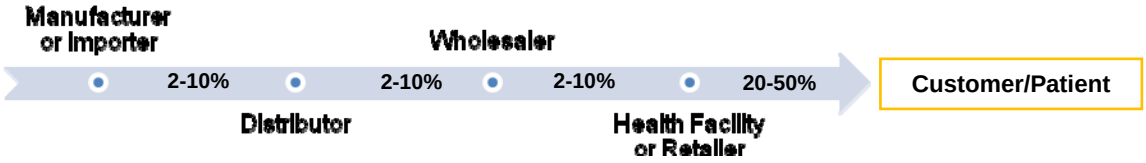
iii. Sale or Provision to Patients

There are a range of private outlets that provide anti-malarial treatment in Nigeria, including:

- Private Hospitals and Clinics (6,378) – Facilities that are staffed with medical doctors who offer both basic and specialized health services
- Registered Retail Pharmacies (2,751) – A basic outlet that must have a licensed pharmacist attached, and is authorized to sell both prescription-only and OTC medicines;
- Registered Proprietary Patent Medicine Vendors (8,824) – A PPMV is an individual who operates a basic drug store and is licensed to sell OTC status products only.
- Informal Drug Sellers (Approximately 200,000) – Informal drug sellers consist of unregistered PPMVs and others such as mobile medicine vendors and general shops

ACTs are accessed at a price that is determined by the provider based on a range of factors including the price at which they purchased the drug, the level of demand, and the amount of competition, among others. Mark-ups can vary significantly by region and population demographics, and range from 20-50% of cost (Annex 8).

Total Markup of Anti-Malarials From Manufacturer to Patient



3. **Not-For-Profit Sector**

As noted in Section 3b, faith-based and nongovernmental organizations play an important role in delivering treatment and care, including for malaria. These organizations typically operate their systems to ensure regular supply of ACTs and services to populations in lower socio-economic segments.

i. **Procurement and distribution:**The not-for-profit sector leverages both public and private sector distribution mechanisms to source its ACTs. Most of the not-for-profit and faith-based organizations distribute medicines to their own health facilities or those of their partners, while others also target pharmacies, clinics, PPMVs and community based healthcare workers. For example, one of the larger FBOs in Nigeria, CHAN, operates 7 warehouses and uses a logistics partner, CHAN Medipharm, to supply its mission clinics.

iii. **Sale or provision to patients:** These organizations distribute directly to patients through the mission hospitals or other clinics usually at a subsidized price. Both FBOs and NGOs conduct outreach program for reaching the poor and hard to reach people also at highly subsidized prices or at no cost.

Challenges

3. AMFm in the national malaria context

Despite recent progress in increasing ACT access through the public sector, several key challenges in the public and private supply chains remain and will impede broad access to ACTs under the AMFM unless resolved. These challenges, as well as the planned interventions to address them, are summarized in Table 2.

Table 2: ACT Supply Chain Challenges and Targeted Solutions

Distribution Sectors	Inhibiting Issues	Resolution Approaches
Public	Storage facilities require refurbishing to maintain quality of ACTs during distribution	Resources to refurbish the relevant facilities are included in GFR8 malaria and HSS grant
	PSM capacity (e.g. forecasting and stock management) is weak in public facilities	Working with a third party logistics contractor is included in GFR8 malaria and HSS grant
	Staff attrition in public sector facilities impedes efficient ordering and storage	Expansion of health care provider supportive supervision under GFR8 and AMFm
Private	Resistance from in-country manufacturers due to concerns on loss of business	AMFm Taskforce stakeholder meetings aim to continue to facilitate dialogue to find productive solutions to in-country manufacturer concerns. The FMoH has taken the lead on exploring capacity building measures for improving the quality of locally produced ACTs.
	Improper storage of medicines at shops and dispensing of non-recommended drugs	Initial training on good practices and importance of ACTs followed by regular supervision for private outlets throughout the country under AMFm (see Section 4d)
	A majority of PPMVs are not registered and could be closed down	PCN will be supported to increase registration of PPMVs
	Limited private sector reach in remote areas due to high cost of transport and small market size	PRs and SRs will carry out AMFm supporting intervention to subsidize transportation of ACTs down the supply chain and to hard-to-reach places

ACTs to be co-paid under AMFm Phase 1

(3d) Complete the table below to nominate which ACT combinations and regimens you are requesting to be co-paid under the AMFm, in accordance with the criteria provided in the Guidelines for AMFm Phase 1 Applications.

List the requested ACTs by international non-proprietary name (INN). Do not list by manufacturer or brand name.

ACT INN	Strength	Presentation	Listed in WHO STG *[yes or no]*	Listed in national STG *[yes or no]*
Artemether-	20/120mg	Tablets	Yes	Yes

3. AMFm in the national malaria context

Lumefantrine				
Artesunate-Amodiaquine	50/153.1mg (co-blistered)	Tablets	Yes	Yes
Artesunate-Amodiaquine	50/135mg (co-formulated)	Tablets	Yes	No (Treatment guidelines will be reviewed and updated in 2009)

Please note: if you request an ACT combination that is listed in the national standard treatment guidelines but **not** in the WHO standard treatment guidelines, or vice versa, you must **attach a technical rationale** to justify its inclusion under AMFm. See the Guidelines for AMFm Phase 1 Applications	***[Insert Annex name and number if providing a technical rationale for inclusion of certain ACTs]***

4. Supporting interventions

Supporting interventions for AMFm

In order to support the implementation of the co-payment on ACTs, **the AMFm requires countries to implement supporting interventions to improve malaria case management and ensure safe and effective scale-up of ACT use**.

Required supporting interventions include:
- Public awareness raising and education regarding ACTs
- Training, supervision and ongoing support for ACT providers
- National drug monitoring, including pharmacovigilance, resistance monitoring and quality surveillance
- Improving the regulatory environment for ACT distribution; *and*
- Interventions to reach poor people, children and other vulnerable groups

Applicants must demonstrate that all required supporting interventions either are already implemented, or will be implemented, in order to purchase co-paid ACTs through AMFm Phase 1.

Applicants are also encouraged to include **additional** supporting interventions to improve malaria case management, such as introducing/expanding the use of diagnostics and introducing patient-friendly packaging on co-paid ACTs.

Applicants are strongly advised to refer to the Guidelines for AMFm Phase 1 Applications for specific guidance on each supporting intervention.

Public awareness and education campaigns for ACT treatment

(4a) Existing public awareness and education campaigns for ACT treatment

Describe any existing efforts to promote the effectiveness, availability and/or affordability of ACTs in your country [1 page maximum].

Existing activities

Malaria treatment public awareness and education campaigns are currently managed and implemented by the NMCP, State governments, YGC and SFH. Key funding bodies are the Nigerian FMoH, World Bank and Global Fund. The existing campaigns are outlined in the National Malaria Control Behavior Change Communication Strategy document (Annex 9). Key messages that are promoted across all activities currently conducted include the importance of prompt treatment seeking for malaria, using ACTs as the first treatment for malaria, and completing the recommended dose of ACTs.

The objective of these campaigns is to increase informed demand for ACTs. The activities that are being pursued to achieve this objective fall into three categories: Advocacy, Social Mobilization and Mass Media.

*Advocacy***:** Advocacy visits, sensitization meetings and support to key events such as World Malaria Day provide a platform to continually engage opinion leaders at all levels to increase their knowledge and commitment to communicate key messages to their constituencies. Target groups for this form of advocacy include political, religious and traditional leaders. A separate advocacy intervention is directed to policy makers and professional associations such as Food & Drug Services (FDS),

Nigerian Medical Association (NMA), Pharmaceutical Society of Nigeria (PSN), and National Association of Patent and Proprietary Medicine Dealers (NAPPMED) to strengthen regulatory policies and improve prescription practices. Approximately 407 advocacy visits were carried out in 25 states in 2008 and early 2009.

*Social Mobilization***:** These activities are used to specifically target the poor who are not adequately exposed to mass media as well as the general public. They typically include interventions that can be mobile and incorporate targeted messages into other forms of entertainments, such as community dramas, theatre events, and presentations to community groups. A total of 1,921 such live activities have been completed in 18 states over a period of 12 months.

*Mass Media***:** Campaigns are conducted to deliver key messages to the general public through radio and television channels, billboards, and newspaper adverts. These campaigns are being rolled out under the Mothers Against Malaria Attack (MAMA) concept, which is the umbrella campaign for all malaria control messages, and which leverages the concept of mothers as custodians of care-giving at home. The 'Thief in the Night' radio and television campaign, which is managed under the MAMA initiative, was launched in November 2008. The campaign focuses on the importance of swift treatment with appropriate ACTs to prevent severe malaria and death in children under five years, and will be aired in three waves per year.

Currently these campaigns are occurring in 25 states with funding from GFR4 and the World Bank The GFR8 malaria grant plans to expand these core advocacy, mass media, social mobilization activities to all 37 states of Nigeria.

Weaknesses

Messages on radio and television are only broadcast in two of the four major languages: Pidgin English and Hausa. In order to reach a broader audience it will be necessary to also conduct campaigns in the other two major languages Ibo and Yoruba. Although under GFR8 these activities are being significantly expanded, the penetration, mediums, and frequency of messaging are not adequate to achieve the desired change in terms of malaria treatment behavior. For example, the activities planned in the original Round 8 proposal were intended to support ACT distribution through the public sector and targeted social marketing in the private sector. However, with the broader distribution of ACTs under the AMFm, including through the informal sector, it will be critical to expand IEC/BCC activities to reach a much larger population.

(4b) New or expanded public awareness and education campaigns for ACT treatment

Summarize your proposal for **new or expanded public awareness and education campaigns** to promote the effectiveness, availability and/or affordability of ACTs. [1½ pages maximum].

Rationale

As stated, the private sector plays a critical role in providing malaria treatment to Nigeria's population. For the successful implementation of the AMFm model, there must be sufficient demand from consumers who use the private sector to shift their purchasing to ACTs over alternative therapies. To generate and sustain this demand, Nigeria will carry out activities to target the determining factors of malaria treatment seeking behavior: provider recommendation (through advocacy and sensitization events) and patient demand (through social mobilization and mass media).

Nigeria's GFR8 application includes an IEC/ BCC component to support expanded treatment and other key interventions, but there are significant gaps, particularly following recent cuts due to insufficient GFR8 funding. The AMFm proposes to build on these activities and increase their intensity and scope to generate and sustain strong demand for ACTs and other key treatment-related behaviors. This plan

to scale up GFR8 activities also considers the contributions of other key partners, notably the World Bank. As the World Bank will support intensified IEC/ BCC in its 7 focus states, across the majority of proposed IEC/ BCC activities, this application budgets for the remaining 30 states. Another important addition of this proposal is the implementation of public awareness and education campaigns in two major languages, Ibo and Yoruba, that were not covered by the original proposal. In addition, new effective communications methods not included in the original proposal (e.g. Mobile Video Units for disseminating messages) have been added to the IEC/BCC campaigns in order to support the rapid and responsible uptake of ACTs.

Key messages

Key messages to be conveyed correspond with those promoted by Nigeria's existing IEC/ BCC efforts, including: prompt recognition of malaria, recognition of ACTs as appropriate treatment for malaria, the importance of adherence to dosing regimens, affordability of ACTs and reporting of Adverse Drug Reactions (ADR). Messaging on ADR reporting is a new addition under the AMFm. In addition, a logo will be applied to all quality assured ACTs and appropriate messages developed to inform consumers that those products are both high quality and low priced and should be the first choice for malaria treatment.

Implementation Approach

Effective IEC/BCC is critical to the achievement of Nigeria's malaria treatment goals and as such will be a central focus of implementers involved in the GFR8 and AMFm. While the addition of further IEC/BCC activities under this proposal will increase the workload of the PRs and implementing partners, capacity will be appropriately expanded to meet the need, including through the appointment of a third PR and selection of additional SRs. The existing PRs will also increase their capacity by training and equipping existing staff, hiring additional staff and leveraging external technical assistance as needed. Moreover, while the framework for IEC/ BCC in the AMFm relies on national level partners for management and planning, the ongoing implementation will be conducted by a range of state and LGA level actors. Some SRs are also appropriately increasing capacity. For example, the Association of Civil Society Organizations in Malaria, Immunization and Nutrition (ACOMIN), which is a coalition of NGOs throughout Nigeria, has received resources for Community Health Systems Strengthening from the GFR8 HSS grant, which is enabling them to expanding staffing and systems and will place them in a strong position to execute some of the expanded activities under the AMFm.

SDA 4.1: BCC Community Outreach - Advocacy

As described in section 4a, advocacy activities target policy makers at federal, state and LGA levels to engage leaders, increase their knowledge and receive their commitment to communicate key messages to their constituencies. In GFR8, it was proposed to conduct a variety of advocacy activities for 18 states; under the AMFm these activities will be scaled up to cover a total of 30 states (Table 3). This increased number of advocacy visits is necessary because with the AMFm, affordable ACTs will be available at a national scale and will require close collaboration with a broader range of stakeholders, notably in the private sector.

4. Supporting interventions

Table 3: Advocacy Activities Planned and the AMFm

Advocacy Activities	GFR8 (Phase 1)	AMFm Addition		Total
		Assumptions	2 year total	
Advocacy to opinion leaders and gatekeepers	18	2 meetings per state, 30 states	60	78
Advocacy to policy makers at the national levels	54	2 meetings per state in 30 states	60	114
Advocacy to policy makers at state level	36	2 meetings per state in 30 states	60	96
Advocacy to policy makers at LGA level	462	2 activities per LGA in 598 LGAs	1196	1658
Advocacy visits to community, traditional and religious leaders	140	2 activities per LGA in 598 LGAs	1196	1,336
Advocacy to media executives and entertainment industry (Nollywood)	6	1 media executive and 1 entertainment meeting per state in 37 states *less 6 GFR8 funded*	68	74

SDA 4.1 Community Outreach - Social mobilization

Social mobilization activities are a demonstrated method of effecting behavior change as they enable interactive interpersonal communication with individuals at a community level. Furthermore, one of the core aims of the AMFm is to ensure that affordable ACTs reach the poor, vulnerable, and people living in hard-to-reach areas. Social mobilization activities will be a primary tool for communicating key messages of the IEC/ BCC campaign to these target groups.

Nigeria comprises 774 LGAs, with an estimated 120 communities in each LGA. In GFR8, Nigeria has resources to carry out a range of social mobilization activities in 10 under-served communities per state across 37 states (371 communities in total). Under the original grant, Nigeria planned to carry out these activities in 20 communities per LGA (15,480 communities), but due to funding constraints, this number was cut to the currently planned 371 communities. Therefore under the AMFm, Nigeria will return to its plans to cover 20 communities per LGA in 30 states (11,960 communities). See Table 4 and the detailed budget assumptions in Attachment B for further analysis of this gap.

As with the GFR8 plans, implementation of IEC/ BCC activities will draw on the capacity of individuals and existing organizations at the community level, among these (but not limited to):

- Trained Role Model Mothers (RMM) and community development committees for sensitization meetings, workshops, and large events,
- The Nigeria Inter Faith Agency Action (NIFAA) and ACOMIN, and occupational groups for sensitization meetings, workshops, large events and deploying mobile video unit shows.
- Local drama troupes for community drama shows

4. Supporting interventions

Table 4: Social Mobilization Planned and in AMFm

Social Mobilization Activities	Overall target	GFR8	AMFm Additions		Total
			2 year total	Assumptions	
Sensitization meetings with community based opinion leaders *Target: 2 meetings per LGA per 37 states*	1,548	388	808	2 per LGAs in 404 LGAs	1196
Sensitization meetings with special groups (media, Nigerian film/video industry -Nollywood, youth groups) *Target: 7 meetings per state per 37 states*	259	75	150	5 per state in 30 states	225
Community drama road shows in communities *Target: 15 shows per LGA per 37 states*	11,610	743	8970	15 shows per LGA in 598 LGAs	9713
Mobile video unit shows in remote areas *Target: Quarterly runs in each zone*	48	0	48	Quarterly 20 day periods per 6 zones, annually	48
Support to states for special events *Target: 7 per state in 37 states*	259	111	120	4 events per state in 30 states	231
Workshop for community mobilizing Civil Society Organizers (CSO) and peer educators *Target: 30 participants for 1 workshop in each LGA in 37 states*	23,220	13,140	10,080	30 pple per 336 workshops	23,220

SDA 4.2: Mass Media

Mass media has proven to be a highly effective tool for communicating common messages to the extensive rural and urban populations in Nigeria. As explained in Section 4a, Nigeria has already initiated a limited mass media campaign through radio and television channels, billboards, and newspaper adverts. Because the AMFm aims to bring ACTs to an expanded population, reach additional areas of the country, and use additional private sector channels, campaigns will be accordingly expanded in frequency, diversity of content, and number of languages. Malaria treatment campaigns will fit under the unified MAMA umbrella, and will convey the same key messages as noted in 4b above.

Radio listenership is high in Nigeria at 42.4%, particularly in the northern part of the country where much of the nomadic population resides (Annex 10). Radio will therefore be a primary vehicle through which messaging on ACT availability and affordability can reach the entire population, and will complement the more targeted interventions of advocacy visits and social mobilization activities. The promotional messages and radio dramas will be aired in four languages (instead of the two under GFR8) and will leverage the British Broadcasting Corporation (BBC) Hausa service to reach usually hard-to-reach groups in the northern zones of the country.

In the GFR8, Nigeria proposed to carry out mass media activities for 37 states. However, the frequency or quantity of many activities was reduced due to the funding constraints. The AMFm proposal will fill this gap and ensure that consistent messages are broadcast to all areas of the country (Table 5).

4. Supporting interventions

Table 5: Mass Media Planned and in the AMFm

Mass Media Activities	Overall Target	GFR8	AMFm Additions		Total
			2 year total	Assumptions	
IEC Placement Printed Media *Target: 3 newspapers per quarter per state in 37 states*	888	518	370	3 newspapers per state in 37 states for 2 quarters; 1 newspaper per state in 37 states for 2 quarters	888
Placement Billboard *Target: 20 billboards per state*	740	259	481	8 boards per 74 LGAs, 5 boards per 185 LGAs, 10 boards per	740
Placement TV (local stations) Spots *Target: 4 spots per day in 37 states*	54,020	14,400	14,400	Four spots per day for 30 days in 30 TV stations, 2 30 day waves per year for 2 years	28,800
Placement TV (national) Spots *Target: 3 spots per day*	2,190	540	960	4 spots per day for 30 days, four 30 day waves per year for 2 years	1500
Placement Radio Media *Target: 4 spots per day in 37 states*	54,020	14280	28,800	4 spots per day for 60 days, two waves per year in 30 states and once nationally	47,760

Provider training, supervision and ongoing support (multi-sector)

(4c) Existing provider training, supervision and ongoing support to promote safe and effective use of ACTs

Describe any existing efforts to train providers in the safe and effective use of ACTs [1 page maximum].

Existing Activities

With resources from GFR4, the World Bank and others, the NMCP and its partners have carried out three core work streams related to health worker training over the last two years: 1) training public and private health facility-based workers, 2) training community based service providers, 3) and monitoring and evaluation of training. Training is a critical component of the country's efforts to promote proper case management through health care providers, and achieve national treatment targets. Broadly, training content covers case management for malaria (symptoms, diagnosis, treatment and referrals) and drug supply management (forecasting, ordering and stock monitoring). The specific content and approach to training varies based on the targeted cadre of health worker. The tools used for these trainings include cadre-specific manuals, job aids, bench aids, and IEC/BCC materials. These tools equip workers with Standard Operating Procedures and guidance on treatment algorithms.

Prompt and effective anti malarial treatment at health facilities (public/private)

Provider training has been conducted in both the public and private sector, and at all three levels of the formal health sector:

- 10,512 of approximately 289,891 health care providers from tertiary, secondary and primary health facilities within the public and private sectors were trained between 2007 and 2009. These trainings involved health workers from all 37 states of the country
- 1626 of 5819 registered pharmacists and pharmacy technicians were trained on drug

forecasting, ordering and management.

HMM through community based service providers

Recognizing that a significant proportion of the population seeks treatment for malaria at the community level, the NMCP has introduced a Home Management of Malaria program to ensure effective treatment can be accessed through community-based service providers who have the skills and commodities to treat malaria. As Role Model Mothers, trained female leaders from communities, and Propriety Patent Medicine Vendors are the pillars of community level treatment in the public and private sectors, respectively, training has focused on these two groups:

- 5,314 of the targeted 30,000 RMMs planned were trained in the last two years
- 11,500 pharmacists and PPMVs, including both registered and unregistered vendors, were trained;
- 86 personnel of CSOs have been trained on HMM, enabling them to supervise malaria treatment through RMMs.

M&E and supportive supervision of training

Monitoring and evaluation of training and consistent supportive supervision is essential to ensure successful absorption of training and to help continued inappropriate practices. The key activities that have been conducted in this area to date, include:

- For the public sector, supportive supervision should occur at all three levels of the system. NMCP officers at the national level conduct quarterly supervisory visits to health facilities in the 37 states, while state malaria focal persons carry out monthly supervisory visits to LGA health facilities. At the LGA level, malaria focal persons conduct supervisory visits to primary health facilities and to community health extension workers.
- For the 18 GFR4 states, SFH, as the private sector PR, has enlisted private sector associations to provide supportive supervisory visits to their member health facilities.
- Professional associations of different cadres of private sector health providers (e.g. NMA, NAPPMED) hold regular meetings to update members with new information on practices and policies and to identify and address cross-cutting concerns;

Weaknesses

Despite efforts to train a broad set of health care providers, three critical challenges have hindered impact. First, the health work force in Nigeria includes nearly 290,000 individuals and therefore only a fraction of those practicing are trained. Second, high attrition rates result in untrained individuals continuously entering the system. As a result of these challenges, there is a need to increase training across all cadres and in both sectors. Under GFR8, Nigeria has resources to train 20 public/ private health care workers per LGA in 19 of the 37 states. For a country that aims to achieve 80% treatment coverage and to augment the formal facilities with community level distributors, this amount of training is insufficient.

The third training challenge stems from under-resourced supervision for trained health workers in the public sector. Despite the intention of carrying out supportive supervision at all levels of the system, the resources to conduct these often do not exist. With the frequent turnover and high workload of staff, the lack of strong supportive supervision limits the impact of training on treatment practices.

(4d)New or expanded provider training, supervision and ongoing support to promote safe and effective use of ACTs

Summarize your proposal for **new or expanded provider training, supervision and ongoing support to promote safe and effective use of ACTs** across the public, private and not-for-profit sectors[1½ pages maximum].

4. Supporting interventions

Rationale
To encourage safe and effective use of ACTs in all sectors and through all levels of care, the AMFm will scale up planned training efforts for public and private health facility staff, RMMs, pharmacies and PPMVs. With the roll out of an expanded training program, supportive supervision acquires even greater significance to ensure that resources invested in training have translated into proper quality of care at the provider level.

Key lessons
Training content will build on the materials that have been deployed for recent trainings and will be leveraged again for the GFR8-funded trainings. As stated in Section 4c, the lessons of this training focus on malaria case management and drug supply management.

Implementation approach
Currently, training occurs in cascades, with trainers transferring knowledge and skills from the national to state to LGA to community level. The AMFm training will maintain this cascade approach and importantly, will leverage NGO and private sector organizations to implement training as necessary. For GFR8, lead implementers have been selected: the NCMP for the public sector and JHPIEGO and the Gede Foundation for the private sector. For the AMFm, these SRs will maintain responsibility for additional trainings; however, the PRs will supplement the selected SR capacity with additional SRs through a transparent selection process.

SDA 2.1: Prompt and Effective Anti-Malarial Treatment
With resources from GFR8, Nigeria plans to conduct malaria management trainings for 20 senior health providers and 20 primary health care workers in 19 states; and quantification/ forecasting trainings for 11 pharmacists in 37 states and 10 PHC workers in 19 states. The AMFm and government/ partner resources will fill the gap in the remaining 18 states, by training similar levels (Table 6).

Table 6: Health Worker Training Planned and in the AMFm

Training Activities	Overall Target	GFR8 Total	Gov. & Partners	AMFm Additions		Total
				2 yr total	Assumptions	
Malaria management for senior health providers *Target: 20 trained per LGA*	15,480	8760	266	6452	19 per LGA in the remaining 18 states	15,480
Malaria management for primary health care workers *Target: 20 trained per LGA*	15,480	8760	1861	4859	14 per LGA in the remaining 18 states	15,480
Pharmacists and drug handlers on quantification and forecasting *Target: 80 trained per state*	2960	400	266	2294	62 per state in 37 states	2960
Training of PHC workers on forecasting and quantification *Target: 10 per LGA*	7740	4380	1861	1499	4 per LGA in 18 states	7740

SDA 2.2: Home based Management of Malaria (HMM)
Expanded distribution of ACTs at the community level will be critical to the achievement of Nigeria's malaria treatment targets, particularly among poor and rural populations that are less likely to access care at formal facilities. To be effective, this approach needs to encompass both the public and private sectors.

4. Supporting interventions

Nigeria has 8,824 registered PPMVs and community pharmacists and many more unofficial outlets of this class. Each of these private sector outlets employs several individuals to dispense medicine to customers; in Nigeria, it is assumed that for every private sector outlet, at least 2 individuals in addition to the owner will dispense drugs. Based on this assumption, a target of at least 34,725 individuals from official outlets should be trained to ensure strong provider knowledge and appropriate case management practice, ideally on a continuous basis to account for high turnover rates. Under GFR8, Nigeria expects to train 10 PPMVs or pharmacists per LGA for a total of 7,740 private sector providers. The government and partners will support training of a further 1,861 PPMVs and community pharmacists over the next two years. In the AMFm, Nigeria will expand training to 10 additional PPMVs/ community pharmacists per LGA for a combined total of 17,341 private sector dispensers trained (roughly 50% of the target).

To extend community-level treatment in the public sector, Nigeria plans to build an RMM network of 30,000 trained mothers – roughly 40 per LGA. With resources from GFR8, 10 RMMs per LGA will be trained and a further 531 will be trained with government and partner resources. Under the AMFm, RMM training will be expanded to an additional 10 RMMs per LGA for a combined total of 16,011 RMMs in the country (roughly 50% of targeted RMMs; Table 7). RMMs will be provided work kits and funds for transportation to their focal health facilities; this monthly trip will be an opportunity for drug collection and data submission. Training of CSOs will be expanded to ensure strong supervision of RMMs.

Table 7: Community-level Training Planned and in the AMFm

Training Activities	**Overall Target**	**GFR8 Total**	**Gov. & Partners**	**AMFm Additions**		**Total**
				2 yr total	**Assumptions**	
Training of community pharmacist on malaria and PPMVs *Target: 3 individuals per registered private outlet*	34,725	7740	1861	7740	10 PPMVs/ pharmacists per LGA	17,341
Training of Role Model Mothers *Target: 40 RMMs per LGA*	30,000	7740	531	7740	10 RMMs per LGA	16,011
Transport for RMMs *Target: 40 RMMs per LGA*	30,000	7740	-	7740	10 RMMs per LGA and for 2/3 of GFR8 RMMs	15,480
Orientation workshop for CSOs *Target: 2 per LGA in 37 states*	1548	876	0	672	2 per LGA in 18 states	1548

SDA 2.1: Prompt and Effective Anti-Malarial Treatment – Supportive Supervision

Scheduled and unscheduled supportive supervision visits will be conducted to health facilities using a pre-designed checklist to observe and provide hands-on feedback on case management and other relevant practices.Professional groups, including but not limited to NMA, PSN, National Association of Nigeria Nurses & Midwives (NANMN), Association of Medical Laboratory Scientists of Nigeria (AMLSN), and the Association of Health Educators (AHE), will be leveraged to implement supportive supervision of their members. As the focus of these visits is supporting improvements in practices, they will distinguish from regulatory oversight visits (private providers are often less cooperative if a regulator is present). At the community level, CSOs will supervise RMMs while private sector distributors will be targeted for sales detailing activities.

In GFR8, Nigeria plans to deploy two officers for quarterly supervisory visits to the 37 states, and two focal people to cover all health facilities per state, in 37 states. Given the number of facilities to visit

per state at the different levels of care, this supportive supervision remains severely limited. For AMFm, supervision will be scaled up to by increasing the number of individuals who are deployed to carry out supervisory visits per state. In addition, as the AMFm will expand the HMM program, supervision of RMMs and PHCs will be strengthened. The AMFm will supplement GFR8 resources to enable quarterly supervisory visits for 2000 RMMs and for PHCs in all 37 states (Table 8).

Table 8: Supportive Supervision Planned and the AMFm

Supportive Supervision Activities	**Overall Target**	**GFR8 Total**	**AMFm Additions**		**Total**
			2 yr total	**Assumptions**	
Support quarterly supervisory visits to states and LGAs and by national M&E officers (4 day visit) *Target: Quarterly visits by 3 officers in 37 states*	888	592	296	1 additional person visiting each state annually	1084
Support monthly supervision of LGAs and health facilities by State Malaria Program Managers *Target: Bimonthly visits for 37 states*	1924	1036	888	Monthly visits by 2 managers	1924
Support monthly supervision of health facilities by LGA malaria focal persons *Target: Quarterly visits by 3 focal persons per LGA in 774 LGAs*	9288	6192	6192	Quarterly visits by 1 person per LGA in 774 LGAs	9288
Detailing support to private sector health providers		0	25% of one per state		25% of 37 teams
Monitoring and supervision of Role Model Mothers by CSOs *Target: 2000 RMMs supervised quarterly*	16,000	6000	10,000	1000 RMMs per quarter in YR 1; 1000 for 2 quarters in YR 2	16,000
Supervision by NPHCDA to support HMM through PHCs *Target: Quarterly visits for 774 LGAs*	3096	876	2220	Quarterly visits for 336 and biannual visits for 438 LGAs	3096

National drug monitoring, including pharmacovigilance, resistance monitoring and quality surveillance

(4e) National focal point for pharmacovigilance

Complete the table below to nominate a **national focal point for pharmacovigilance**.

	National focal point for pharmacovigilance
Name	Pharm. (Mrs.) Adeline Osakwe
Position	Deputy Director / National Focal Point Person
Department	NationalPharmacovigilance Centre NAFDAC, Abuja
Telephone	+2348033154512
Fax	
E-mail address	Nafdac_npc@yahoo.com, addyosakwe@yahoo.com

4. Supporting interventions

(4f)Existing national drug monitoring efforts Describe the existing system for national drug monitoring, including the national systems for pharmacovigilance, quality surveillance and resistance monitoring. Identify any weaknesses in the system [1 page maximum].	***[Insert annex name and number if providing an extract from a national policy document]***

Pharmacovigilance

The purpose of the national pharmacovigilance program is to assess and communicate risks and benefits of drugs on the market, and to promote rational and safe use of medicines. Nigeria uses both passive (e.g. spontaneous reporting) and active (e.g. Cohort Event Monitoring; CEM) pharmacovigilance approaches to achieve these goals.

Nigeria's pharmacovigilance system, with specific reference to ACTs, aims:

- To regularly monitor the risk of ADRs associated with ACTs supplied through the public, private and NGO sectors.
- To develop and implement strategies for communication to the public and feedback to healthcare providers based on information generated through the pharmacovigilance system.
- To develop effective policy solutions to maximize patient health and safety based on the data generated by the pharmacovigilance system.

The National Pharmacovigilance Centre (NPC) consists of the Pharmacovigilance Unit of NAFDAC (6 technical staff) and the National Drug Safety Advisory Committee. The committee comprises eight members representing the six geopolitical zones of the country, the Food and Drug Department of the FMoH and the Registration Directorate of NAFDAC. The committee meets quarterly to review ADR reports and other pharmacovigilance related activities. Some tertiary health institutions also have pharmacovigilance units/committees that coordinate drug safety monitoring and related activities.

With support from the Nigerian government, NPC has carried out the following over the last five years:

- Developed and distributed yellow ADR reporting forms and guides for detecting and reporting ADRs (over 45,000 forms and 5,000 guides distributed)
- Designed a guide for pharmaceutical industry ADR reporting
- Conducted a healthcare provider training on ADR reporting (over 700 doctors, nurses and pharmacists trained).
- Conducted one-on-one information sharing sessions at healthcare institutions to encourage healthcare practitioners to report ADRs.
- BroadcastADR jingles and messages in the electronic media for the general public; displayed ADR messages on posters and exercise books.
- Provides feedback to relevant stakeholders through quarterly newsletters and bulletins
- Currently conducting a pilot phase ACT CEM at six health institutions across the country, where 3000 patients treated with ACTs are actively followed up

Weaknesses

The greatest current weakness of the pharmacovigilance system is the limited involvement of the private sector in many activities such as training, detailing and CEM, with many activities confined only to community pharmacists and not the broader range of private sector stakeholders. As a result of this, ADR reporting rates are low – only 1,077 ADR reports have been received from 2004 to date through spontaneous reporting (115 of these reports are on ACTs).In comparison, the Uppsala Monitoring Center's (UMC) classification of adequate reporting is 200 ADR reports/million inhabitants/year. For Nigeria, this translates into 28,000 individual case reports per year. Actively engaging the private sector for ADR reporting by training practitioners and creating awareness will improve reporting rates

and subsequently safety monitoring. Other key challenges include:

- Public sector involvement in the pharmacovigilance system has been limited to tertiary levels of healthcare delivery with little involvement of secondary and primary levels;
- There is limited capacity in terms of staff strength, adequate training and funds in the NPC and many tertiary health institutions to carry out safety monitoring activities.

Quality surveillance
NAFDAC collects samples of all imported medicines at air and sea ports for laboratory analysis. This allows for quality assessment before distribution throughout the country, which reduces the risk of counterfeit medicines entering the marketplace. Routine and unscheduled inspections are carried out for quality monitoring at production sites and at retail outlets. NAFDAC laboratories conduct quality analyis of products, and those that fail the assessment are recalled from the market.

Weaknesses

The frequency of these surveillance activities are hampered by inadequate staffing and funding. Although NAFDAC collaborates with WHO and other organizations to enhance its capacity to monitor the quality of medicines, NAFDAC requires more skilled staff and resources to manage the large volume of medicines that flow through the country.

Resistance monitoring
As part of its efforts to monitor the efficacy of ACTs, the Federal Government has expanded the number of sentinel sites from six to fourteen in each of the country's six epidemiological zones. The sentinel sites are supervised by Principal Investigators who are expected to carry out Drug Therapeutic Efficacy Tests (DTET) biennially, and to maintain sentinel surveillance of the approved medicines. DTETs were conducted in 2002 and 2004 for CQ/SP and AL/AA respectively.

Weaknesses

No DTETs have been completed since 2004; however, existing sites are being strengthened to perform this task. As these activities are not fully supported by other partners, there is a need to carry out efficacy trials under the AMFm.

(4g) Strengthening the national drug monitoring system

Summarize your proposal for strengthening the national system of pharmacovigilance, quality surveillance and/or resistance monitoring through AMFm [1½ pages maximum].

To date, the Centre's training activities have involved only about 700 practitioners of the 300,000 registered health providers in the country, most of whom are in the public sector. This leaves a large number of those in the private and public sector untrained and unequipped to carry out safety monitoring. Furthermore, most safety monitoring activities (i.e. training, detailing, CEM) in the public sector have concentrated on the tertiary level of healthcare delivery, with little done at secondary and primary.

SDA 5.1: Pharmacovigilance and Resistance Monitoring – Passive Pharmacovigilance
The provision for pharmacovigilance in the GFR8 grant was completely removed due to funding constraints. Yet the broader distribution of ACTs under the AMFm makes it imperative that this gap be filled. As such, the originally proposed activities will be conducted to build the capacity of the national pharmacovigilance system at the national, zonal and institutional levels (Table 9). This will center on the provision of new and refresher training for health practitioners from both the public and private

sectors on appropriate reporting of ADRs.

Following an assessment of existing capacity for pharmacovigilance in the public and private sectors, separate training sessions adapted for doctors, pharmacists, nurses and patent and proprietary medicine vendors will be conducted as shown on the table below. Training of senior staff and secondary level health workers will occur independently of all other trainings proposed under the AMFm – where possible, pharmacovigilance training for primary and private sector health workers will be timed with general case management training to add a day of pharmacovigilance content. In addition, a number of interventions will be implemented to maintain health practitioner's and the general public's awareness of and compliance with ADR reporting, including regular distribution of newsletters and sending of text messages with key information.

Table 9: Passive Pharmacovigilance Planned and in the AMFm

Passive Pharmacovigilance Activities	Assumptions	AMFmTotal	Unit
Assessment of existing resources and capacity for pharmacovigilance	NA	1	Event
Advocacy/sensitization meetings with stakeholder groups	1 meeting per month over 2 years	24	Meetings
Training of senior staff on pharmacovigilance	Includes 10 NPC staff and 4 staff from 6 zonal centers and 6 additional health institutions each	58	Participants
Development and printing of training of trainers manuals on pharmacovigilance	For 58 trainees, 5 trainers and additional for distribution	70	Documents
Training of health workers at secondary level on pharmacovigilance	3 per LGA for 774 LGAs	2,322	Participants
Training of health workers at primary level on pharmacovigilance	6 per LGA for 774 LGAs	4,644	Participants
Training of private sector health providers on pharmacovigilance	10 per LGA for 774 LGAs	7,740	Participants
Equip zonal and institutional pharmacovigilance centers	6 zonal centers and 6 additional health institutions	12	Centers
Creating public awareness on pharmacovigilance using short text messages	25,000 SMS messages per month over 2 years	600,000	SMS Messages
Develop and disseminate newsletters and bulletins to healthcare practitioners at all levels on pharmacovigilance issues	5,000 quarterly newsletters over 2 years; 5,000 annual bulletins over 2 years	50,000	Documents

SDA 5.1: Pharmacovigilance and Resistance Monitoring – Active Pharmacovigilance

With the expansion of the use of ACTs, there is the need to scale up active pharmacovigilance on patients treated with ACTs in order to pick up early, serious ADRs that may occur, as passive pharmacovigilance may not be sufficient for this purpose. This will be achieved under this proposal by supporting quarterly follow up of patients who have been treated with ACTs from public, private and NGO outlets. Staff from the 6 zonal centers will carry out follow up visits to a sample of public, private and NGO outlets and submit reports to the NPC (Table 10).

Table 10: Active Pharmacovigilance Planned and the AMFm

Active Pharmacovigilance Activities	Assumptions	AMFm 2 year total	Units
Undertake quarterly follow-up of selected patients in selected public, private and not-for-profit sector.	Each of the 6 zonal centers undertakes a quarterly follow up visit for 2 people per visit over 2 years	48	Follow up visits

4. Supporting interventions

SDA 5.1: Pharmacovigilance and Resistance Monitoring – ACT Quality Surveillance
As noted above, NAFDAC has a mandate to conduct sporadic checks on the quality of products on sale to the public in private and public outlets but often lacks the capacity to effectively implement. Given the importance of overseeing quality ACT distribution under the AMFm, this proposal will support NAFDAC to carry out random surveillance of ACT distribution on a quarterly basis by first training staff on surveillance method and use of mini-labs (Table 11). Because this surveillance activity will be decentralized to the state level, state-level actors will be empowered to determine the locations for quality surveillance. These staff submit gathered information through the existing reporting system from the state to zonal and then national level. Lastly, Nigeria will conduct a DTET study with AMFm resources given the absence of such a study for the last five years – this study will be carried out in 4 of the 8 sentinel sites.

Table 11: Quality Surveillance Planned and the AMFm

ACT Quality Surveillance Activities	Assumptions	AMFm 2 year total	Units
NAFDAC staff training on quality surveillance and use of mini-labs	4 state-level NAFDAC officers per state for 37 states over 2 years	148	Participants
Conduct quarterly quality assurance testing on ACT from all outlet types	1 per quarter per state for 37 states over 2 years	296	Follow up visits
Conduct ACT DTET	1 study in 4 zones (supports 4 out of 8 sentinel sites)	1	Study

National policy and regulatory environment efforts

(4h)Existing national policy and regulatory environment Summarize your existing national policy on the classification ("scheduling") of ACTs either as 'over the counter' or 'prescription only' medicines.	***[Insert annex name and number if providing an extract from a national policy]***
In the National Anti-malarial Treatment Policy (NATP), the ACT recommended for the treatment of uncomplicated malaria is AL while the alternate medicine is AA. AL and AA were classified as OTC medicines in 2006. All other ACTs remain as Prescription-Only Medicine (POM). In order to support broader adoption of ACTs and to displace artemisinin monotherapies, since 2006 NAFDAC has stopped registering new artemisinin monotherapies. Furthermore, all remaining licenses will expire by late 2009 and will not be renewed. To mitigate the risk of artemisinin monotherapy stockpiling prior to the end of registration, NAFDAC has provided incentives to promote ACTs, including reduced ACT registration costs. Given the OTC classification and expedited registration, Nigeria's policy and regulatory landscape provides ideal circumstances for Phase 1 of the AMFm. As other new quality assured formulations are approved, they will be considered for OTC distribution under the AMFm in Nigeria.	
(4i) Efforts to improve the national policy and regulatory environment for ACTs If ACTs are not **widely available** 'over the counter' in your country, describe the actions you are	

proposing to ensure that the AMFm objectives of increasing ACT availability and use will be achieved. Also describe any other **actions you propose to strengthen the policy and regulatory environment** to relevant to the AMFm in this section [1½ pages maximum].

First line ACTs AL & AA are widely available over-the-counter in Nigeria so it is not expected that additional policy changes will be required to ensure broad access to these drugs under the AMFm.

SP and all ACTs other than AL and AA are currently registered as POM; however, these commodities are still widely available without prescription in the private sector. Thus, there is a need to communicate and enforce the POM status of these anti-malarials more effectively in the marketplace. As outlined in Section 4b and 4d, advocacy and training for key groups including importers are planned. Additionally, new enforcement visits to improve the regulatory environment for ACTs are described below.

SDA 5.2 Leadership and Governance – National Policy and Regulatory Preparedness

For pharmaceuticals in Nigeria, NAFDAC regulates products whereas PCN regulates the practice of pharmaceutical distribution by private sector retailers. In order to ensure that ACTs are stored and distributed properly and to effectively limit the continued use of monotherapies, it will be important to support PCN to conduct supervisory visits to private sector outlets and conduct appropriate enforcement when breaches are observed. PCN will also be supported to register PPMVs to enable more of these outlets, which play an important role in anti-malarial access, to operate officially thereby encouraging their compliance with good practices.

With the additional resources, the PCN will scale-up its supervisory visits of private outlets and its workshops to facilitate registration of PPMVs (Table 12).

Table 12: AMFm National Policy and Regulatory Preparedness

Enforcement Activities	Assumptions	2 Year Total	Units
PCN to conduct quarterly supervision visits to registered private sector outlets to ensure that POM anti-malarials are properly dispensed	4 per year in each of 6 zones, for two years	48	Visits
PCN national meetings with NAPPMED to coordinate PPMV registration	Biannually for two years	4	Meetings
PCN zonal meetings with NAPPMED to coordinate PPMV registration	4 per year in each of 6 zones, for two years	48	Meetings
PCN to conduct PPMV registration workshops at zonal offices	4 per year in each of 6 zones, for two years	48	Workshops

Implementation
All activities in this area will be led by the PCN due to its mandate to oversee private sector medicine dispensing.

(4j) Tax exemption for AMFm co-paid ACTs

Explain whether ACTs co-paid by AMFm (including those purchased by public, private and not-for-profit sector buyers) will be exempt from duties and taxes. If they are not exempt, explain how the higher cost of co-paid ACTs will be mitigated to ensure that the price to patients becomes comparable to that of less-effective anti-malarials [1/2 page maximum].

ACTs are subject to a 5% duty tariff for private and not-for-profit sectors, which is already low compared to the 20% tariff for all other finished medicines. However, ACTs that are procured with donor funds benefit from tariff exemptions. The Federal Ministry of Health is committed to ensuring that duty waivers are secured for all health commodities especially ACTs and LLINs.

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For local manufacturers, artemisinin actives, Lumefantrine and Amodiaquine are not subject to duties. It is unlikely that Nigeria will extend additional tax relief to private sector organizations or buyers**.** However, given that tax and duty tariffs are already low for these products relative to other medical commodities, it is envisaged that these fees are unlikely to be a significant inhibitor to private sector procurement.

Reaching poor people and other vulnerable groups

(4k) Existing interventions to reach poor people, children and other vulnerable groups How do your national malaria treatment interventions, with special reference to ACT treatment, currently **reach and/or target poor people, children** (particularly those under 5 years of age), **women and other vulnerablegroups**? [1 page maximum]	***[Insert Annex name and number if providing an extract from a national malaria control plan, a Global Fund Round 7 or 8 proposal]***

According to Nigeria's Federal Bureau of Statistics, 70% of Nigerians live on less than a dollar a day. These individuals and families are more vulnerable to malaria illness and death due to poor access to healthcare. In line with the national development goals, the NMCP has integrated efforts to reach poor populations into its malaria strategic plan. In addition, the strategy specifically targets other groups that are particularly vulnerable to malaria and in need of support, notably young children, pregnant women and people living with HIV/AIDS.

As part of this strategy, the program has pursued a range of interventions to reach poor and vulnerable groups to date, including:

Public sector

- Malaria treatment is provided free to U5s and pregnant women at al public health facilities, with donors and partners supporting similar free treatment through complementary programs;
- Integrated services delivery (including malaria activities) for vulnerable groups in the Community Directed Treatment with Ivermectin (CDTI)
- Integrated care management directed at U5s is emphasized in the expanded Community Integrated Management of Childhood Illness (CIMCI) implementation in States
- Integrated Maternal and Newborn Childhood Health (IMNCH) strategy is being implemented
- Medical outreach promote ACT access in hard-to-reach areas
- The home-based management of malaria approach increases access to effective malaria treatment and care in remote, poor communities through Role Model Mothers

Private sector

- A community-based health insurance scheme that provides reduced price coverage to poorer groups is currently being piloted in 6 states;
- Use of PPMVs to distribute ACTs to hard to reach areas.

Not-for-profit sector

- Provision of care and treatment services in underserved areas at low cost to poor and indigent populations by faith-based organizations;
- Use of civil society organizations at community levels to promote ACT use and other important treatment seeking behaviors;

- Provision of subsidized malaria treatment services to the nomadic populations

Weaknesses
Key weaknesses include a limited scope of projects and therefore a need for massive scale up. For example, the HMM program is currently only active in 18 states despite its central role in delivering effective treatment to remote communities. In addition, although efforts have been made to include subsidized malaria treatment with ACTs toPLWHAs,, this is still being done on an ad-hoc basis. Lastly, the reach of PPMVs into remote areas has not been properly leveraged to date due to lack of low cost ACTs and insufficient training and supervision of these outlets.

(4l) New or expanded interventions to reach poor people, children and other vulnerable groups

Summarize your proposal to introduce new or expanded interventions to reach poor people and other vulnerable groups with affordable ACTs [1½ pages maximum]. Refer to the Guidelines for AMFm Phase 1 Applications for specific guidance.

In GFR8, several innovative interventions are planned to reach poor persons, children and other vulnerable groups. However, the coverage of these interventions in GFR8 was reduced due to budgetary constraints despite existing capacity to implement. As such, these interventions will be expanded during the roll out of the AMFm to increase the coverage of and further reduce the barriers to ACT access for the poor and vulnerable. These activities, which are described in greater detail in other areas of the proposal, include:

SDA 2.2: Home management of malaria

Scaling up Role Model Mothers
As stated in Section 4d, 10 additional RMMs per LGA will be trained to deploy ACTs. Because these women operate within their communities and provide treatment free of charge, they are an effective channel for reaching the poor and vulnerable. To equip RMMs for effective work, their focal health facilities will not only supply them with work kits but also transport costs to facilitate their monthly drug collection and data submission.

Conducting Targeted BCC
As stated in Section 4b, Nigeria proposes to conduct a multi-pronged communications campaign to promote messages regarding the affordability and increased availability of proper malaria treatment. Among the tools deployed, the advocacy and social mobilization events will be specifically targeted to reaching and benefitting the poor and vulnerable. Furthermore, the campaign will have a broader reach among underserved populations by expanding it to include two additional languages.

Complementary Private Sector ACT Distribution to Remote Areas
It is recognized that both the public and private sector face challenges in distributing ACTs to people living in hard-to-reach areas, and at the same time, the poor and vulnerable people who live on the periphery struggle to travel and access appropriate treatment. Nigeria assumes that 20% of its population falls into a category of people who will not be able to access ACTs from the existing public and private sector supply chains. To reach part of this population of roughly 30 million, SFH as PR will procure 7.5 million ACTs using GFR8 resources (in the AMFm, 7.5 million additional ACTs will be procured and distributed for this population; see Section 9b). Originally, GFR8 covered the distribution costs to supply these 7.5 million doses of ACTs to hard-to-reach areas. However, due to budget constraints, these resources were removed. Under the AMFm, the costs for SRs to distribute 7.5 million doseswill be reinstated to extend the supply chain:

- To PPMVs in rural and difficult to reach areas
- Through medical outreaches, which are mobile treatment units staffed with registered

health personnel. These outreaches travel to rural communities and provide basic preventative and treatment services
- o Through the network of mission hospitals, clinics and treatment homes

Table 13: Interventions to Reach the Poor Planned and the AMFm

Activities	Overall Target	GFR8	AMFm Additions	Total
Build RMM and PPMV capacity		See Section 4d		
Targeted BCC activities		See Section 4b		
ACT distribution to hard-to-reach areas (transport support to remote areas)	28.4 million ACTs	7.5 million ACTs	Reinstated	

Additional supporting interventions

(4m) Additional supporting interventions to promote safe and effective use of ACTs

If applicable, summarize your proposal for **other additional supporting interventions** to promote safe and effective use of ACTs across the public, private and not-for-profit sectors. [1½ pages maximum]

Additional supportive interventions to support implementation of AMFm will be carried out under GF R8 Objective 2 contributing to increasing prompt and effective treatment of malaria using ACTs to 80% of the population at risk by 2011 and sustained through 2013

SDA 2.1: Prompt, effective treatment of malaria – Additional interventions – AMFm Taskforce

There is an urgent need for a dedicated oversight body for the AMFm in Nigeria in order to maximize the impact of the AMFm within the Phase 1 timeframe. Key activities of the AMFm Taskforce will include the following:

- Technical and secretarial assistance to coordinate PRs, SRs, and other implementing partners. This support will ensure that key stakeholders and implementers maintain regular communications, and that issues can be addressed in an informed and coordinated manner as they arise.
- Targeted monitoring and data gathering from varied sources (e.g. PRs, FMOH, the Global Fund) on import and distribution of ACTs in Nigeria. The consolidation of first line buyer level procurement and distribution data will allow the oversight committee to make recommendations for strategic adjustments to supporting interventions much more quickly
- In order to ensure ongoing broad stakeholder engagement continues, quarterly stakeholder meetings will be held to serve as a forum on the AMFm. Membership will tentatively be comprised of the NMCP, CCM, ACOMIN, NAFDAC, YGC, SFH, the Importers Association, WHO, and Clinton Foundation

To carry out the above activities, 3 full time equivalents will be hired to staff the Taskforce. The core members of the Taskforce will meet once a month (25 people), and a larger stakeholder group will convene once a quarter (100 people).

SDA 4.1: BCC – Community Outreach – Additional intervention: Support rapid and sustained supply of AMFm ACTs through private sector distribution channels

4. Supporting interventions

Due to the existence of sole agent agreements between key qualified AMFm international manufacturers (suppliers) and importers in Nigeria, access to AMFm ACTs will initially be restricted to distributors linked to sole agents. The aim of this intervention is to fast track the linkages between key distributors and the first line importers to ensure quality affordable and appropriate ACTs readily available for malaria treatment at private sector outlets. SFH, the PR responsible for private sector under GF R8, in collaboration with private sector first line buyers, will work with key distributors and wholesalers to increase awareness of the sources of supply of affordable ACTs and facilitate availability of ACTs across major distribution channels.

The primary activity will be quarterly meetings with major pharma distributors and key wholesalers in five distribution hubs in Nigeria (including Abuja, Kano, Lagos, and Onitsha). The purpose of these meetings will be to disseminate information and address issues related to availability, pricing and promotion of outlets selling AMFm ACTs. These meetings will be organized and facilitated by a four-person coordinating team comprising representatives from PRs and other first-line buyers.

Workplan

(4n) Workplan for new or expanded supporting interventions You must support your proposal for **new or expanded supporting interventions** for AMFm by attaching a detailed Work Plan for the duration of AMFm Phase 1 (attached a separate annex). The detailed budget for these activities should also be provided in Section 8e of this application form.	***Annex 16***

Risk Analysis

(4o) Complete the following table to identify any potential risks to the successful implementation of AMFm in your country and to describe the measures that will be undertaken to mitigate these.

A non-exhaustive list of possible risks is included in the table. If you believe that a listed risk does not apply to your country, you must provide an explanation of why this is the case. Insert additional rows to include further potential risks and mitigation strategies.

Potential risk	**Mitigation strategy**	
	Influencing Factor(s):	**Mitigation Plan(s):**
Slow implementation of supporting interventions	Unclear plans and guidelines for participating stakeholders.	All national AMFm policies, guidelines, and relevant manuals will be finalized prior to the end of 2009 and distributed to all stakeholders
	Potential implementation capacity constraints among PRs	Existing PR capacity is being strengthened; a third PR will be brought on; external TA will be leveraged when necessary; implementation of activities will be delegated to SRs.

4. Supporting interventions

Lack of demand for ACTs	**Influencing Factor(s):**	**Mitigation Plan(s):**
	Poor acceptance of ACTs due to insufficient ACT information dissemination among public	GFR8 BCC activities will be scaled up significantly under the AMFm
	Ubiquity of SP in outlets	The regulatory environment will be strengthened to enforce POM status of SP
	Poor awareness of ACT availability and efficacy	Demand will be generated in the general public through IEC/ BCC activities and professional bodies will be engaged to inform membership and distribute communications resources
	Poor provider acceptance/promotion of ACTs over other drugs	IEC/ BCC and training on ACT will be targeted at providers
Lack of supply of ACTs through supply chain	**Influencing Factor(s):**	**Mitigation Plan(s):**
	Provider misinformation leads to continued sales of ineffective anti-malarials	Provider training will improve treatment practices and patient counseling
	Gaps in distribution and supply chains	Detailing and supply management assistance will be provided for key private sector distributors through private sector PR
	Insufficient incentives for retailers to lower prices	Non-financial incentives will be provided to the private sector supply chain; competition will drive lower prices
Excessive price mark-up through the supply chain	**Influencing Factor(s):**	**Mitigation Plan(s):**
	Excessive margins at wholesaler, distributor and retail level	IEC/ BCC campaign will promote a message on affordable price to patients
	Price speculation associated with scarcity	The AMFm task force will receive information on first line buyer purchases from the Global Fund to oversee steady supply and pricing
Limited purchase of ACTs by private sector first-line buyers	**Influencing Factor(s):**	**Mitigation Plan(s):**
	Importers not realizing consumer demand	PRs and NMCP will engage will first line buyers to ensure that they are aware of the AMFm
Poor diagnosis and	**Influencing Factor(s):**	**Mitigation Plan(s):**

4. Supporting interventions

inappropriate supply of ACTs by providers	Inadequate diagnostic tools	Operational research will be conducted to introduce RDTs into the private sector
	Poor perception or distrust in diagnostic tool results	Expanded deployment of RDTs and training under pilot to health care provider
Inappropriate use of ACTs by patients	**Influencing Factor(s):**	**Mitigation Plan(s):**
	Cost of full course of ACT medication results in incomplete dosing	Drugdosage and treatment regimen information will be communicated on leaflets that are distributed
	Poor knowledge of proper use among providers	Provider training will be expanded to public and private sector providers
	Poor knowledge of proper use among patients	IEC/ BCC will provide education to patients on proper drug usage
Inadequate interventions to increase coverage of poor, people, children and other vulnerable populations	**Influencing Factor(s):**	**Mitigation Plan(s):**
	Difficulty supplying drugs to remote areas	Transport subsidy will be provided to suppliers who carry drugs to hard to reach areas and the poor and vulnerable
Massive leakage of co-paid ACTs to non-AMFm countries	**Influencing Factor(s):**	**Mitigation Plan(s):**
	Limited oversight and enforcement of PPMVs	PCN and NAFDAC will collaborate to register more PPMVs and conduct training/ monitoring of PPMVs
	Too many unmonitored wholesalers may result in significantly higher incidence of leakage	It is expected that manufacturers and the Global Fund will work together to ensure a international or national level AMFm brand/ logo
Increase in poor quality or counterfeit ACTs	**Influencing Factor(s):**	**Mitigation Plan(s):**
	Inadequate capacity for local manufacturers to achieve WHO PQ may result in low quality competitive products being launched in the short term to compete against AMFmACTs	Local manufacturers will be engaged as distributors in Phase 1 of the AMFm and continue to facilitate discussion to identify government support for PQ and infrastructure upgrades
Other [Opposition from local manufacturers]	**Influencing Factor(s):**	**Mitigation Plan(s):**
	Potential for profit loss to importers or local manufacturers	Local manufacturers will continue to be engaged as

4. Supporting interventions

	due to the availability of low priced ACTs	distributors where possible

5. Monitoring AMFm Phase 1

In-country monitoring of AMFm Phase 1
The purpose of in-country monitoring for AMFm Phase 1 is to monitor progress in implementation, measure performance in delivering supporting interventions, inform decisions during implementation, and help identify problems that need the attention of managers.Applicants are requested to outline their monitoring system for AMFm Phase 1 in this section.

Independent Evaluation
The independent evaluation will assess whether and the extent to which AMFm Phase 1 achieves its objectives. The main parameters for evaluation are as follows:

- Availability of ACTs in outlets across the public, NGO and private sectors
- Affordability of ACTs to patients in outlets across the public, NGO and private sectors
- Market share of ACTs relative to monotherapies (e.g., AMTs, SP, CQ, AQ)
- Access to and use of ACTs by vulnerable groups of interest (e.g., poor people and children)

The Independent Evaluation will be undertaken by an independent contractor. Applicants are required to ensure cooperation with the independent contractor. Applicants are **not** asked to respond to questions regarding the Independent Evaluation in this application form.

(5a) Describe the **in-country monitoring system**, including its strengths and weaknesses, that will be used to monitor the AMFm supporting interventions and other relevant activities, including drug procurement and supply chain management. If relevant, refer to and attach as separate annexes extracts from previously submitted applications to the Global Fund or applicable health sector documents [1 page maximum].	***[Insert annex name and number if referring to health sector documents or applications previously submitted to the Global Fund]***

The NMCP has developed an M&E Framework that is designed to guide and improve program implementation, ensure accountability, and provide timely and relevant information to decision makers (Annex 11). At the national level, the M&E Working Group (led by the NMCP M&E Unit and composed of partners and PRs) acts as a central coordinating body for all monitoring and evaluation activities. The data management unit in the NMCP manages a comprehensive and continuously updated database, which has been established to support the analysis and use of the indicators in the M&E framework. At the state level, the State Disease Surveillance and Notification Officers' Forum meets monthly, while at the LGA level, the Health Management meeting regularly reviews data reported from facilities and local partners.

The key outcome indicator in the framework that is relevant to the AMFm and included in the host grant is the "proportion of U5 children with fever receiving appropriate treatment within 24hrs of onset of symptoms." A range of process indicators related to the AMFm and malaria case management are also monitored and evaluated through routine NMCP-led data collection (see Annex 12).

This core M&E process is complemented and supported by a number of activities by partner organizations. The most notable of these is ACTWatch, a consortium of organizations led by PSI/SFH, which is working with the NMCP to conduct a series of nationally representative surveys on the distribution, availability, and use of ACTs and other ant-malarials (see Annex 7).

There are several existing M&E activities that will be used to monitor and manage AMFm supporting interventions, including:

Public awareness campaign

- A media tracking service (conducted by a third party) that captures the volume, number and

location of aired media spots;
- Knowledge Attitudes and Practice surveys (part of ACTwatch household survey) to assess changing perception and behaviors of caregivers;
- A media impact survey will be supported through the GFR8 grant to assess the specific effect of BCC messages on perceptions and practices. However, the current planned scope of the survey will not adequately cover AMFm-related outputs so additional questions and target populations will need to be added;
- Supervisory visits of health providers and implementation reports provided partners and civil society organizations.

Training and supportive supervision
- Regular reports on training implementation provided by relevant implementing partners;
- Supportive supervisory visits of health providers conducted by NMCP and other agencies to observe and further encourage changes in practices;

Drug monitoring
- Regular reports from implementing partners on the progress against relevant pharmacovigilance targets (e.g., completion of key trainings or outputs of active PV visits to facilities)
- Reports from NAFDAC on the sampling of ACTs and results of quality tests

Strengthening regulatory environment
- Quarterly reports from PCN on the results and corresponding follow up actions of regulatory visits;
- Analysis of private outlet registration and dispensing practices from regular ACTwatch retail outlet surveys and supply chain assessment;

Reaching poor and vulnerable populations
- Reports of supervisory visits of RMMs by CSOs;
- Annual NMCP program review to assess socioeconomic and geographic equity of ACT access

Strengths
The M&E system in Nigeria currently benefits from a number of strengths that will facilitate the effective tracking and management of AMFm-related interventions. These include:
- Good M&E capacity within the NMCP and collaboration with relevant health information programs (HMIS and IDSR);
- Strong coordination of M&E activities between implementing partners through the national M&E Technical Working Group;
- Strong collaboration between the NMCP and relevant partners and NAFDAC for ACT regulation and pharmacovigilance interventions;
- Adoption of a Public-Private Partnership (PPP) policy that will facilitate improved reporting of data from the private sector on malaria treatment;
- Robust and relevant planned data collections by partners, notably ACTwatch surveys

Weaknesses
Despite concerted efforts to strengthen the national malaria M&E system, a number of challenges persist that could impede the effective monitoring of AMFm supporting interventions. These include:
- Weak capacity for M&E at sub-national levels resulting in late and incomplete reports from all sectors;
- Lack of an effective system to consistently capture data from most private health facilities;

- An insufficient Logistic Management Information System (LMIS) to track the ACT supply chain pipeline;
- Insufficient use of data analysis to inform decision making process at the local level anda poor data feedback mechanism from higher levels of the system.

Some of these challenges are already scheduled to be robustly addressed with support from the GFR8 and/or other partners. For example, a third party logistics provider will be brought on to support the strengthening of supply chain data management for ACTs and other commodities. A summary of these actions and the additional interventions that will be implemented under the AMFm to fill remaining gaps is provided in Section 5b below.

(5b)Explain how the weaknesses of the existing monitoring system will be addressed, so AMFm activities and achievements can be monitored [1/2 page maximum]

Following a thorough review of the M&E system in 2007, a range of activities have been initiated to address the identified key weaknesses and strengthen the outputs of the system. These activities are being supported through the GFR8, the World Bank Booster Project, and other sources and will be expanded on through the AMFm to ensure that supporting interventions are effectively monitored and managed.

Table 14: Weaknesses of and approach to strengthening M&E system

Weakness	Approach to strengthen M&E
Weak capacity for M&E at sub-national levels	More LGA M&E focal point persons and DSNOs are being trained and supported to carry out more effective reporting and analysis of data at the lower levels of the system. National-level staff will support this process through regular support feedback on performance.
Insufficient system to capture data from most private health facilities	Under GFR8 and World Bank Booster Project, the NMCP and key partners are engaging the private sector in malaria surveillance and M&E. A policy on public-private information sharing has been approved and forums to provide feedback to private sector stakeholders are being conducted.
No functional LMIS	Tools for an effective LMIS have been finalized and comprehensive training of relevant staff has been planned for 2009. A third party logistic provider will also provide detailed ongoing support to identify and address weaknesses in the system.
Data not used for decision making process at the local level and poor feedback mechanism	Advocacy tools are being developed to facilitate use of data for appropriate decision making by key stakeholders, especially policy makers at all levels. Feedback dissemination workshops are being organized at national and state levels, as well as at the town/ community level.

SDA 5.3 HSS Information Systems

Monthly coordination meetings for data retrieval and reporting from communities and health facilities at LGA level

These coordination meetings will held to address the gap in regular reporting of data from the lowest levels of the system: RMMs, community-based distributors (e.g. medical outreaches), and primary health facilities. For every LGA, five representatives of local government and relevant implementing partners will meet each month to review the relevant data from these sources and clean and collate it for onward transmission to the state level. These meetings will also be used as a mechanism to improve feedback on data trends to these actors, with representatives also distributing and discussing

summary reports with relevant staff.

Quarterly supportive supervision visits by national M&E officers

As described in Section 4d, national M&E officers will participate in supportive supervision visits to state and LGA levels to observe M&E practices and provide detailed feedback. These visits will be aligned with other supervision (e.g., by State and LGA malaria focal points) and data review meetings where possible to generate efficiencies.

Mass media tracking

Although regular tracking of media activities has been planned under GFR8, due to the increased intensity and scope of mass media activities, there is a need expand this service. A contractor will be competitively selected to track the airing of TV and radio spots throughout the country and report on a monthly basis to the PRs and relevant implementing partners. This information will enable implementers to identify gaps in the timing, frequency, or location of key messages and make appropriate adjustments.

Media impact survey

Media impact surveys will be conducted to assess the effect of the BCC activities on the targeted behaviors and attitudes. The surveys will use structured interviews with caregivers and other target populations to determine exposure and reactions to the key messages promoted by the campaign. Under GFR8, one survey is planned to coincide with the end of the first year of the AMFm, and again at the end of the second year. With the expanded IEC/ BCC campaign for the AMFm, there is a need to scale up the media impact survey to cover the broader scope of activities.

Expand Malaria Indicator Survey to include assessment of relevant knowledge and practices

Nigeria is scheduled to conduct a comprehensive Malaria Indicator Survey (MIS) in the second quarter of 2010. This survey will provide the program with critical information on the malaria burden and access to key interventions such as ACTs. However due to funding constraints, the scope and scale of this MIS were reduced. Given that MIS data is essential to assessing the impact of BCC activities to inform ongoing implementation and potential further scale-up, the MIS will be further supported under AMFm to be an effective baseline for Nigeria.

Mystery client and exit interviews

As described in 5a, a number of steps are being taken to establish an effective system for capturing key data from private providers. However, it is expected that reporting from some facilities will remain inconsistent for some time. As such, to ensure that the national program and implementing partners have consistent information, particularly regarding pricing and stocking, mystery clients and exit interviews will be employed three times during Phase 1 (baseline, end Year 1, end Year 2). Information gathered will enable the AMFm Task Force to determine whether the package of interventions is having sufficient impact. While these collections employ completely different methods than ACTWatch, these activities will still be closely coordinated with that project in order to enable useful comparison and joint analysis of data.

5. Monitoring AMFm Phase 1

Table 15: New M&E Strengthening Interventions

Training Activities	GFR8 Total	AMFm Additions		Total
		Total 2 years	Assumptions	
Regular coordination meetings on community level data	0	18,576	1 meeting per month in 774 LGAs	18,576
Quarterly supportive supervision visits by M&E officers	See Section 4d			
Mass media tracking	60 days	60 days	60 days of TV/ radio placement per year to be monitored	120 days
Media impact surveys	300			
Mystery client and exit interview surveys	0	3	1 survey at baseline, year 1, year 2	15,480

(5c) Describe the **in-country data quality assurance systems** (including tools) that will be used and/or strengthened to provide regular and quality data to monitor AMFm activities and achievements [1/2 page maximum]

As part of the national M&E Framework, the NMCP and its partners have designed systems to consistently quality check key data provided and collated at all levels of the health system. This includes audits to asses the accuracy, completeness, and timeliness of data provided and spot verification that reported activities (e.g., training) have been completed. With the support of the GFR8 grant, a number of interventions will be conducted to further strengthen the operation of this system. The table below summarizes those interventions that are relevant to the AMFm. As funding is already provided under the host grant, no additional funding is sought in this proposal for this area.

Table 16: Data Quality Assurance System

Data Quality Assurance Activity	Responsibility	Timing	Level	Funding source
Produce and disseminate adequate quantities of standardized M&E tools	PRs and SRs (NMCP, SMCP, LGA) with TA from partners	Q1 – Q2	National	GFR8
Training, retraining and supportive supervision for data collectors, analysts and managers	SRs (NMCP, SMCP, LGA Focal points) with TA from partners	Q1 - Q8	All levels &both public/private sectors	GFR8
Data quality audits of health facilities	PRs and M&E contractors	Quarterly	Health facility	GFR8
Regular analysis & vetting of implementation reports	PRs and SRs	Monthly	All levels	GFR8
Feedback to officers concerned	PRs, SRs (NMCP, SMCP, LGAs) and Partners and Stakeholders	Bi-annual (Natl RBM Partners) Quarterly (PRs) Monthly (SMCP, LGA, Community)	All levels	GFR8

(5d) Provide a **summary budget** for activities to monitoring AMFm Phase 1 in your country. This

should also include any funds requested to strengthen the existing monitoring system.

M&E Activity	Year 1	Year 2	Total
Monthly coordination meetings for data retrieval from communities and health facilities at LGA level	$789,480	$263,160	$1,052,640
Quarterly supervisory visits to state and LGAs by national M&E officers	$269,571	$269,571	$539,143
Mass media tracking	$51,600	$51,600	$103,200
Media impact survey	$171,600	$171,600	$343,200
Mystery client exit interviews to assess quality of care	$270,000	$135,000	$405,000
Contribution to MIS survey – knowledge and practice	$250,000	$500,000	$750,000
TOTAL	**$ 1,802,251**	**$ 1,390,931**	**$ 3,193,183**

(5e) Include as an attachment a draft revised version of the Performance Framework of the 'host' malaria grant. If available, attach the updated monitoring and evaluation plan for the AMFm 'host' grant[1].

Due to challenges in highlighting, the revised indicators are below, with new indicators in **bold**:

- Objective 2: Prompt, effective anti-malarial treatment - # of CSO members trained on case management of malaria
- Objective 2: Prompt, effective anti-malarial treatment - # of ACTs utilized/ distributed to children under five years
- Objective 2: Prompt, effective anti-malarial treatment - # of ACTs distributed to children under five years through the private sector
- Objective 2: Prompt, effective anti-malarial treatment - # of ACTs utilized/ distributed to persons five years and above
- Objective 2: Prompt, effective anti-malarial treatment - # of ACTs distributed to persons five years and above through the private sector
- Objective 2: Prompt, effective anti-malarial treatment - Proportion of participating health facilities in the public/ private sector reporting no stock outs of ACTs for 1 week of more in the last 3 months
- Objective 2: Prompt, effective anti-malarial treatment - # of health care providers trained in malaria case management and prevention
- Objective 2: Home Management of Malaria - # of Role Model Mothers trained
- Objective 2: Home Management of Malaria - # of PPMVs, drug handlers and pharmacists trained
- **Objective 2: Home Management of Malaria - # of ACTs distributed (disaggregated by sector) through outreach services**
- Objective 4: BCC Community Outreach - # of communities and

Annex 13

[1] *Upon grant amendment, countries will be encouraged to share a complete description of the 'AMFm Monitoring Plan' as an addendum to the Monitoring and Evaluation plan of the AMFm 'host' grant. The AMFm Monitoring Plan will be required to enable disbursements for AMFm supporting interventions.*

groups reached through advocacy and social mobilization • Objective 4: BCC Mass Media - Proportion of people exposed to the campaigns who can recall appropriate treatment of malaria • Objective 5: HSS Information systems - Proportion of health facilities participating in the project who completed timely and complete reports • **Objective 5: HSS Pharmaocovigilance and resistance monitoring - # of health workers trained on pharmacovigilance** • **Objective 5: HSS Leadership and Governance - # of PPMV workshops carried out by PCN**	

6. Operational research

Operational research
This refers to studies whose findings will be applicable to the local context, to enable "learning by doing" and to alleviate constraints on implementation. The emphasis is on relevance and application of knowledge in a particular context. Countries will identify and either perform or commission operational research for their own use during AMFm Phase 1. The operational research questions should be directly relevant to the objectives of the AMFm and the real-life barriers to the achievement of those objectives. Suggested areas for investigation are provided in the Guidelines to the AMFm Phase 1 Application Form.

In addition to this country-specific operational research, **multi-country operational research** will examine cross-cutting questions across sub-sets of Phase 1 countries. The design and conduct of multi-country operational research will be contracted by the Global Fund to qualified research and academic institutions. The cost of multi-country operational research will be funded directly by the Global Fund. Applicants are not asked to respond to sections regarding multi-country operational research in this application form.

(6a) Operational research planned during AMFm Phase 1

Complete the table below for each proposed operational research topic to be addressed during AMFm Phase 1. Copy and paste the rows below to complete the table for each proposed operational research topic. [1 page maximum per research topic]

Title	***Exploring The Introduction of RDTs Into The Private Sector***
Duration	6 months starting in the 2nd quarter of 2010
Design and methods	***Problem Statement:*** Parasitological diagnosis is essential to enabling effective case management of febrile patients, saving both money (from wasted drugs) and lives (from inappropriately treated infections). Microscopy is cumbersome and requires expertise that is often hard to secure. Alternatively, RDTs provide rapid and unambiguous results. However, concerns about the reliability of RDT results persist. In addition, when used in a private setting, it is critical that the incentives of the provider be appropriately aligned to provide the RDT at a low cost prior to treatment and to respect the results of the test. There is currently little evidence or experience on how these challenges can be overcome and RDTs effectively deployed to improve case management in the private sector. An operational research project will thus be conducted to inform policy in this area. ***Research Questions*** • What is the level of malaria misdiagnosis by private health care providers? • How do RDT results influence private sector prescription behavior? • At what stage in a patient's consultation process at a private outlet should RDTs be administered? • What are the measurable costs and benefits of using RDTs in the private sector?

6. Operational research

	• Which RDTs are most reliable for use in Nigeria? ***Study Design*** After selecting appropriate research partners and an RDT product, the explorative phase will be conducted in the field where population of subjects will be randomized for correlation between clinical diagnosis and RDTs, identifying the most appropriate RDT test point in the consultation process, and evaluating RDT cost effectiveness and implementation in the private sector. A cross sectional study will be conducted in 6 sites across the country. A total of 1200 hundred subjects will be recruited into the study, and at presentation all eligible subjects will be examined with a clinical diagnosis made by private sector health care workers. The subjects will thereafter be randomized to two groups to be tested with either an HRPII or pLDH based RDT. Each of the subjects will also have blood smears for malaria parasite. The health worker and the personnel conducting the tests will all be blinded to the each other's diagnosis. Treatment of the subjects will be left to the discretion of the health worker using a structured questionnaire. For the behavioral component of the study, a sub-population of 50 subjects per site will be enrolled. Test groups will be stratified into the patient handling categories. Some RDTs will be administered before patient consultation by a trained nurse or another health staff who will not be responsible for consultation, and others will be conducted at the point of consultation. In both settings the health worker will treat the patient at their discretion in light of the results. The confidence of the health worker on the test results and utilization of the results will also be assessed. A follow-up questionnaire will be administered to assess the factors responsible for their behavior.
Lead research organization	*To be competitively selected*
Translation of results into improved performance	As noted in Section 3, the private sector is the principal channel through which patients obtain anti-malarials in Nigeria. As such, efforts to improve case management through the use of confirmed diagnosis will always be limited unless methods of introducing diagnostic tools into the private sector can be determined. This study will provide policymakers with critical initial evidence on the feasibility of deploying RDTs into the private sector. The results generated could lead to large-scale expansion of this approach alongside the distribution of subsidized ACTs and/or exploration of other approaches to improving diagnosis.
Title	**Scale-up of the Cohort Event Monitoring (CEM) of ACTs**
Duration	One year beginning in second quarter 2010, including patient recruitment, data collection, data analysis, data interpretation and data presentation. The scale up will cover 24 healthcare centers across the country.
Design and methods	***Problem Statement*:** Artemisinin and its derivatives are generally thought to be safe. However, there is currently little or no data on their safety among

	populations in Nigeria. Furthermore, the Over the Counter (OTC) classification of AL and AA raises more concern, as they will be readily available to Nigerians with little mechanism in place to monitor their effects on users. In view of this, there is need for active monitoring of these medicines in Nigeria to evaluate their safety by obtaining early knowledge of their risk profiles, possible interactions with other medicines, herbal medicines and concomitant diseases. ***Research Questions*** 1. What adverse events may occur in patients treated for uncomplicated malaria with ACTs (AL and AA)? 2. What is the causality relationship between observed adverse events and use of ACTs (AL and AA) in the cohort? 3. What interactions may occur between ACTs and other medicines, herbal medicines and concomitant diseases? 4. What are the risk factors for adverse events following the use of ACTs among populations in Nigeria? 5. Are ACTs rationally prescribed, properly dispense and correctly used in Nigeria? ***Study Design/Methodology:*** The study will be a prospective, longitudinal, observational cohort study of adverse events in 7,000 patients following the use of AL and AA. The study will be non interventional whereby patients will be observed under real life clinical settings. Since ACTs are taken within 3 days, using study coordinators, patients will be monitored from the onset of therapy to 3 - 7 days from first day of treatment to identify clinical adverse events/experiences that may occur following use of ACTs. This will necessitate asking patients to come for follow up visits 3 - 7 days after commencement of treatment or following them up with home visits if they fail to come for follow-up visits. Within this period, it is expected that common adverse events will manifest and patients can still clearly remember any adverse event they have experienced. For the scale-up study, a cohort of 7000 patients will be enrolled. This will bring the total number of patients recruited into the study to 10,000. A cohort of 10,000 patients gives a 95% chance of identifying an event with an incidence of 1:3000 i.e. uncommon or rare events. New patients will be added to the study as they come until the required number of 7,000 patients is recruited (dynamic). No exclusion criteria based on age, sex, presence of other disease conditions different from malaria, and use of other medicines will be applied as all patients with malaria are considered eligible to participate in the study. Data collection will be done using the pre and post treatment questionnaires already developed and tested in the pilot phase of the cohort event monitoring study. Data storage and analysis will be done using the CemFlow software developed by the Uppsala Monitoring Centre.
Lead research organization	NAFDAC

6. Operational research

Translation of results into improved performance	Data from the CEM study will facilitate characterization of risks (if any) associated with the use of AL and AA. Where risks exist, such information will guide in making necessary changes in the use of ACTs in the country as well as communicate potential risk factors. Where no risk exists, information from the study will be used to allay public apprehension about the safety of ACTs especially AA and hopefully increase public uptake of ACTs.
Title	**Measuring Effectiveness of Redesigned Packaging**
Duration	One year beginning in Q2 2010
Design and methods	*Research Questions* 1. What impact does locally appropriate repackaging/overbranding of ACTs have on patient selection of and adherence to these drugs 2. What is the most cost-effective approach to improved ACT packaging? 3. What is the most appropriate packaging for gaining ACT market share in the private sector and displace non-artemsinin and artemisinin monotherapies? *Study design* Nigeria will look at the use of packaging to improve comprehension/ adherence of ACT treatment regimen, and to promote ACTs over other anti-malarials. Repackaged ACTs will be distributed through two channels. In the **public sector,** Role Model Mothers (RMMs) will recruit patients and distribute packaged ACTs. RMMs will be instructed to deliver ACTs of three different types of packages: one that represents the most basic local packaging, one that incorporates simple usage instructions, and one that is considered to be among the best available in terms of comprehensive, country-specific packaging and instructions. After three days – the amount of time needed to complete the treatment course – a member of the study team will return to each patient's home in order to check the patient's health, and to collect data on comprehension and adherence of treatment regimen. Comprehension data will be collected through an interview with the patient or caretaker. The RMM will ask questions to test understanding of the correct pack size given age and weight, the number of pills to take and when, what to do if tablets are vomited up, implications of not completing the treatment course, and other key aspects of usage. Adherence data will be collected through the use of Electronic Compliance Monitors (ECM) – this will be decided through further consultation with the lead research organization. ECMs track medication usage through sensors applied to paper labels on blister packs; each time a tablet is removed from the pack, the ECM records the date and time. Upon collection of used blister packs, the information can be downloaded through a wireless reader to a computer or handheld device.

6. Operational research

	In the **private sector,** in addition to the above mentioned process for tracking patients that frequent drug shops, the study will explore the extent to which different types of packaging drives retailer and consumer uptake of the product. This project will leverage already planned research methods (from the AMFm – exit interviews, mystery shoppers; from ACTwatch – retail outlet audits) to understand the drivers of uptake.
Lead research organization	Society For Family Health
Translation of results into improved performance	This study will generate evidence around the most cost effective, appropriate packaging that will contribute to better comprehension/ adherence and product uptake. With this evidence, Nigeria will be in a position to make informed decisions on resource allocations for packaging costs. In addition, findings from this study will feed into negotiations at the international level with ACT suppliers and the global public health community.

(6b) Financing for operational research

Provide a summary budget for operational research over the period of AMFm Phase 1. This summary must also be included within the detailed budget requested in Section 8e of this application form.

Table 17: Summary budget for operational research

	Year 1	Year 2	Total
Exploring the introduction of RDTs into the private sector	$2,720,784	$507,415	$3,228,200
Scale up of the Cohort Event Monitoring of ACTs	$400,000		$400,000
Measuring Effectiveness of Redesigned Packaging	$226,307	$113,154	$339,461
Total	**$3,347,092**	**$620,569**	**$3,967,660**

7. Estimating savings in existing grants

Where the AMFm 'host' grant and/or other existing Global Fund malaria grants contain an ACT procurement component, it is expected that **substantial savings will be generated** from the AMFm co-payment on the cost of ACTs.

Applicants may reallocate these savings to fund AMFm supporting interventions. The Global Fund encourages countries to return any savings remaining after supporting interventions have been funded ('excess' savings) to the Global Fund. Alternatively, an implementing country may choose to spend these savings on malaria control activities. In this case, the Global Fund requires that savings must be reallocated in the grant budget according to the following order of priorities:

1. To fund additional ACT procurement through the public sector to expand access, with a focus on the poor and children
2. To fund ACT-related activities to strengthen the health system (HSS)

Applicants are able to propose reallocating savings towards these priorities in the budget table in Section 8a and in Sections 9a and 9b. Savings from ACT budgets cannot be used for any other purpose and 'excess' savings must be returned to the Global Fund.

(7a) Estimated savings gained in existing malaria grants through lower cost of ACTs

Complete the table below to estimate the savings that will be gained in your country's existing Global Fund malaria grants, through purchasing ACTs at the lower, AMFm price. Refer to the Guidelines for AMFm Phase 1 Applications for further guidance on completing this table. [Add additional columns as necessary to complete for all relevant malaria grants.]

	Global Fund Round 8			
	[Use the columns below for different ACT weight dosages, as appropriate]			
	ACT 1 (AL) 120/20mg (1x6)	***ACT 1 (AL) 120/20mg (2x6)***	***ACT 1 (AL) 120/20mg (3x6)***	***ACT 1 (AL) 120/20mg (4x6)***
LINE A **Number ACT treatments to be procured in grant during AMFm Phase 1**	15,194,335	8,923,635	15,804,198	17,121,214
LINE B **Current budgeted unit cost of ACT treatment**	0.37	0.74	1.11	1.40
LINE C ["LINE A" MULTIPLIED BY"LINE B"] **Estimated total cost of planned ACT procurement at original budgeted cost**	5,621,904	6,603,490	17,542,660	23,969,700
LINE D **Estimated unit cost of ACT treatment to Principal Recipient under AMFm Phase 1**	0.05	0.05	0.05	0.05
LINE E ["LINE A" MULTIPLIED BY"LINE D"] **Estimated total cost of planned**	759,717	446,182	790,210	856,061

7. Estimating savings in existing grants

ACT procurement at estimated AMFm Phase 1 cost				
LINE F ["LINE C" LESS"LINE E"] **Estimated savings gained in existing grants**	4,862,187	6,157,308	16,752,450	23,113,639
LINE G **TOTAL ESTIMATED SAVINGS**	**50,885,584**			

8. Budget for Supporting Interventions and Funding Request

(8a) Summary of Funding Request to the Global Fund
Clarified Table 8a.
Note: The estimated savings identified in Line B are based on the estimated cost to the country of AMFm co-paid ACTs. The Applicant understands that the net additional funding request is therefore subject to adjustment based on the actual price of AMFm co-paid ACTs, which will be set prior to the Global Fund Board's decision on the Applicant's funding request.

Budget item (*where applicable*)	*(Use the same currency as indicated at the start of this application form)*		
	Year 1	**Year 2**	**Total**
	Note: If preferred, adjust the above year headings from AMFm funding years to financial years to align with "host" grant cycles, national planning and fiscal periods. Funding may be requested for 24 months.		
LINE A: **Total budget for new and expanded AMFm supporting interventions** ***[MUST equal annual amounts and totals provided in the detailed budget (Section 8e) and in sections 8b and 8c]***	$29,332,316	$14,407,794	$43,740,111
LINE B: **Total estimated funds from reallocating savings from existing Global Fund malaria grants** ***[as estimated in Section 7]***	$50,885,584	0	$50,885,584
LINE C: **Total funds from other sources** ***[Must equal total funds from other sources listed in section 8d]***	0	0	0
LINE D: [LINE A, LESS LINE B, LESS LINE C] **Net Additional Funding Request to the Global Fund** ***[Where amount is NEGATIVE, applicants may propose additional ACT procurement and additional HSS activities relevant to ACT scale-up. These proposals should be detailed in Section 9]***	**-$21,553,268**	$14,407,794	**-$7,145,473**

8. Budget for Supporting Interventions and Funding Request

(8b) Summary of detailed budget for AMFm supporting interventions by objective and service delivery area

Objective Number *(Use same numbering as in revised Performance Framework for 'host' grant)*	Service delivery area	*(Use the same currency as indicated at the start of this application form)*		
		Year 1	Year 2	Total
		Note: If preferred, adjust the above year headings from AMFm funding years to financial years to align with "host" grant cycles, national planning and fiscal periods. Funding may be requested for 24 months.		
2	**Prompt, effective anti-malarial treatment**	$ 5,229,025	$ 2,209,422	$ 7,438,448
2	**Home based Management of Malaria**	$ 3,746,270	$ 1,831,607	$ 5,577,876
4	**BCC Community Outreach**	$ 3,728,124	$ 2,972,874	$ 6,700,998
4	**BCC Mass Media**	$ 5,867,119	$ 3,564,640	$ 9,431,759
5	**HSS: Information Systems**	$ 2,439,402	$ 1,514,928	$ 3,954,329
5	**Pharmacovigilance and Resistance Monitoring**	$ 4,459,138	$ 758,654	$ 5,217,793
5	**HSS: Leadership and Governance**	$ 1,142,454	$ 1,048,254	$ 2,190,708
	Diagnosis	$ 2,720,784	$ 507,415	$ 3,228,200
Total budget for new and expanded AMFm supporting interventions*[MUST equal annual amounts and totals provided in the detailed budget]*		**$29,332,316**	**$14,407,794**	**$43,740,111**

8. Budget for Supporting Interventions and Funding Request

(8c) Summary of detailed budget for AMFm supporting interventions by cost category
Clarified Table 8c.

Cost category *Avoid using the "other" category unless necessary.*	*(Use the same currency as indicated at the start of this application form)*		
	Year 1	**Year 2**	**Total**
	Note: If preferred, adjust the above year headings from AMFm funding years to financial years to align with "host" grant cycles, national planning and fiscal periods. Funding may be requested for 24 months.		
Human resources	$ 725,214	$ 546,880	$ 1,272,094
Technical and Management Assistance	$ 1,268,126	$ 1,238,689	$ 2,506,816
Training	$ 8,282,138	$ 319,859	$ 8,601,998
Health products and equipment (NOT pharmaceuticals)	$ 1,210,733.56		$ 1,210,733.56
Pharmaceutical products (medicines)			
Procurement and supply management costs (PSM)	$ 1,495,128	$ 1,299,218	$ 2,794,346
Infrastructure and other equipment	$ 518,398	$ 22,175	$ 540,573
Communication Materials	$ 8,717,113	$ 5,916,974	$ 14,634,087
Monitoring & Evaluation (including operational research)	$ 5,453,590	$ 3,625,926	$ 9,079,516
Living support to clients/ target populations			
Planning and administration	$ 1,318,251	$ 1,170,115	$ 2,488,365
Overheads	$ 343,625	$ 267,958	$ 611,583
Other: *(Use to meet national budget planning categories, if required)*			
Total budget for new and expanded AMFm supporting interventions ***[MUST equal annual amounts and totals provided in the detailed budget]***	**$ 29,332,316**	**$ 14,407,794**	**$ 43,740,111**

8. Budget for Supporting Interventions and Funding Request

(8d) Funding from other sources

If applicable, detail any funding for new or expanded supporting interventions that will be provided from sources other than the Global Fund (including domestic resources or other donor funds). List the specific interventions, the source of funding and the amount of funding that will be provided in the table below. [Add extra rows to the table below as required]

Intervention	Funding source	Year 1	Year 2	Total
N/A				
Total funding from other sources [Must equal total funds from other sources listed in Line C, Section 8a]				

(8e) Detailed budget for AMFm supporting interventions

Submit a detailed budget for new and/or expanded AMFm Phase 1 supporting interventions*in **Microsoft Excel format** (only) as a clearly numbered annex.* The detailed budget should account for all **new and/or expanded supporting interventions** for AMFm Phase 1. The detailed budget should also include a summary budget for monitoring AMFm Phase 1 and operational research (as provided in Sections 5d and 6b). It **should not include funding for additional ACT procurement nor additional health system strengthening activities**. These activities may only be funded when savings gained in existing Global Fund malaria grants exceed funding required for AMFm supporting interventions. These proposals should be detailed in Section 9 of the application form. *Applicants may use their own budget tools to provide this detailed budget, or, if preferred, may use the **detailed budget template** found at Attachment D.*	***Annex 16***

9. Use of savings in existing Global Fund grants

(9a) Additional ACT procurement through savings gained from lower AMFm cost of ACTs

As explained in Section 7, applicants may propose to use 'excess' savings gained from ACT budgets in existing Global Fund malaria grants to purchase additional ACTs for the public sector, if there are savings remaining after supporting interventions for AMFm have been budgeted. The total cost of additional ACT procurement must be less than or equal to these remaining savings.

i. Do you propose to reallocate savings to fund additional ACT procurement in your existing Global Fund malaria grant(s)?	☐ Yes Complete Sections 9aii and 9aiii
	☒ No
ii. Provide a rationale for this additional procurement, demonstrating the need for additional ACTs and identify the target population. [2 pages maximum]	

There are an estimated 120 million cases of malaria annually in Nigeria. It is estimated that roughly 20% of these cases (28.4 million) occur in remote areas or among underserved populations, and therefore will not be covered through the existing public and private sector health services. Nigeria has defined its universal coverage target as >80% of patients using ACTs within 24 hours of the onset of symptoms. In its ACT gap analysis for the GFR8, Nigeria therefore calculated its need based on 80% of the malaria burden, under the assumption that 20% of the population would not be reached.

With GFR8 resources, Nigeria's PRs will strive to reach a portion of these 28.4 million underserved people by procuring 7.5 million doses for hard-to-reach areas. As described in Section 4l, additional resources will be provided to support the distribution of these 7.5 million doses to outlets in the hardest to reach areas of the country. However, since this will only meet a quarter of the estimated need, this proposal will enable the procurement and distribution of a further 7.5 million doses to increase the equity of the AMFm's impact. After detailed consultation with the PRs and relevant SRs, it was determined that there was sufficient capacity to manage the effective distribution of this amount, but any further increase would be untenable. Thus in total, Nigeria will distribute 15 million ACTs over the next two years to underserved areas and populations, meeting roughly 50% of the national need in particularly underserved areas.

The age-weight breakdown for the 7.5 million-dose AL procurement under AMFm has been calculated based on the percentage of the population falling in each age category and incidence of fever per age category (Table 17). This order will be placed in the first year of AMFm Phase 1 and be distributed through a staggered delivery schedule. The ACTs will be distributed to the targeted areas through a public/private mixture of PPMVs, medical outreach, mission hospitals, and PLWHA through care networks to reach as many patients in the target areas as possible (Table 17). ACTs distributed through the private sector will be sold with minimal mark-ups in order to minimize the price to the target poor populations and apply competitive pressure on other private ACT distributors in the area. The PRs and SRs for AMFm will liaise closely with the National AIDS Control Agency, USAID PEPFAR programs and other GF HIV/AIDS PRs to maximize ACT distribution to this particularly vulnerable population.

9. Use of savings in existing Global Fund grants

Table 18: Additional AL Procurement Age-weight Breakdown

Additional AL Procurement	Year 1	Year 2	Total
1 x 6	2,368,421	--	2,368,421
2 x 6	1,657,895	--	1,657,895
3 x 6	1,105,262	--	1,105,262
4 x 6	2,368,421	--	2,368,421
TOTAL	7,500,000	--	7,500,000

Table 19: Distribution Channel Breakdown

Channel	%	AL Quantity
Not-for-profit and private sector medical outreaches	60%	4,500,000
Non-profit organizations' health facilities	40%	3,000,000

iii. **Complete Table B1 in Attachment B** of this application form to provide details of the proposed increased ACT procurement.

(9b) Additional health system strengthening (HSS) activities

Applicants may propose to use 'excess' savings gained in existing Global Fund malaria grants to fund additional health system strengthening activities relevant to ACT scale-up, if there are savings remaining after supporting interventions and any additional ACT procurement have been budgeted. The total cost of additional health system strengthening activities must be less than or equal to these remaining savings.

i. Do you propose to reallocate savings to fund additional health system strengthening activities relevant to ACT scale-up?	☐ Yes Complete Sections 9bii and 9biii
	☐ No
ii. Summarize your proposal to introduce additional health system strengthening activities relevant to ACT scale-up. Refer to the Guidelines for AMFm Phase 1 Applications for guidance on activities that will be supported. [2 pages maximum]	
iii. Provide a summary budget for the proposed additional health system strengthening activities relevant to ACT scale-up.	

9. Use of savings in existing Global Fund grants

Section	Document description	Annex Number
2bii	Minutes of 22nd CCM Nigeria Meeting held on 18th May 2009 ES.doc	1
2bii	GFR8 Principle and Sub Recipient Assessment Tool	2
Exec. Summary	National Malaria Strategic Plan (NMSP) 2006 – 2013	4
Exec. Summary	Mid-Term survey Report for GF	5
3a	2008 National Demographic Health Survey (NDHS)	6
3b	ACTwatch – Nigeria Draft Baseline Outlet Survey Report.pdf	7
3b, 3c	ACTwatch – Nigeria Rapid Supply Chain Diagnostic Executive Summary 2009	8
3b	National Anti-malarial Treatment Policy (Standard Treatment Guidelines)	8i
4a	National Malaria Control Behavior Change Communication Strategy	9
4b	National HIV/AIDS Health Survey	10
5a	NMCP M&E framework	11
5a,5e	Global Fund Round 8 Grant M&E Framework (existing)	12
5e	Global Fund Round 8 Grant M&E Framework (updated)	13
2bii	AMFm Phase 1 Application Form – Attachment C.xls	15
4n, 8e	AMFm Phase 1 Application Form – Workplan and Budget	16