



Investing in our future

The Global Fund

To Fight AIDS, Tuberculosis and Malaria

**Seventeenth Board Meeting
Geneva, 28 – 29 April 2008**

**GF/B17/4
Attachments**

**ATTACHMENTS
TO THE REPORT OF THE POLICY AND STRATEGY COMMITTEE**

Attachment 1: Draft version of the “Memorandum of Understanding”
between the Global Fund and UNAIDS

Attachment 2: Roadmap for UNITAID (GF/PSC9/02)

Attachment 3: AMFm Phase-in Document



Memorandum of Understanding

UNAIDS and The Global Fund to Fight AIDS, Tuberculosis and Malaria

Background

UNAIDS, the Joint United Nations Programme on HIV/AIDS, is an innovative joint venture of the United Nations family, bringing together the efforts and resources of ten UN system organizations (UNHCR, UNICEF, WFP, UNDP, UNFPA, UNODC, ILO, UNESCO, WHO and the World Bank) in the AIDS response to help the world prevent new HIV infections, care for people living with HIV, and mitigate the impact of the epidemic. UNAIDS helps mount and support an expanded response to AIDS – one that engages the efforts of many sectors and partners from government and civil society.

The Global Fund to Fight AIDS, Tuberculosis and Malaria (“Global Fund”) is a unique global public/private partnership dedicated to attracting and disbursing additional resources to prevent and treat HIV and AIDS, tuberculosis and malaria. This partnership between governments, civil society, the private sector and affected communities represents a new approach to international health financing. The Global Fund is one of the major organizations funding the international response to AIDS, as well as the largest provider of international funding to fight malaria and tuberculosis.

Through this Memorandum of Understanding, the Global Fund and UNAIDS (“partners”) set forth their mutual intention to collaborate to strengthen the global response to the AIDS epidemic and to accelerate progress towards Universal Access and the Millennium Development Goals (MDGs). In recognition of their complementary strengths and shared commitment, UNAIDS and the Global Fund plan to cooperate in a working relationship (“partnership”) based on overarching principles, agreed objectives and clear terms of partnership review and management.

This Memorandum of Understanding provides a framework for cooperation that enhances the roles of both the Global Fund and UNAIDS to strengthen support to national AIDS responses and to develop a more detailed relationship. This Memorandum of Understanding articulates objectives for cooperation in core activity areas, drawing on the complementary functions of UNAIDS and the Global Fund.

In all instances of this Memorandum of Understanding, the term UNAIDS refers to the Secretariat and its ten Cosponsors. The engagement of UNAIDS cosponsoring agencies with the Global Fund Secretariat, however, is not limited to the provisions of the present Memorandum of Understanding and not all Cosponsors are necessarily involved in every and all UNAIDS activities covered by this MOU. UNAIDS Secretariat and relevant Cosponsors will develop in partnership with the Global Fund follow-up operational arrangements under the framework of this Memorandum of Understanding.

Overarching Principles

UNAIDS and the Global Fund will continue to cooperate in a partnership based on the following Overarching Principles:

To move towards Universal Access to prevention, treatment, care and support by 2010

The Global Fund, as a financial mechanism, provides a large portion of the resources required to scale up towards Universal Access. UNAIDS works to empower countries in their efforts to move rapidly towards Universal Access and the Millennium Development Goals.

Empowering inclusive national leadership and ownership

The Global Fund supports country ownership and leadership through a performance-based funding process that responds to country-proposals, based firmly on country need and priority. UNAIDS works to support countries as they develop, implement and monitor evidence-based strategies and to support national efforts to make the funding from all partners work¹.

Alignment and Harmonization

UNAIDS and The Global Fund strive to harmonize support to national programs and align financial and monitoring and evaluation processes to increase aid-effectiveness, whenever possible. The importance of harmonization and alignment in increasing aid-effectiveness has been highlighted by the OECD/DAC, and agreed to through the Paris Declaration. The Three Ones Principle² introduced and championed by UNAIDS, along with the Global Task Team and the Division of Labour, are important examples of the operationalization of harmonization and alignment. By moving towards financing national plans, consolidating grants, and defining shared monitoring indicators with major partners, the Global Fund and UNAIDS will work together to link the principles of performance-based funding, multi-stakeholder participation and national ownership with harmonization and alignment and the Three Ones principle as well as gender equity and human rights.

Advocacy

UNAIDS guides and supports global advocacy efforts to ensure high level political support for a comprehensive response to AIDS. It works closely with Civil Society and other stakeholders including the World AIDS Campaign. The Global Fund in fulfilling its mandate to raise significant additional resources to mitigate the impact caused by AIDS coordinates closely with UNAIDS and its partners on advocacy efforts. Both organizations are complementing each other in reaching decision makers and key influencers around the world and achieving maximum synergies in advocacy and resource mobilization.

Partnerships

Partnerships and promoting inclusiveness has been a defining feature of both Partners and their approach to the epidemic. The multi-sectoral approach advanced by UNAIDS and the Global Fund has spanned the public, private and civil society arenas as well as thematic sectors (education, health, workplace). The Global Fund without a country presence of its own and a limited mandate as a financing agency is by its very nature an organization that

¹ In addition, the World Bank is a major funder of AIDS programmes in low and middle income countries.

² **One** agreed HIV/AIDS Action Framework that provides the basis for coordinating the work of all partners. **One** National AIDS Coordinating Authority, with a broad-based multisectoral mandate. **One** agreed country-level Monitoring and Evaluation System.

relies heavily on partnerships. UNAIDS with its global network and regional hubs provides a key structure to make the resources of the Global Fund work.

Core Activity Areas of the Partnership

1. Strategic Analysis and Policy Advice

- 1.1 The Global Fund will solicit UNAIDS support in the process of identifying membership of the Technical Review Panel (TRP) and providing input on content and participation when organizing comprehensive technical briefings. Both partners recognize that the TRP is an independent body and that the technical review process is subject to policies and procedures specified by the Global Fund.
- 1.2 UNAIDS will support the development of policies of the Global Fund through active participation on its board and committees; offering technical expertise, promoting accountability and helping to build consensus among stakeholders. The Global Fund Secretariat will be invited to send a representative to attend all meetings of the UNIADS Programme Coordinating Board (PCB) as an observer and to participate, as such, in discussions on the Global Fund.
- 1.3 UNAIDS and the Global Fund will work to keep AIDS a priority on the global agenda, including the UN and the G8. They will cooperate to mobilize various constituencies and to recognize the unique contribution of each. Both partners will advocate jointly to make sure that sufficient resources are mobilized for a comprehensive and sustainable response to the pandemic.
- 1.4 UNAIDS will continue work to support the development and validation of well articulated National Strategic Plans (NSPs), based on scientific evidence and human rights. UNAIDS and the Global Fund will work together to ensure, to the extent possible, within each partner's policy framework continuation of programmes and services in humanitarian settings.
- 1.5 UNAIDS and the Global Fund will support multi-stakeholder membership of Country Coordinating Mechanisms (CCMs) in coordination and oversight of Global Fund grants and promoting national ownership by a broad range of national stakeholders, including Civil Society Organizations (CSOs), People living with HIV (PLHIV), gender experts and young people.
- 1.6 UNAIDS Country Coordinator or the Cosponsor(s) representative(s) sitting in the CCM will represent UNAIDS as a whole and ensure that a proper and timely consultative process is in place.
- 1.7 The Global Fund is committed to fund programmes that are driven by scientific evidence. In particular, the Global Fund emphasizes its continuing commitment to reach the most-at-risk populations, especially in countries with concentrated epidemics. UNAIDS and the Global Fund will support development and funding of programmes that cover the needs of vulnerable groups and most-at-risk populations, including displaced persons.
- 1.8 UNAIDS will support the Global Fund and its in-country partners by sharing epidemiological and other data to help in the development of Global Fund policy priorities including information relevant for assessing country eligibility for Global Fund

support. The Global Fund and UNAIDS will harmonize, to the greatest extent possible data collection procedures, analysis and calendar timing.

- 1.9 UNAIDS and the Global Fund are committed to work on generating high quality proposals from as many countries as possible, and to work on the implementation and monitoring of existing grants, in support of national strategies that are acceptable for Global Fund financing. UNAIDS Regional Offices will provide support to regional projects funded by the Global Fund.
- 1.10 In order to further strengthen the partnership and coordinate support at regional and country level, the Global Fund and UNAIDS will coordinate and, to the extent practical and useful, hold their meetings regional and country level jointly I.

2. Technical Support

- 2.1 UNAIDS, through engagement at political level and advocacy at regional and country level, will act as a steward for National Strategic Plans and grant life cycle support; providing constructive reviews and comments to the principal recipient (PR) and CCM on grant performance for results-based sustained accountability.
- 2.2 Both partners recognize the unique role and contribution of UNAIDS in technical support as agreed within UNAIDS' Division of Labour, in providing high quality technical assistance, norms, guidance and operational tools and ensuring that technical assistance is effective.
- 2.3 Both partners will work with country programs to identify early technical support needs at the country and regional level (recognizing programmatic and financial gaps); sharing information through joint country, regional and global meetings.
- 2.4 UNAIDS and The Global Fund encourage national ownership of program implementation and agree that country programs are ultimately responsible for identifying and coordinating resources for technical support. To this effect, UNAIDS will work with country programs when requested to help ensure that adequate plans and technical support resources are built into Global Fund proposals and contracts.
- 2.5 Both partners will encourage use of existing initiatives and resources, and will avoid duplicating the capacity of other partners. Specific examples of existing capacity include the Global Implementation Support Team (GIST) and the AIDS Strategy and Action Plan.
- 2.6 UNAIDS and The Global Fund recognize the importance of health systems strengthening for achieving the objective of Universal Access and commit to jointly fostering coordination of key actors at country level and better integration of HIV responses in national health systems.
- 2.7 Both partners will work together to build capacity of national stakeholders and in particular the non-governmental and community sectors to be able to participate more fully in CCMs and will promote participation of civil society, people living with HIV, women, gender expertise and representatives of marginalized groups.

3. Monitoring and Evaluation

There are two major areas for collaboration for monitoring and evaluation (M&E) within this Memorandum of Understanding: (i) monitoring the implementation and impact of Global Fund grants within the context of the overall response to the epidemic, and (ii) monitoring the actual implementation of the MOU.

3.1 Monitoring the effectiveness of the response:

- 3.1.1 Monitoring AIDS strategies and programmes to ensure that they are effective in reducing the epidemic and its impact is a central element in the mandate of UNAIDS. Equally, evaluating and reporting the results, effect and impact of the programs it supports are a fundamental component of the Global Fund's model and mandate. UNAIDS is well positioned to support the Global Fund's monitoring and evaluation needs and will work with the Fund to establish the best ways of providing that support at country, regional and global level. Illustrative examples of areas of collaboration are outlined below. These will be further defined over the next six months through close collaboration among the Global Fund, UNAIDS and relevant partners.
- 3.1.2 At the country level, the Global Fund is committed to providing ongoing resources to recipients on the basis of demonstrated needs and positive results. Countries require assistance in meeting the challenges of performance-based financing of programmes. UNAIDS' monitoring and evaluation experts can provide support in establishing and strengthening national monitoring and evaluation systems and contribute to the design of monitoring and evaluation plans. This includes developing indicators that are aligned to international measures and making consistent data available on a regular basis on key national prevention, treatment and care activities. UNAIDS has established annual reporting, which builds on the work of the United Nations General Assembly Special Session on HIV/AIDS. Annual statistics on services allow the Global Fund to place their coverage numbers in a national context.
- 3.1.3 UNAIDS can also assist in implementing the joint M&E systems strengthening tools with countries, and provide support to and join in coordinated efforts to strengthen M&E systems. Additionally, UNAIDS can support the Global Fund and national stakeholders in the monitoring of gender-specific indicators for AIDS and also ensure that all indicators and targets (including those that may change during the course of a grant) are in line with national plans.
- 3.1.4 Country Coordinating Mechanisms (CCMs) have a central role in overseeing the implementation by the Principal Recipient (PR) of Global Fund supported programs. UNAIDS can support CCMs and PRs to fulfill these functions, as part of its overall support for country-driven monitoring and evaluation processes and consistent with its objective of building national capacity to monitor performance and to use this information effectively.
- 3.1.5 The Global Fund reviews ongoing progress of grant implementation, both centrally and through Local Fund Agents (or "LFAs"), who receive and review reports from PRs. LFAs and UNAIDS should have access to one and each other's information at country level. To the extent possible, the Global Fund will facilitate UNAIDS' access to findings of LFA

reports in order to better support grantees in the implementation and monitoring of programmes.

3.1.6 At regional level, UNAIDS Regional Support Teams and regional offices of Cosponsors can provide data and analysis to monitor and evaluate regional activities that receive Global Fund grants.

3.1.7 At global level, the Global Fund acknowledges the responsibility and expertise of UNAIDS in monitoring and evaluation in relation to HIV and will draw on this support in the ongoing development of its own monitoring and evaluation framework. Through participation in the UNAIDS Monitoring and Evaluation Reference Group (MERG), which advises on harmonized approaches to HIV transmission and AIDS HIV/AIDS monitoring and evaluation among stakeholders, the Global Fund Secretariat can access this expertise and draw on UNAIDS for assistance in determining appropriate indicators, methodologies and quality assurance mechanisms.

3.1.8 In evaluating its own performance at the aggregate level, including its overall contributions to global AIDS resource flows and the achievement of clear, measurable and sustainable results in the fight against AIDS, the Global Fund will use data provided by UNAIDS, including information on existing country and international resources and the additionality of the Global Fund to the overall response.

3.2 Monitoring the implementation of the Memorandum of Understanding

3.2.1 UNAIDS and the Global Fund will develop a monitoring and evaluation framework that will provide an ongoing assessment of the successful implementation of this MoU. The Framework will focus on assessing adherence to the principles that are laid out in the MoU and will monitor implementation of the defined Partnership Objectives.

3.2.2 This Framework will build on existing reporting systems, such as those designed as part of the Performance Monitoring and Evaluation Framework for the UNAIDS Unified Budget and Workplan. Multiple data sources are also available, including national reporting on the indicators for the UN General Assembly Special Session on HIV/AIDS, the UCC annual surveys, the UNAIDS Inter-Agency Task Team (IATT), National HIV/AIDS Secretariat (NAS), the Country Response Information System (CRIS) and data from the Technical Support Facilities that document utilization of technical assistance.

Terms

The partnership agreements specified in this Memorandum of Understanding will be reviewed regularly and will be supplemented by more detailed work-plan agreements to incorporate particular activities with relevant Cosponsoring agencies. This Memorandum of Understanding is a living document and both partners agree that as the partnership develops the agreement will strengthen accordingly and provide basis for future cooperative arrangements. UNAIDS and the Global Fund agree to adhere to the principle of mutual accountability and responsibility for the implementation of this Memorandum of Understanding.

Both partners will communicate and share information in advance of arrangements they make that could have direct implications for or directly impact on the other partner and to make those arrangements in keeping with the provisions of this Memorandum of Understanding.

Both partners will nominate global coordination focal points, who will serve as the main channels of communication and information in relation to this Memorandum of Understanding.

Effective Period

This Memorandum of Understanding replaces the memorandum of understanding between the Global Fund and UNAIDS Secretariat, dated 4 August 2003 and will be valid from the date of signature by both partners and will be reviewed on an annual basis, at which time the partnership framework will be evaluated and revised as appropriate by the partners.

Signed:

Peter Piot
Executive Director
UNAIDS

Michel Kazatchkine
Executive Director
The Global Fund

Date: _____

Date: _____

**ROADMAP FOR THE STRATEGIC COLLABORATION
 BETWEEN THE GLOBAL FUND AND UNITAID**

Outline: This paper presents to the Policy and Strategy Committee (PSC) a description of the UNITAID-Global Fund strategic framework “roadmap” for ongoing cooperation between the two institutions, and requests approval for the collaboration proposed therein.

Executive Summary:

At the Fourteenth Board Meeting, the Global Fund Board requested the Secretariat under the oversight of the PSC, to develop a strategic framework (“the roadmap”) to guide the design of collaborations with UNITAID. Building on progress made and reported to the PSC and the Board in late 2007, the Secretariat has further defined areas for collaboration with UNITAID. The roadmap spans the three diseases and describes what can be achieved in each area, focusing on UNITAID’s treatment niches of second line and paediatric antiretrovirals, second line tuberculosis treatments and artemisinin-combination therapies. In addition, the framework describes collaborations in the cross-cutting areas of information sharing and diagnostics.

The PSC is requested to recommend the following decision point to the Board:

Decision point: Strategic Framework for Collaboration (“Roadmap”) with UNITAID

The Board refers to its decision (GF/B14/DP23) to request the Policy and Strategy Committee to work with the Secretariat and the Finance and Audit Committee to develop a roadmap for future collaboration with UNITAID. The Board approves the proposed framework and requests the Secretariat under the oversight of the PSC to proceed with collaboration in the five areas described in the proposed framework, and delegates to the PSC the authority to approve any new policies or policy changes arising out of these collaborations to facilitate their implementation.

The budgetary implications of this decision point in 2008 amount to US\$ 146,069, which includes an allocation for one staff position.

Part 1: Introduction

1. At the Fourteenth Board Meeting, the Global Fund Board requested the PSC to work with the Secretariat and the Finance and Audit Committee to develop a strategic framework (or “roadmap”) for future collaboration with UNITAID. At the Sixteenth Board Meeting, the PSC presented the Board with a progress update on the Roadmap. In 2007 the Global Fund and UNITAID signed three agreements for ongoing initiatives: the artemisinin-combination therapy (ACT) Scale-up Initiative; the multi-drug-resistant tuberculosis (MDR-TB) Scale-up Initiative and a collaboration to fund medicines in UNITAID niches for Round 6 recipients.¹

2. This paper describes five proposed areas for collaboration with UNITAID under a roadmap framework. Roadmap development has been informed by the experience of collaboration on current initiatives and the further strategic development of both organizations both of which have increased clarity on the areas, objectives and approaches for collaboration.

Part 2: Roadmap – Areas of Collaboration

1. Discussions between the Global Fund and UNITAID have focused on opportunities for collaboration in **each of the three disease areas** and **cross-cutting information sharing**. All proposed joint efforts are seen to further the objectives of both organizations and to have low transaction costs if designed appropriately.

2. Malaria: Improving access and affordability of ACT malaria medicines through the AMFm

- i. **Background and objectives:** The Boards of both UNITAID and the Global Fund have discussed the Affordable Medicines Facility for Malaria as an opportunity for greatly increasing access to affordable artemisinin combination therapy (ACTs). The key objectives of the AMFm of reducing end user prices and thus contributing to increased access to ACTs are consistent with the objectives of both organizations. In addition, the AMFm is expected to increase the long-term stability of the ACT market by ensuring a sustainable supply of ACTs through better forecasting of demand and a predictable co-payment mechanism. As a result, both organizations have engaged in discussions about options for collaboration in financing and implementing the AMFm building on the strengths and priorities of each. This is subject to agreement by the Global Fund Board to host the AMFm.
- ii. **The concept:** The Global Fund would integrate the AMFm as a business line within the Global Fund and be responsible for its management. UNITAID could contribute to the sustainability of the AMFm for the currently anticipated life-span of the facility through annual contributions to the co-payment fund held by the Global Fund’s trustee, as one of the AMFm’s major donors. Discussions will take place to define the specific role for UNITAID including ACT demand forecasting and price negotiations with suppliers.
- iii. **How it would work:** In the AMFm business model, a separate sub-fund is envisaged with the Global Fund Trustee for the financing of co-payments for ACTs. UNITAID would become a key contributor to the ACT copayment fund. In addition, UNITAID could make an important contribution to the price and copayment negotiations with manufacturers which the Global Fund, as the manager of the facility, would have to perform. The related skills are very specific, and a potential strategic partnership with UNITAID, with its experience in working with negotiation specialists could be advantageous. The scope and details of this strategic partnership would need to be worked out based on the evolving negotiation. In addition, UNITAID could play an important role in ACT demand forecasting, strengthening global treatment projections and market expertise critical to the success of this venture.

¹ More information on current initiatives is given in Annex 1

- iv. **Next steps:** Should the Global Fund Board decide to host the AMFm, the delineation of responsibilities and accountability between the Global Fund as the manager of the AMFm and UNITAID would need to be further elaborated to allow a final decision by both Boards.

3. Tuberculosis: Achieving market impact and increasing access to MDR-TB medicines

- i. **Background and concept:** UNITAID has selected MDR-TB medicines as one of the niche areas in which it aims to achieve market impact. The scale-up initiative between UNITAID, Stop TB and the Global Fund targets well-performing Global Fund grants that have capacity to treat additional patients. This is achieved through the donation of MDR-TB medicines funded by UNITAID and supplied by the Global Drug Facility (GDF) and the re-programming of Global Fund funds to cover operational costs for scale-up. In addition, UNITAID contributes funds to support the procurement of MDR-TB medicines for Round 6 recipients. Whilst implementation of both initiatives is successfully underway, transaction costs could be reduced.
- ii. In the future collaboration, UNITAID would still fund TB drug components for Global Fund grantees, with a special focus on MDR-TB. However, the collaboration would be exclusively for new grantees and grantees requesting additional funding at the end of a grant's five year term ("rolling continuation channel" funds or RCC) to enable better forecasting of treatment needs and required funding commitments. In addition, financial transactions would be streamlined to reduce transaction costs and promote market impact through greater predictability of cash flow.
- iii. **How it would work:** The Global Fund would aggregate the need for MDR-TB medicines submitted in approved proposals so that UNITAID and GDF could project a treatment forecast and determine the required funding commitment by UNITAID to finance the medicines. Grant recipients would receive drug contributions directly, rather than first receiving funding to pay GDF/GLC for the purchase MDR-TB drugs through the mandated GDF/GLC mechanism. This would have the significant benefit of reducing transaction costs, particularly in allowing direct payment to GDF resulting in a potentially improved bargaining position for GDF with manufacturers, with the aim of improving prices and the overall stability of this market. Moreover, this will also shorten delivery lead-times. The disbursement of drugs, like Global Fund financing, would be linked with the Global Fund's performance requirements.
- iv. **Policy implications:** The above process is consistent with existing Global Fund policy mandating Principal Recipients (PRs) to use GLC/GDF for the procurement of 2nd line TB medicines. However, instead of PRs receiving finances for MDR-TB drugs from the Global Fund and then paying GDF, PRs would receive drugs directly from GDF. This shift would need to be documented as a specific policy to facilitate UNITAID funding of MDR-TB medicines.
- v. There are also policy implications for UNITAID. Experience with current initiatives has demonstrated that compliance with UNITAID's eligibility criteria² needs to be reconsidered. If the collaboration described above as well as any other initiatives focused on MDR-TB are to achieve significant market impact, the inclusion of middle income countries with a high disease burden will need to be addressed.
- vi. **Next steps:** Additional work on necessary policy changes and related Board decisions would be completed for review by the PSC in September and subsequent Board consideration.

4. HIV/AIDS: Improving access to affordable paediatric and 2nd line antiretrovirals (ARV)

- i. **Paediatric ARV:** UNITAID is currently working closely with the Clinton HIV/AIDS Initiative (CHAI) to lower prices and increase access to paediatric ARVs and other essential paediatric medicines in a number of countries. UNITAID and CHAI have just signed an agreement to expand this work

² UNITAID's eligibility criteria requires that at least 85% of UNITAID funds must be dedicated to purchase commodities for low income countries (LICs). No more than 10% of UNITAID funds must be dedicated to purchase commodities for lower middle income countries (LMICs). No more than 5% of UNITAID funds must be dedicated to purchase commodities for upper middle income countries (UMICs) with priority given to those with a high disease prevalence, subject to these countries providing co-financing for their projects of 20% in year one rising to 40% in year five for a project of that duration.

in the number of countries and timeframe, extending programs until 2010. To ensure sustainability and meet the increasing needs of these programs once the desired market impact has been achieved, UNITAID, CHAI and the Global Fund will engage in joint planning for the transition and scaling up of these programs via Global Fund and/or other funding sources. PRs would be assisted in submitting new HIV grant proposals incorporating paediatric treatments. To this end, the Global Fund Secretariat and UNITAID will agree on steps for a smooth transition and optimal coordination for the program duration.

- ii. **2nd line ARV, concept and background:** UNITAID's partnership with CHAI in this niche has resulted in significantly reduced prices for a number of products, benefiting countries receiving direct UNITAID financed medicines procured through CHAI. The proposed future collaboration between the Global Fund and UNITAID would expand on the UNITAID/CHAI pooled procurement partnership model. In future proposal Rounds and within RCC, applicants would be able to choose whether to receive drugs directly through pooled procurement or to receive grant funds to purchase drugs themselves. For those choosing to receive drugs, the pooled procurement mechanism established by UNITAID/CHAI could be used, and UNITAID would finance the products purchased and delivered through this mechanism.
- iii. **How it would work:** The envisioned model would be similar to that outlined for MDR-TB above, the key difference being that the choice to receive drugs directly, rather than funding for the drugs through the Global Fund, would be voluntary, in line with the decisions of the Global Fund Board. PRs would select to receive either the drugs or funding. The Global Fund would aggregate quantities of treatments requested by PRs opting to receive drugs. The finalization of the Global Fund's pooled procurement model may help to further define the options available for the most efficient collaboration and the optimal flow of funds.
- iv. **Next steps:** The Global Fund Secretariat would work with UNITAID to assess whether and how the proposed collaboration could fit with the Global Fund's pooled procurement mechanism, including how the disbursement of drugs through the UNITAID financed pooled procurement system would meet the Global Fund's performance-based funding requirements. Further details and proposed policy changes will be presented to the PSC and Board later this year.

5. Improving and aligning data and information sharing

- i. **Concept:** UNITAID and the Global Fund have a shared interest in improving procurement data and their use in analysis and forecasting. This has led to a commitment by both organizations to upgrade their own systems to provide improved data from their activities to be compiled into a global repository of procurement related information. This system, hosted by WHO, will allow the Global Fund, UNITAID and other partners to perform detailed market analysis in a number of areas including pricing. It will also be available to PRs in country allowing them to compare procurement related costs and make better informed procurement choices. In addition, UNITAID and the Global Fund would proactively share market forecast data and programmatic treatment projections for ACTs within AMFm as well as for ARV and MDR-TB.
- ii. **How it will work:** At present, the Global Fund and UNITAID, along with nine other organizations that directly procure or fund procurement of medicines, input procurement data into a shared global tool, hosted by WHO AIDS Medicines and Diagnostic Services (AMDS). The system, called the "Global Price Reporting Mechanism" (GPRM) tracks procurement related data covering medicines for all three diseases but is limited by the scope, completeness and accuracy of data. In the future, UNITAID and the Global Fund would work with its partners to increase the quality, volume and analysis of data captured in the GPRM. In the meantime, the Global Fund is strengthening its PRM, with compatibility with the GPRM as an important element.
- iii. The next steps within this area will be guided by the ongoing work and discussions at WHO around the development of the GPRM. Progress for the redesign of the PRM is well underway and it is expected that this work will be completed in early 2009.

6. Diagnostics

- i. Discussions at the UNITAID Board have highlighted the need for better access and more affordable diagnostics to improve the impact and efficient use of medicines in the fight against the three diseases. UNITAID is currently evaluating the market impact of providing funding for diagnostics and, pending a UNITAID Board decision in this area, the Global Fund and UNITAID will discuss collaboration in this area.

This document is part of an internal deliberative process of the Fund and as such cannot be made public. Please refer to the Global Fund's documents policy for further guidance.

Annex 1

Progress on current initiatives

1. Agreements for all three current initiatives with UNITAID (MDR-TB and ACT Scale up; Round 6) were signed in 2007 for a value of \$144.5 million. For recipients involved in ACT or MDR-TB scale-up, grant amendment to include increased treatment targets as a result of the additional UNITAID treatments is ongoing. Orders for scale-up drugs have been placed with both UNICEF and GDF (as the chosen procurement partners for each initiative) and the first drugs are expected to be delivered soon.
2. The Global Fund Trustee has received UNITAID's financial contribution for Round 6 procurement of UNITAID niche products. The Global Fund will report on the procurement of Round 6 participating grants using the price reporting mechanism, allowing UNITAID to use this data for market analysis and forecasting of treatment needs.

**AFFORDABLE MEDICINES FACILITY – MALARIA
ASSESSMENT OF IMPLEMENTATION APPROACH WITH AN INITIAL ROLL-OUT**

1. Background: Initial Roll-Out approach

At the request of the PSC chair, the Secretariat has explored a phasing approach to the AMFm which involves an initial roll-out to a first set of countries. The purpose of this approach would be to ensure that initial implementation is appropriately monitored and evaluated before moving to global implementation. This assessment focuses on whether this phasing approach would be feasible and what the pre-requisites would be for it to be successful.

A decision to pursue an implementation approach with an Initial Roll-out would have implications for the implementation plan for launching the AMFm which are described below.

2.1 Design for an implementation approach with an Initial Roll Out

The key added design features of an Initial Roll Out would include:

- Selection of a first group of countries for the initial phase of the AMFm implementation with consequent reduced financial requirements
- Roll-out of the AMFm in these countries for a limited time period of 9-12 months
- Independent review of objectives for the initial roll-out of the AMFm, using a set of pre-defined key indicators
- Board decision to extend the AMFm to all countries that have demonstrated preparedness; alternatively adjustments to (or even suspension of) the AMFm if basic objectives are not met

Intensive monitoring and operational research would be carried out during this initial phase to measure whether the AMFm can reach its objectives and provide learning about the intervention that would inform a subsequent Board decision on full roll-out. An initial phase-in of the AMFm would have specific limitations that would need to be reflected in its design, particularly in terms of market impact and added risks such as hoarding and cross-border arbitrage. The initial phase would allow markets to respond partially but it may not be realistic to expect the full targeted impact in terms of price outcomes, access for poor populations and displacement of antimalarials or prevention of resistance within the limited period.

The sections below discuss the approach, challenges and risks step by step.

2.2 Selection of Countries in the initial phase

Participation in the initial phase would be determined by the application of specific criteria to the selection of countries. Feasible criteria that could be applied in this selection include:

- Suitable malaria-treatment profile, which could for example include a) high malaria endemicity, b) ACT as first line treatment, c) suitable approach to re-scheduling ACTs for wide access
- Conditions that would be conducive to rapid application, approval and roll-out after the GF Board decision in November 2008, which for example would be influenced by a) strong regulatory environment, b) presence of existing GF grants, c) presence of on-going subsidy schemes.
- Regional grouping to limit risk of cross-border arbitrage and hoarding, which would negatively impact the costs and impact in the Initial Phase

The Secretariat would require a mandate to perform further analysis to facilitate selection of this first group of countries, in conjunction with RBM.

This selection of a group of countries to participate in the initial phase may represent a partial departure from some of the principles of demand-driven Global Fund financing. However, it should be noted that the initial phase would be time-limited and in preparation for a planned full global roll-out to all prepared countries. Countries would also retain full national ownership and accountability in rolling out the AMFm.

Due to the constrained scope, the financial requirements for the Initial Phase would be relatively modest compared with the planned full scope launch of the AMFm. A preliminary estimated USD 90-120M would be required, for both co-payment and supporting interventions, assuming an expected grouping of 10-15 countries and a roll-out period of 12 months.

2.3 Milestones for the initial phase

The initial partial roll-out would proceed subsequent to an affirmative Board decision in November 2008, with a targeted roll-out to the selected countries in April/May 2009. The implementation plan for this Phase would be developed prior to the November Board Meeting.

Table 1: Timeline for the initial phase

Activity	Timing
Board decision on initial phase of AMFm implementation (including policy framework, resource mobilization; manufacturer pre-negotiations)	November 2008
Preparation for initial phase launch (e.g. definition of OR baselines, country application, approval of country preparedness; manufacturer negotiations)	November 2008 – April 2009
Launch of AMFm initial phase (first co-payments)	April-May 2009
Collection of M&E and operational research data	January 2010
Submission of evaluation of initial phase as part of the PSC and Board documentation	March 2010
Board decision on AMFm launch in all eligible countries	April 2010

It will be important to make clear the intent of the Global Fund to proceed from the initial phase to a full implementation in all eligible countries unless clear “red flags” arise. This means that preparation of countries other than those included in the initial phase should be pursued in parallel in order to minimise delays in implementation should the Board decide positively in favour of an extension of the AMFm in April 2010. This is the only way to guarantee, at least to the maximum extent possible, that

the initial roll out approach will not reduce the impact of the AMFm as a means to limit the onset of artemisinin resistance. The behaviour of manufacturers, buyers and local providers and their decisions about producing, buying, stocking and selling co-paid ACTs will be shaped by their expectations about the implementation of the AMFm. It is expected that, if it is clearly communicated that a Global Roll out is planned following the initial phase, pharmaceutical manufacturers will still extend their current public sector prices (no-profit-no-loss) to the AMFm. However, decisions about entry of new manufacturers, investment in production capacity, and levels of artemisinin production may be negatively impacted by the increased uncertainty and should be closely monitored.

2.4 Learning from the initial phase

During this first phase, extensive monitoring and operational research would be carried out to assess whether the AMFm can meet its objectives. Monitoring in the Initial Phase would track key indicators of progress that can be collected in a short period of time and that have already been proposed in the AMFm technical design by the RBM Monitoring and Evaluation Reference Group (MERG):

- Cumulative percentage mark up between retail median unit price and manufacturers unit price for full course of ACTs
- Median cost to patient of full course of ACT relative to daily minimum wage for a government unskilled worker
- Proportion of providers reporting no disruption of stock of ACTs for more than one week during the previous three months
- Proportion of distributing outlets stocking ACTs
- Absolute volumes of ACTs sold by distributing outlets in the last month
- Relative share of co-paid ACTs to other anti-malarials as bought by consumers in distributing outlets in the last month

Further work with the MERG would be required to finalize and complete this indicator set, including identification of indicators that could help to assess equity in access to ACTs. In addition, operational research in initial phase countries would focus on the effectiveness of supporting interventions and programmes to reach the poorest.

“Red flags” that would establish the case for considering serious adjustments to the technical design of the AMFm or to not proceed to full implementation of the AMFm would be based around this set of indicators. Their evaluation would need to take into account that the impact at the end of the initial phase (after approximately 6-8 months) would not have reached the expected long-term level of impact of the AMFm, and targets would have to be adjusted accordingly. There is a risk that hoarding and cross-border arbitrage to countries not participating in the Initial Phase would bias monitored indicators. This could potentially be mitigated through selection of cooperative and trusted wholesalers.

Operational research during the initial phase could provide additional valuable insights into the response and success factors for the AMFm in different country environments and supply chain structures. However, there would be specific limitations to what could be learned from an initial phase. It would not provide data on the reduction in malaria mortality associated with the AMFm due to the limited duration and the inherent difficulty in establishing causality. Other targets for global implementation of the AMFm, particularly its impact on manufacturing markets, and on delaying the onset of resistance can also not be observed in an initial phase.

The period of approximately 6-8 months for evaluating the initial phase represents a significant constraint in this phased implementation design. An alternative would be to delay collection of data,

pushing the Board decision on a global launch to November 2010, but this would delay full AMFm launch by an additional six months, and increase the negative impacts of a delayed global roll-out.

3 Conclusion

In conclusion, an initial roll out of the AMFm is a technically feasible approach which is in line with the basic principles of the AMFm. The constraints and risks of this approach need to be weighed against its potential benefits such as additional learning opportunities and lower initial resource needs which may allow for a consensus to move forward with the AMFm.

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