



Investing in our future

The Global Fund

To Fight AIDS, Tuberculosis and Malaria

**Ninth Board Meeting
Arusha, 18 - 19 November 2004**

GF/B9/9

REPORT OF THE PORTFOLIO MANAGEMENT AND PROCUREMENT COMMITTEE

Outline: This report covers the deliberations of the Portfolio Management and Procurement Committee, including on the Technical Review Panel, continuity of services, reprogramming in the light of changing scientific evidence, and quality assurance of single- and limited-source pharmaceutical products.

Summary of Decision Points:

The PMPC recommends that:

1. The Board adopts the decision points related to the Technical Review Panel (decision points 1 – 3 on pages 2 and 4);
2. The Board adopts the decision points related to the Guidelines for Proposals for the Fifth Call for Proposals (decision point 4 on page 6);
3. The Board adopts the decision points related to continuity of services (decision points 5 – 6 on page 8);
4. The Board adopts the decision points related to reprogramming in the light of changing scientific evidence (decision points 7 – 8 on page 10); and
5. The Board adopts the decision points related to quality assurance for single- and limited-source pharmaceutical products (decision point 9 on page 11 – 12).

Part 1: Introduction

1. The Portfolio Management and Procurement Committee met on 27 – 28 September 2004 in Geneva. The agenda for the meeting is included as Annex 1. The Chair and Vice-Chair of the meeting were Professor Francis Omaswa (East and Southern Africa) and Dr. Kate Taylor (Private Sector), respectively. The list of attendees is included as Annex 2A. The committee had a follow-up teleconference on 21 October 2004 (attendees listed in Annex 2B).
2. All recommendations represent the consensus of the committee except the last, which is a near unanimous recommendation (as described in Part 10).

Part 2: Renewal of the Technical Review Panel

1. Prior to the Fourth Call for Proposals, a major effort was undertaken to identify new TRP experts. In addition to addressing immediate needs, a pool of qualified candidates was created, the TRP Support Group. It was envisioned that future selection of TRP members would be greatly facilitated by being able to draw from this pool.
2. However, the initial recruitment yielded insufficient experts on tuberculosis, so a dedicated recruitment process was needed for TB experts for the Fifth Call for Proposals. Based on the lessons learned during the last renewal process the Secretariat requested constituencies, WHO and the Stop TB Partnership to nominate suitable experts.
3. Similar to previous TRP renewals the Secretariat engaged the Health Systems Resources Centre (HSRC) to provide a ranking of candidates against the same criteria as previously. The Secretariat received 45 nominations of which 27 applied and were ranked by HSRC. The ranking of candidates indicated that the pool was of a very high standard with around 80% being considered to be well or very well qualified for the TRP.
4. The PMPC and the Executive Director ultimately recommended two of these candidates as members for Round 5, with two others identified as alternates. The remaining candidates were placed in the TRP Support Group in ranked order. The PMPC and the Executive Director drew upon the TRP Support Group to find a replacement for a departing cross-cutting expert. An HIV/AIDS expert was also replaced, but in this case a TRP member who had been selected for Round 3 but who had been unavailable for Round 4 simply returned to active membership.
5. The complete list of recommended new TRP members is included as Annex 3, along with a list of existing TRP members and demographic statistics. Annex 4 contains the new members of the TRP Support Group, along with the existing TRP Support Group members.

Decision Points 1-2:

1. The Board approves the list of persons contained in Annex 3 of the Report of the Portfolio Management and Procurement Committee (GF/B9/9) who have been recommended by the Portfolio Management and Procurement Committee and the Executive Director to fill the vacancies on the Technical Review Panel.

There are no material budgetary implications for this decision point.

2. The Board approves the list of persons contained in Annex 4 that have been recommended by the PMPC and the Executive Director to comprise the TRP Support Group.

There are no material budgetary implications for this decision point.

Part 3: Length of Time TRP Members are Permitted to Serve

1. At the Eighth Board Meeting, the Board requested the PMPC “to address the length of time TRP members are permitted to serve on the TRP at the Ninth Board Meeting.” This decision was taken in the context of concern on the part of the Board as to the impact on the TRP of the loss of expertise and institutional memory as a result of the mandatory limit set on the number of Rounds that a TRP member may serve.
2. The duration TRP members are allowed to service has been a regular feature of Board discussions on the TRP. The rotation period was originally set at two Rounds of proposal review, but was subsequently increased at the Fourth and Sixth Board Meetings to the current four Rounds. This was seen as balancing between the need to retain sufficient institutional knowledge and the desire to have a certain amount of regular reinvigoration of the TRP membership.
3. At the Eighth Board Meeting, two distinct types of concerns were voiced about the current system. The TRP itself indicated that it felt that the current system was generally satisfactory, but was concerned by the fact that the limit of four Rounds might limit continuity in the leadership of the TRP. In this context, the Board extend the maximum period that the incoming Chair of the TRP can serve from four Rounds to five Rounds.
4. Separately, some Board Members queried the existence of any term limits on the length of time TRP members can serve. Some Board Members suggested that it would be more appropriate to allow well-performing TRP members to serve indefinitely.
5. During discussions the PMPC concluded that the current system adequately balances between the need for stability and the added-value of a rotation system that ensures members regularly join the TRP, thereby introducing new perspectives, and that facilitates efforts to improve the current regional and gender imbalances.
6. Further, it was recognized that the current system provides the Board with the flexibility to address concerns related to the tenure of TRP members as needed. For example, to address concerns about continuity, the Board had extended the current Chair’s length of service.

Part 4: Report of the Technical Review Panel to the Eighth Board Meeting

1. At its Eighth Meeting, the Board requested the PMPC “to further consider the Report of the TRP [to the Eighth Board Meeting] and to recommend specific actions to address the issues raised by the TRP” and to report back at the Ninth Board Meeting.
2. The committee reviewed the TRP’s Report, looking at topics including the scope of proposals submitted, how to treat repeated submissions (e.g., when an applicant was already in the course of implementing a proposal from an earlier Round), and how to handle very large proposals. Other aspects of the Report were addressed separately in the context of revising the Guidelines for Proposals.
3. As a result of the experience in Round 4 – in which the TRP recommended that the Board approve reduced financial commitments for three proposals (by spreading the first year budget over two years) – the committee felt that it was appropriate to broaden the scope of how the conditional approval by the Board of proposals in Category 2 is characterized. Previously, the approval was conditional simply on applicants responding to TRP “clarifications,” despite the fact that in some cases the TRP was actually making changes that were beyond a colloquial definition of “clarification.”

Therefore, the committee recommended specifying that proposal approval was contingent upon applicants responding to TRP “adjustments” as well as clarifications.

4. Shortly before the PMPC meeting, the Chair of the committee received a draft of a report from former TRP members (which addressed some of the same topics, but also included further issues). The committee briefly reviewed this report, but felt that it required more time to discuss it. Therefore, the committee noted and appreciated the report prepared by former TRP members, and noted that the committee intends to consider the findings and implications of the report in consultation with former and current TRP members and propose recommendations for Board consideration by the Tenth Board Meeting.

Decision Point 3:

3. Board decides that the language used in its decisions for the approval of Category 2 proposals shall be modified to read as follows:

“Recommended proposals provided adjustments and clarifications are met within a limited timeframe (the initial reply to TRP adjustments and clarifications should be received within 6 weeks of the applicant’s receipt of the initial decision of the Board, and any further adjustments and clarifications should be completed within 4 months from the receipt of the initial reply from the applicant). The TRP Chair and/or Vice-Chair shall give final approval based on consultations with the primary and secondary reviewers.”

There are no material budgetary implications for this decision point.

Part 5: Guidelines for Proposals for the Fifth Call for Proposals

1. At the Eighth Board Meeting, the Board requested the Secretariat to start its preparation for the Fifth Call for Proposals “to enable a decision at the Ninth Board Meeting on the Fifth Call for Proposals.” This decision was based on a recommendation from the PMPC, which had noted in its Report to the Eighth Board Meeting “that it was important for the Secretariat to begin preparations for the next Call for Proposals, including taking lessons learned from the Fourth Call for Proposals to commence the revisions of the Guidelines for Proposals.” (GF/B8/7 page 7)

2. The process of revising the Guidelines included a series of consultations with key stakeholders in the Global Fund. The Secretariat received feedback from the following sources:

- a. CCMs during Secretariat visits to recipient countries, at regional meetings and through the Partnership Forum in Bangkok;
- b. WHO and UNAIDS, including from consultants who had assisted countries in the proposal development process in Round 4; and
- c. The current and former members of the Technical Review Panel.

3. A major revision of the Guidelines for Proposals occurred between the Third and Fourth Calls for Proposals. The changes in the Guidelines for Proposals for the Fifth Call for Proposals are therefore of a much more modest scope, primarily in order to incorporate more recent Board decisions (e.g., on the definitions of the eligibility criteria and on CCMs), to clarify areas that key stakeholders had identified as confusing, and to assist the TRP’s review process. The PMPC readily endorsed these changes, which are reflected in the revised version of the Guidelines included in Annex 5. A few areas of more considerable change have been recommended by the PMPC, which are described below.

4. Most significantly, the committee recommended removing the “HIV/TB” component from the list of components on which a proposal can be submitted (see section III.A, Focus of Proposals). This

recommendation stems primarily from the concern that having a dedicated HIV/TB component has discouraged applicants from building TB control dimensions into HIV components, and HIV interventions into TB proposals. These approaches of systematically (at least in regions in which the two epidemics are heavily intertwined) integrating HIV activities into TB programs and vice versa is now recommended by the World Health Organization and the Stop TB Partnership and has been widely identified as a key to controlling both diseases. Having a separate HIV/TB component seems to suggest to applicants that programming between the two diseases should be handled as a separate endeavor, rather than as an integral part of HIV and TB proposals.

5. Further, the limited number (and poor success rate) of HIV/TB proposals suggests that the original rationale behind the inclusion of this component has not been realized. In the first four Rounds, only 33 HIV/TB components have been reviewed, compared to more than 325 HIV/AIDS proposals and more than 180 tuberculosis proposals. Out of the HIV/TB proposals, only seven have been approved, an approval rate well below that of HIV/AIDS and tuberculosis components.

6. The committee recommended replacing the separate component with language that, in contexts in which HIV and tuberculosis epidemics are intertwined, encourages joint HIV/TB activities.

7. The committee discussed replacing the “Integrated” component as well, but ultimately agreed to retain it. The committee recognized that this component was not successful as currently structured, as only 16 proposals have been reviewed in the first four Rounds of which only two have been successful. Further, the original rationale for having a distinct component – namely creating a space for the consideration of systems strengthening activities – needed to be adapted to reflect the fact that the Guidelines have increasingly described how the “cross-cutting” aspects of systems strengthening (such as human capacity development and infrastructure development) should be included in all components (section III.C).

8. However, the committee finally agreed that there are some aspects of systems strengthening that cut across the three diseases and cannot be easily fit into one of the disease components. Examples cited included:

- Monitoring and evaluation (e.g., setting up sentinel surveillance systems, or monitoring and evaluation structures);
- Procurement and supply management (e.g., strengthening capacity to ensure quality control, or to distribute and track health products);
- Human resource capacity development (e.g., training programs in fields such program management or public health, incentives for working in disadvantaged areas); and
- Laboratory strengthening (e.g., infrastructure development to strengthen diagnostic capacity).

9. The committee thus felt that it would be inappropriate to eliminate the “Integrated” component. However, the committee recognized that defining the boundaries of what health systems strengthening the Global Fund should finance – and how to define the required links to AIDS, tuberculosis and malaria – was not a simple matter. Therefore, it agreed that three further steps were needed: first, the committee asked the Secretariat to review what was addressed in Integrated proposals and why their success rate was so low; second, further work was needed to more clearly delimit the scope of the component; and finally additional guidance was needed for the TRP. The committee nonetheless agreed that this work should not hold up the approval of the Guidelines for Proposals or the launch of the Fifth Call for Proposals.

10. The committee also reviewed two changes in the Guidelines for Proposals that were initially discussed at the Eighth Board Meeting in the context of the Governance and Partnership Committee Report to the Board on Country Coordinating Mechanisms. The first of these narrowed the scope of the existing language in the Guidelines for Proposals on what was political commitment to CCMs. The committee agreed that the CCMs is a critical locus for demonstrating political commitment, but felt that the language approved was overly restrictive, as it would not recognize the political commitment of parties outside the CCM, including, for example, Presidents, Parliaments,

Ambassadors, and other figures unlikely to be directly involved in CCMs but nonetheless important for establishing an environment conducive to the successful implication of programs financed by the Global Fund. It therefore agreed to alternative language (see section IV) that highlighted the role of CCMs in mobilizing political commitment but was not overly restrictive.

11. Similarly the committee recommended replacing language on technical assistance for CCM functioning with broader text covering the range of technical assistance needs encountered throughout the grant cycle (section V.B.6).

12. With these changes, the committee recommended that the Board approve the Guidelines for Proposals for the Fifth Call for Proposals as included in Annex 5. The committee acknowledged that any further guidance from the Board on the timing and nature of the launch of the Fifth Call for Proposals might affect the Guidelines for Proposals, in which case the Board might wish to ask the PMPC to amend or supplement (e.g., through the provision of additional information) the document prior to the Call.

Decision Point 4:

4. The Board approves the Guidelines for the Fifth Call for Proposals.

There are no material budgetary implications for this decision point.

Part 6: Eligibility Criteria

1. Two outstanding issues relating to the eligibility criteria for proposals from Upper-Middle Income countries were briefly discussed:

- a. The definition of “poor or vulnerable populations”; and
- b. The eligibility of “proposals from Upper-Middle Income countries focusing exclusively on vulnerable populations that do not receive significant funding from domestic or external sources.”

2. As agreed at the preceding PMPC meeting, a number of interested delegations had agreed to work further on these topics, convened by UNAIDS. These delegations noted that work had begun on the former topic, a fact that was appreciated by committee members. The committee indicated that it would like to be able to make recommendations on a definition to the Tenth Board Meeting. The committee also felt that the working group should present options for the topic of the eligibility criteria for proposals from Upper-Middle Income countries in time for recommendations to be made to the Tenth Board Meeting.

Part 7: Continuity of services

1. At its Eighth Meeting, the Board of the Global Fund discussed the possible implications of the Board deciding to stop financing a proposal after Phase 1. The Board recognized that while some programs would not be successful enough to merit continued funding in Phase 2, they might have nonetheless started interventions that would require ongoing support.

2. The Board therefore “recognize[d] the importance of sustaining ongoing treatment, as well as prevention, care and support services. The Board request[ed] the Secretariat urgently to explore internal mechanisms and to work with partners to develop options for the continuity of services through broader country partnerships associated with common national strategic framework[s] for the three diseases. The Board request[ed] the Secretariat to report back to MEFA, PMPC and the Ethics Committee on these issues in time for the development of recommendations by the Ninth Board

Meeting. Up to the Ninth Board Meeting, Secretariat priority shall be given to addressing issues related to discontinuation of treatment within Global Fund grant programs.”

3. The PMPC took the lead in developing recommendations to respond to the Board request, receiving valuable feedback from both the MEFA and Ethics Committees. The committee based its recommendations on a discussion paper, included as Annex 6.

4. The committee recognized that this is a complex topic, as the cessation of Global Fund financing has ramifications that can range from medical and public health, to ethical, legal, and reputational. To address these, the committee agreed on a two-pronged approach, differentiating between a pressing short-term concern that can be addressed through an internal mechanism, and a broader solution that can only be accomplished through a longer-term process of working with partners.

5. As directed by the Board, the short-term solution focused on treatment. The committee narrowed this further to life-long therapy, out of the concern that a proposal that has started patients on antiretroviral therapy will not be renewed into Phase 2, and that this decision will come too close to the end of the program to allow others to step in and provide financing for the patients that need their treatment continued. The discontinuation of financing does not have the same consequences for other forms of treatment. The need to develop a system on this immediately is underscored by the fact that there are approximately 20 proposals containing antiretroviral therapy that are due for their Phase 2 renewal decision before the Tenth Board Meeting (although there was broad recognition that the first priority was to ensure that these proposals receive adequate support to be extended into Phase 2).

6. Therefore the committee recommended that the Board establish a procedure whereby programs that are not being continued into Phase 2 but that have started some patients on life-long therapy be allowed to submit an Extra-Ordinary Request for Continued Funding for Treatment, which would provide them with financing to continue a cohort of patients that has begun treatment with therapy for a further year. This time would provide recipients with an opportunity to seek other forms of financing for these patients. The details of this are provided in the decision point below.

7. Second, the committee recognized that a lasting solution to this problem would only be likely to result from broader work with partners, as it touches upon questions about the nature and role of development finance, and sustainability. As such, the committee felt that the process should ultimately engage a wide range of stakeholders in the fight against these three diseases, although the committee subsequently agreed that looking at questions common to financiers would be an appropriate place to start the process.

8. The committee further agreed that these discussions should encompass prevention and care and support in addition to treatment, and that they should not be limited to AIDS, but should also include tuberculosis and malaria. The committee discussed the appropriate role of the Global Fund in the process at length, ultimately agreeing that while the Global Fund should not drive the process, it needed to play a catalytic role in highlighting the problem and mobilizing partners. Such a process is likely to take some time, so the committee recommended that the topic not return to the Board until the Eleventh Board Meeting (although the committee would be involved in the intervening period).

9. The MEFA Committee agreed with and endorsed the PMPC recommendations, making two slight amendments (one for clarity and the second to emphasize the fact that effective service delivery was an important condition for receiving ongoing financing), which the PMPC later agreed to. The Ethics Committee also agreed with and endorsed the recommendations. It asked the PMPC to consider the importance of ensuring that patients are aware that the financing for their antiretroviral therapy could be discontinued.

10. The PMPC agreed with the importance of ensuring that patients are informed, although it did not feel that it would be appropriate or necessary to establish a formal informed consent process to do so, with a number of members challenging the idea that such a process would truly result in informed

consent given the practical consequences of a patient not agreeing (i.e., when confronted with a situation in which the only way to access antiretroviral therapy was by signing an informed consent statement, few if any sick patients would pause to consider that the financing for the therapy might be discontinued).

The PMPC, the MEFA Committee, and the Ethics Committee recommend that the Board adopt the following two decision points:

Decision Points 5 – 6:

5. The Board adopts the following system for addressing continuity of services in the context of the Phase 2 renewal decision:

- a. A recipient (typically a CCM) whose Request for Continued Funding is not approved may submit an Extra-ordinary Request for Continued Funding for Treatment.**
- b. The Extra-ordinary Request will be limited to expenses directly related to the continuation of treatment (including medicines [which, in the case of discontinuation of antiretroviral therapy, includes drugs for HIV-related opportunistic infections], diagnostics, and, as appropriate, costs for medical staff and other personnel directly involved in care of the patients on treatment) for those people already placed on life-long treatment under the existing proposal at the time of the Extra-ordinary Request.**
- c. The Extra-ordinary Request will be limited to the amount required to provide services directly related to the continuation of treatment for one year from the date of submission of the Extra-ordinary Request, less the amount granted under the Phase 1 proposal not disbursed at the time of the Extra-ordinary Request.**
- d. In addition to a budget, the Extra-ordinary Request shall contain a description of the steps that are being taken to find sustainable sources of financing for the people on treatment, and to ensure that treatment is being delivered effectively.**
- e. The Secretariat will review these plans for sustainable financing and the budget, and provide a recommendation to the Board on their appropriateness. The Extra-ordinary Request will not be subject to a performance-based review unless the Secretariat has pre-existing information to suggest that the approach to care and/or quality of care was inadequate. The frequency and modality for the provision of the Secretariat's recommendations, and the mechanism by which funds are committed to the Extra-ordinary Requests will be in line with the decision that the Board adopts for the broader Phase 2 decision-making process.**
- f. Throughout the process, the Secretariat will actively engage with technical partners to identify mechanisms to ensure continuity of services.**

6. The Board asks the Secretariat to explore with key partners (including WHO, UNAIDS, the World Bank, bilateral agencies, recipients, non-governmental organizations, and people living with the three diseases) a process that will result in long-term solutions to the issues of continuity of treatment, care and support, and prevention services for HIV/AIDS, tuberculosis, and malaria. The Secretariat should report back to the PMPC on the process before the Tenth Board Meeting. The Secretariat should report back to the Board through the PMPC on potential solutions in time for the Eleventh Board Meeting.

Budgetary implications: The additional cost of implementing this recommendation is estimated at \$90,000.

Part 8: Phase 2 Decision-Making

1. The Eighth Board Meeting jointly tasked the MEFA Committee and the PMPC to look again at the question of the decision-making authority in the Phase 2 renewal process. As the MEFA Committee had initially led the work on the topic, the PMPC simply reviewed the recommendations from the MEFA Committee meeting. The PMPC agreed with and endorsed these recommendations, with a number of members noting their concern that the process would result in delays but appreciating that a compromise had been worked out by the MEFA Committee to accommodate divergent positions. The joint recommendations are contained in the Report of the MEFA Committee to the Ninth Board Meeting, GF/B9/8.

2. At the request of the MEFA Committee, the PMPC discussed the question of whether a Phase 2 decision could be appealed. The committee felt that this topic would require additional work and so noted to the Board that the committee would consider it prior to the Tenth Board Meeting.

Part 9: Reprogramming in the Light of Changing Scientific Evidence

1. At its Eighth Meeting, the Board briefly addressed the question of how to address the implications of changing scientific evidence for recipients of Global Fund financing, a topic that had arisen in the context of artemisinin-based combination therapy (ACT). In addition to a short-term response to the need to reprogram for ACT, the Board also asked “PMPC to consider the issue of reprogramming in the context of changing scientific evidence, and report back to the Ninth Board Meeting.”

2. As covered in more detail in Annex 7, the committee looked at both how to determine where and when reprogramming should occur, and the financial commitment process once reprogramming has been agreed upon.

3. On the former, the committee recommended a pragmatic approach (based in part on the experience with the ACT reprogramming) that eschewed a directive means on identifying new scientific evidence and forcing recipients to change, in favor of a more collaborative mechanism in which the Secretariat would work closely with technical partners to ensure that new scientific thinking is disseminated to recipients.

4. To safeguard this non-prescriptive approach, as well as to address a lacuna in current policies, the committee recommended that the Board codify the ability of the Technical Review Panel, upon request of the Secretariat, to re-review proposals in light of changing scientific evidence. It was appreciated that the likelihood of this being used was quite low, but it was nonetheless deemed to be important to ensure that Global Fund resources would not be used to cause harm.

5. The committee then discussed the issue of making financial commitments in the event that scientific evidence dictates a change in approach that results in the use of interventions that cost more than originally budgeted. The committee recommended addressing this through both an interim response and the initiation of a process for a longer-term solution.

6. The short-term solution is based on the approach of utilizing Phase 2 resources that the Board adopted to address ACT reprogramming. The committee therefore recommended that the additional financing needs resulting from changing scientific evidence be added to the existing grounds for accelerating a Phase 2 decision (currently, this can occur in the context of accelerated implementation and severe exchange rate fluctuations).

7. While this approach sufficed to meet the immediate needs encountered for the ACT reprogramming, it was recognized as a less-than-ideal solution in the longer-term, albeit one that was necessary until such a longer-term response could be identified. Two possibilities for the more permanent solution were discussed: the creation of a special financing window for top-up grants, and the handling of the problem in the context of moving towards more flexible “program” financing. However, the committee felt that since Board constituencies would be examining the latter topic at a

consultation after the Ninth Board Meeting, it was premature for the committee to embark on a detailed discussion of it.

8. The committee noted the need for a longer-term solution for reprogramming in the light of changing scientific evidence, and therefore recommended that the Board consider this in the retreat of Board Members after the Ninth Board Meeting, and provide guidance so that the Secretariat can prepare recommendations for long-term solutions in time to report back through the PMPC for the Tenth Board Meeting.

Decision Points 7 – 8:

7. The Board decides to use the following language in its decisions for the approval of Category 1 and 2 proposals in order to recognize that the Secretariat may ask the Technical Review Panel to re-review proposals in the course of implementation:

“This approval is subject to re-review by the Technical Review Panel if, after consultation with the recipient but in the sole discretion of the Global Fund, changes in scientific evidence (as identified in collaboration with WHO and other technical partners) materially affect the proposal.”

The Board further decides that following such re-review, should the TRP recommend that, in light of the new scientific evidence, the approach taken in the proposal should be changed, the Board should reconsider the approval of the proposal. The recipient will have the opportunity to submit a revised version of the relevant parts of the proposal prior to the Board’s decision.

There are no material budgetary implications for this decision point.

8. The Board expands the circumstances in which the Phase 2 decision-making process can be accelerated by modifying the existing decision on the Phase 2 process, as set forth in GF/B8/2, page 7, to read as follows:

“The decision may be taken earlier in cases of (i) accelerated implementation; (ii) severe exchange rate fluctuations; or (iii) additional financing needs resulting from changes in scientific evidence.”

There are no material budgetary implications for this decision point.

Part 10: Quality Assurance of Single- and Limited-Source Pharmaceutical Products

1. At the Third Board Meeting, in October 2002, the Board established quality assurance standards for pharmaceutical products. In so doing, the Board distinguished between standards for single- and limited-source products and multi-source products. For the latter, quality assurance is easier to determine as there are public reference standards of quality and a longer history of manufacture and use of the product, so the Board decided that quality assurance should be “in accordance with the existing national procedures.”

2. However, for single- and limited-source products, quality assurance is more complicated and some National Drug Regulatory Authorities (NDRAs) do not have the technical capacity to carry out all required steps in assuring the quality of products. To address these concerns, the Board adopted the following quality assurance standard:

“Provided products are accepted by the national drug regulatory agency of the Recipient country, to be eligible for purchase with Fund resources any single or limited source product (that is, a medicinal product for which there are not publicly available quality assurance standards, analytic methods, and reference standards) must:

- a) Have been found to be acceptable by the UN Procurement Quality and Sourcing Project (also known as the WHO Prequalification Project)¹; or
- b) Have been authorized for consumption in their country by a stringent regulatory authority²; or
- c) Have been authorized by the national regulatory authority in the recipient's country.

“Option c) is applicable only until 31 December 2004, after which suppliers must comply with at least one of the two standards set out in a) and b).” (GF/B4/2, p. 23)

3. The transition period created by Option c) was included in the Board policy to recognize both that it could be disruptive to programs should they be required to change suppliers immediately, and that the WHO Prequalification Project was relatively new at the time the Board approved the policy (October 2002) and might need time to be fully functional.

4. The PMPC discussed the potential impact of the expiry of the transition period, with members raising concerns that the impending change would result in reduced supply, higher prices, and additional difficulties in adherence (by virtue of patients having to change formulations, including moving from fixed-dose formulations to non-coformulated products). Additionally, members questioned whether the quality assurance standard established under Option c) had resulted in any quality problems.

5. Concerned about these possible implications, the committee agreed that it would be preferable to extend the transition period while gathering more information about the impact of the expiry of the transition period. The committee therefore recommended that the transition period be extended by one year, while asking WHO and the Secretariat to provide information on five topics to the next PMPC meeting:

- a. The experience using products that have been procured under Option c) of the Third Board Meeting policy, particularly with regard to quality assurance;
- b. The impact on the supply of single- and limited-source products;
- c. The impact on the price of single- and limited-source products;
- d. The impact on adherence to single- and limited-source products; and
- e. The budgetary and programmatic impact for the WHO Prequalification Project.

6. This was a near-unanimous rather than consensus recommendation, with one constituency noting that the deadline in the current Board policy was already a negotiated compromise, and arguing that the committee could review the topics listed above without having to extend the deadline. There is no alternate recommendation as this constituency agreed with Board policy as it currently reads.

7. The committee noted with appreciation that under recently adopted European Union (EU) legislation, the European Medicines Agency is now entitled to give scientific opinions (upon request of WHO) for the evaluation of certain medical products manufactured in the EU intended for markets outside the EU, as well as to give regulatory assistance to developing countries. The European Commission further noted the possible benefits that these moves may have in accelerating market approval procedures in recipient countries.

Decision Point 9:

9. The Board replaces the phrase “Option (c) is applicable only until December 31, 2004” in the Board decision on quality assurance (compliance with quality standards) from the Third Board Meeting (GF/B4/2, p. 23) with “Option (c) is applicable only until December 31, 2005.”

¹ This project is managed by the Essential Medicines and Policy Department of WHO.

² For the purposes of this policy a stringent drug regulatory authority is defined as a regulatory authority in one of the members of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and/or the International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use. See Annex 2 for a list of these countries.

The Board invites the World Health Organization to work with the Secretariat to assess the impact of the expiry of the transition period established in Option (c) and to develop options on the quality assurance of single- and limited-source products, and to report back to the PMPC in time for the development of recommendations for the Tenth Board Meeting.

Budgetary implications of this decision point:

The additional cost of implementing this decision is estimated as US\$60,000.

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Agenda, September meeting of the Portfolio Management and Procurement Committee

<i>Meeting</i>	<i>Portfolio Management and Procurement</i>
<i>Date</i>	<i>27th – 28th September, 2004</i>
<i>Time</i>	<i>9:00am-6:30pm</i>
<i>Place</i>	<i>Global Fund Secretariat, Ground Floor large conference room (Hope Plaza)</i>
<i>Chair</i>	<i>Francis Omaswa</i>
<i>Vice Chair</i>	<i>Kate Taylor</i>

Agenda**Monday, 27 September**

Welcome coffee	8:30
1. Introductory comments from the Chair, approval of the agenda and review of the PMPC workplan to 9 th Board Meeting	9:00 - 9:15
2. Phase 2 policy Process for work with MEFA Committee on decision-making Special considerations for ongoing treatment	9:15 - 12:00
Lunch	12:00 - 1:00
3. Discussion on follow-up to TRP Report to the 8 th Board Meeting	1:00 - 3:30
4. TRP composition: length of time TRP members are permitted to serve	3:30 - 4:00
PMPC adjourns for the day to allow TRP Selection Panel to meet	

Tuesday, 28 September

Welcome coffee	8:30
1. TRP composition: selection of TB experts	9:00 - 10:00
2. Guidelines for Proposals for the 5 th Round	10:00 - 12:30
Lunch	12:30 - 1:30
3. Guidelines for Proposals for the 5 th Round, continued	1:30 - 2:30
4. Reprogramming in the light of changing scientific evidence	2:30 - 5:00
5. Information points: eligibility criteria, prioritization, procurement	5:00 - 5:30
6. A.O.B.	

Attendance list, 27 – 28 September 2004 meeting of the Portfolio Management and Procurement Committee

<u>Constituency</u>	<u>Name</u>
<u>PMPC Members:</u>	
Affected Communities	Kim Nichols
Canada (Germany, UK & Switzerland)	Thomas Fetz
China (Western Pacific Region)	Han Mengjie
Developed Country NGOs	Mogha Kamal Smith
East & Southern Africa	Francis Omaswa (Chair)
Eastern Europe	Zhanna Tsenilova
European Commission (Austria, Belgium)	Patrick Berckmans
France (Luxembourg, Spain)	Frédéric Goyet
Italy	Flavio Lovisolo
Japan	Yasuhisa Nakamura
Latin America & Caribbean	Claudia Guerrero Monteza
Private Sector	Kate Taylor (Vice-Chair)
South-East Asia	Churnrurtai Kanchanachitra
USA	Peter Mamacos & Scott Evertz
WHO	Alex Ross
 <u>Observers:</u>	
UNAIDS	Valerie Manda
 <u>Members not present:</u>	
Eastern Mediterranean	Tariq Farook
World Bank	Jonathan Brown
 <u>Secretariat:</u>	
Brad Herbert	
Toby Kasper	
Paul Lalvani (in part)	
Hans Zweschper (in part)	

Participant list, 21 October 2004 teleconference of the Portfolio Management and Procurement Committee

<u>Constituency</u>	<u>Name</u>
<u>PMPC Members:</u>	
Affected Communities	Kim Nichols
Canada (Germany, UK & Switzerland)	Thomas Fetz
Developed Country NGOs	Mogha Kamal Smith
East & Southern Africa	Francis Omaswa (Chair)
European Commission (Austria, Belgium)	Patrick Berckmans
France (Luxembourg, Spain)	Frédéric Goyet
Italy	Flavio Lovisolo
Latin America & Caribbean	Claudia Guerrero Monteza
Private Sector	Kate Taylor (Vice-Chair)
South-East Asia	Viroj Tangcharoensathien
USA	Peter Mamacos
WHO	Joel Brenner
World Bank	Jonathan Brown
<u>Observers:</u>	
UNAIDS	Valerie Manda
<u>Members not participating:</u>	
China (Western Pacific Region)	Han Mengjie
Japan	Yasuhisa Nakamura
Eastern Europe	Zhanna Tsenilova
Eastern Mediterranean	Tariq Farook
<u>Secretariat:</u>	
Brad Herbert	
Toby Kasper	



Investing in our future

The Global Fund

To Fight AIDS, Tuberculosis and Malaria

**Ninth Board Meeting
Arusha, 18 - 19 November 2004**

Annex 6

**Portfolio Management and Procurement Committee Meeting
Geneva, 27 - 28 September 2004**

DISCUSSION PAPER ON CONTINUITY OF SERVICES

I. Background

1. At its Eighth Meeting, the Board of the Global Fund discussed the possible implications of the Board deciding to stop financing a proposal after Phase 1. The Board recognized that while some programs would not be successful enough to merit continued funding in Phase 2, they might have nonetheless started interventions that would require ongoing support.
2. The Board therefore “recognize[d] the importance of sustaining ongoing treatment, as well as prevention, care and support services. The Board request[ed] the Secretariat urgently to explore internal mechanisms and to work with partners to develop options for the continuity of services through broader country partnerships associated with common national strategic framework[s] for the three diseases. The Board request[ed] the Secretariat to report back to MEFA, PMPC and the Ethics Committee on these issues in time for the development of recommendations by the Ninth Board Meeting. Up to the Ninth Board Meeting, Secretariat priority shall be given to addressing issues related to discontinuation of treatment within Global Fund grant programs.”
3. The Board focused on treatment in this decision primarily out of recognition of the special issues surrounding the provision of antiretroviral therapy, which is one of the few interventions financed by the Global Fund that requires continuous support over the life of an individual and that, once started, poses a direct risk to both individual health and broader public health if it is discontinued.
4. This paper briefly reviews the implications of stopping Global Fund financing before addressing the two aspects of the Board’s request: “internal mechanisms” and “broader country partnerships associated with common national strategic framework[s].”

II. Implications of stopping Global Fund financing

5. Once the Global Fund decided to make commitments that are not of an indefinite nature and decided to commit itself to performance-based funding, it immediately opened itself up to concerns about the implications of stopping financing. By definition, if the Global Fund stops financing a proposal that has initiated some activities of an ongoing nature, there will be an impact if the Global Fund ceases to provide financing. These consequences can be wholly or partially addressed if another financier (whether domestic or external) steps in to provide equivalent funding, but in the analysis below of the possible implications of stopping Global Fund financing, a worst case scenario is assumed, in which financing is stopped in a situation in which some people

have started treatment¹, and no other funding source is immediately available to fill the gap. The loss of Global Fund financing would then translate directly into a shortfall in medicines (and potentially in the associated diagnostics, and in resources to pay medical and other staff directly involved in patient care).

6. Some of the implications of stopping treatment in this circumstance arise regardless of the type of interventions being financed. For example, public health concerns will arise if the absence of financing limits the ability of a program to reach all of those intended to be served, thereby placing some of the population at risk for increased morbidity and mortality.
7. However, most of the impact of a sudden discontinuation of financing differs considerably depending on whether the treatment being financed is life-long or of a limited duration. Almost all treatments financed by the Global Fund are of a limited duration (e.g., treatment for HIV-related opportunistic infections, anti-malarial treatment, tuberculosis therapy). The significant exception is antiretroviral therapy for advanced HIV infection, which currently requires life-long use.
8. With the treatments that are of a limited duration, the Global Fund is able to make a commitment to cover the full duration of a patient's treatment², significantly reducing the impact of discontinuing Global Fund financing.
9. With life-long therapy, the commitment that the Global Fund has made cannot possibly cover the duration of an individual patient's treatment. This difference engenders a number of additional implications, as briefly described below:
 - a. Medical: The lack of access to an ongoing supply of treatment will endanger the life of a patient who has begun therapy and needs to be sustained on it.
 - b. Public health: Sudden cessation of financing can lead to the development of drug resistance, reducing the overall effectiveness of treatment (and likely increasing costs, which potentially leads to a reduction in coverage).
 - c. Ethics and human rights: A recent background paper for a WHO/UNAIDS consultation on the ethics of access to antiretroviral therapy stated the following: "Programmes that are not able to be sustained will have the ethically unacceptable consequence of withdrawing ART [antiretroviral therapy] from people who have been receiving the benefits of treatment."³ This position seems reflective of the broader ethics literature on life-long therapy, although there is a paucity of commentary on the specific situation of a financier's ethical responsibilities, except in the context of continuation of treatment after the end of a clinical trial. Sudden discontinuation also runs the risk of being anti-poor, as the better-off are better able to absorb exogenous shocks with their own resources (i.e., they are more likely to be able to assume the burden of paying themselves).
 - d. Legal: The Secretariat has contracted an independent law firm to prepare an opinion on the potential liability that the Global Fund faces, which will be provided as a supplemental document.
 - e. Reputational and political risk: The public image of the Global Fund (and the resulting political and financial support that it enjoys) may be considerably damaged if the organization is perceived as recklessly endangering the lives of patients by not adequately

¹ In almost all cases, programs that have put considerable numbers of people on treatment are likely to be performing and therefore not at risk for discontinuation. Therefore, the number of people actually started on therapy in programs that are discontinued is likely to be small (if not none).

² This is the case even for treatments that have an extended duration. In particular, treatment for MDR-TB is up to 24 months long, which raises the possibility that Global Fund financing would be stopped in the middle of a treatment course, thereby having considerable additional implications. However, this concern is obviated by the fact that the Green Light Committee, the approval of which is mandatory prior to receiving Global Fund financing for MDR-TB, requires recipients to demonstrate that they have the financial means to sustain patients throughout the full treatment course.

³ Ruth Macklin, "Ethics and Equity in Access to HIV Treatment – 3 By 5 Initiative," prepared for the WHO/UNAIDS International Consultation on Equitable Access to Treatment and Care for HIV/AIDS, January 2004. Available at http://www.who.int/ethics/resource_allocation/en/.

planning for the cessation of financing (a risk that is particularly acute in the case of ongoing treatment). This may also deter future proposals to the Global Fund.

10. These implications are obviously significant and suggest that steps should be taken to minimize the risk of the negative consequences of unplanned discontinuation of Global Fund financing for life-long therapy. The rest of this paper focuses on these responses in the context of life-long therapy.

III. Responses

11. As noted above, there are two distinct types of responses: those focusing on internal mechanisms and those aimed at working with partners to develop a broader response to the problem. These two are not mutually exclusive, and indeed are highly complementary: internal mechanisms may be needed to address the current acute problem, but are considerably less likely to provide a long-term answer, whereas working with partners is likely to take more time but is the only approach that can generate a broad-based policy response.

A. Internal mechanisms

12. There are two fundamentally different types of responses to the problems posed by the Global Fund financing life-long treatment. One approach addresses the problem when it is likely to arise, primarily when the Global Fund halts the financing of a program. The other approach starts with the premise that financing life-long treatment is fundamentally different than funding other types of programs, and thus requires a different approach to financing.
13. In the first approach, there are two distinct types of situations in which the Global Fund might decide to halt financing for an ongoing program⁴:
 - a. The Board decides not to renew a proposal into Phase 2;
 - b. The Secretariat stops financing a particular grant due to corruption, fraud, and/or mismanagement of funds.⁵
14. The latter results only in the termination of the *grant(s)*, rather than the *proposal* itself. Such circumstances would typically result in another PR being identified, through which financing for treatment could continue (as was the case in the Ukraine). This is therefore a purely operational matter and is not discussed further herein.
15. However, addressing continuity of services in the context of Phase 2 decisions does have important policy considerations. The Phase 2 decision is only taken at month 20, meaning that recipients have only four months to identify alternative sources of funding to sustain people on treatment, a period that in some cases may prove to be too short to find other financing.
16. The most feasible and equitable way to address continuity of services in the context of a Phase 2 decision not to renew a grant would be to introduce a provision to commit supplemental resources to cover the continuation of treatment services for a time-limited period.⁶

⁴ The continuation of services after the conclusion of Global Fund financing (i.e., at the end of a proposal's planned duration) is not addressed herein as it is inseparable from broader questions related to the Global Fund's core business model.

⁵ A third possible reason why the Global Fund might stop financing for an ongoing program is if the organization simply did not have sufficient resources to continue to finance renewals. This paper does not cover this topic, as the Eighth Board Meeting agreed to resort to "special procedures" to be decided by the Board if there are insufficient resources for at least one year of Phase 2 renewals, and these procedures that are outside the scope of the present paper.

⁶ Other possible responses considered but not further developed include: Reviewing the different parts of a Phase 2 Request for Continued Funding separately (which was not further developed because it would force

17. The likely use of such a provision would be diminished by the fact that most proposals that are not renewed into Phase 2 are likely to have considerably underspent in Phase 1, meaning that there would typically be resources available for continuation of services. Further, as noted above programs that have put considerable numbers of people on treatment are likely to be performing and therefore not at risk for discontinuation, so the number of people actually started on therapy in programs that are discontinued is likely to be small.
18. The proposed mechanism for this approach would be as follows:
- a. A recipient whose Request for Continued Funding is not approved would be allowed to submit instead an Extra-ordinary Request for Continued Funding for Treatment.
 - b. The Extra-ordinary Request would be limited to requesting financing for services directly related to the continuation of treatment (including medicines [which, in the case of discontinuation of antiretroviral therapy, includes drugs for HIV-related opportunistic infections], diagnostics, and, as appropriate, costs for medical staff and other personnel directly involved in care of the patients on treatment) for those people already placed on life-long treatment at the time of the Extra-ordinary Request.
 - c. The Extra-ordinary Request would be limited to the amount required to provide services directly related to the continuation of treatment for one year from the date of submission of the Extra-ordinary Request, less the amount of the Phase 1 proposal not disbursed at the time of the Extra-ordinary Request.⁷
 - d. In addition to a budget, the Extra-ordinary Request would contain a description of the steps that are being taken to find sustainable sources of financing for the people on treatment.
 - e. The Secretariat would review these plans for sustainable financing and the budget, and provide a recommendation to the Board on their appropriateness. The Extra-ordinary Request would not be subject to a performance-based review unless the Secretariat had pre-existing information to suggest that the approach to and/or quality of care was inadequate. The frequency and modality for the provision of the Secretariat's recommendations, and the mechanism by which funds are committed to the Extra-ordinary Requests would be in line with the decision that the Board adopts for the broader Phase 2 decision-making process.
19. This would build upon existing systems as much as possible while addressing structurally the need to provide supplemental resources to the limited number of programs that have started people on life-long treatment and do not have sufficient resources left over from underspending to cover the cost of therapy.
20. A fundamentally different approach to developing internal mechanisms for ensuring continuity of services for life-long treatment would not wait until a problem was likely to arise, but rather would introduce a differential approach at the beginning of the process, in proposal submission and approval.
21. The Global Fund's current financing modality is entirely undifferentiated: all proposals are treated identically, regardless of whether they are for the provision of one-off commodity purchases, for

recipients to make a fundamental shift in implementation strategy in the middle of an existing program, as well as significantly change the existing decision-making process); replacing the non-performing CCM and PR with an entity identified by the Secretariat as having greater ability to ensure the delivery of treatment (which was rejected as out of keeping with Global Fund principles of local ownership); and conducting differential performance reviews of Requests for Continued Funding from recipients that have started people on life-long treatment (which was not pursued because of the fundamental shift that it would necessitate in the entire performance-based funding system).

⁷ The Secretariat has not identified any suitable benchmarks to assist in the determination of the appropriate period. One year has been proposed because it balances between making an excessively large commitment to a proposal that was deemed not meriting renewal, and allocating an adequate amount to ensure that recipients have sufficient time to identify alternative sources of financing.

the long-term development of health systems to support the sustainable scaling-up of interventions (e.g., through human resources capacity development), or for the supply of life-long treatment.

22. Although this approach has the benefit of simplicity, it is not the only possible approach and indeed is not consistent with the approaches taken by some other major financiers (who have different possible mechanisms for financing in different contexts). Further, the needs for predictability of financing differ considerably between product lines, raising the specter that recipients are less likely to apply for activities that require a greater measure of predictability without more assurance than can be provided by the current system.
23. To specifically address the problem of continuity of services for treatment, an alternative approach to the current model would entail asking recipients to submit dedicated proposals to address life-long treatment, which, if technically-sound, would receive an immediate five-year commitment, rather than the current two-year commitment. Introducing such a shift would obviously have considerable implications for the entire Global Fund system and so is not something that can be effectuated without considerable additional analysis and discussion.
24. The question of whether the current business model best ensures continuity of services for life-long term was briefly raised in the context of GF/B8/13, "Discussion Paper on the Core Business Model of a Mature Global Fund," and so may be discussed at a retreat of Board members after the Ninth Board Meeting.

B. Working with partners

25. As noted above, working with partners is likely to generate the most sustainable approach to ensuring continuity of services. A shared vision of the responsibilities of the different actors in the financing, provision, and support of services would be far more likely to result in a long-term solution than a Global Fund-specific response.
26. The below sets out some of the considerations that would shape the approach of working with partners. The Secretariat would not propose attempting to answer all of these questions now, but factoring them into the development of a recommendation to the Board on the process for working with partners.
27. The distinction drawn above between life-long treatment and other types of financed activities suggests that the need for an international consensus is greatest around life-long treatment. However, although the problems surrounding life-long treatment may be most immediately pressing, it is clear that there are major challenges associated with the collective ability to sustain the scaled-up response to HIV/AIDS, tuberculosis, and malaria in the context of the Millennium Development Goals.⁸ It could be argued, therefore, that if the international community is to engage in a process of developing consensus around continuity of services, this should not be limited to life-long treatment but rather should address the full gamut of treatment, care and support, and prevention services.
28. A second key question is the desired ultimate outcome of any international consensus, and therefore the partners that should be involved. At one end of the spectrum, the process could aim at generating a narrowly-focused international agreement between financiers of life-long treatment that sets out certain prerequisites (financial or otherwise) for a treatment program to be initiated, or that commits each organization to set aside a reserve for the financing of life-long

⁸ The Eighth Board Meeting decision recognized the need to simultaneously focus on the immediate challenges presented by treatment while not neglecting other aspects of controlling HIV/AIDS, tuberculosis, and malaria: "The Board recognizes the importance of sustaining ongoing treatment, as well as prevention, care and support services... Up to the Ninth Board Meeting, Secretariat priority shall be given to addressing issues related to discontinuation of treatment within Global Fund grant programs."

treatment. At the other extreme, an international process could result in a policy framework that would set out roles and responsibilities for the range of actors involved in the fight against HIV/AIDS, tuberculosis, and malaria to ensure continuity of services. Although this would obviously be far broader than the Global Fund, it would potentially have direct impact on the organization by, for example, ensuring that members of a Country Coordinating Mechanism undertake commitments to provide continuity of services when they submit a proposal to the Global Fund.

29. A related question is the extent to which an existing international mechanism could be used to generate a consensus on ensuring continuity of services. The answer to this would of course depend on the output desired, but one obvious candidate would be the High-Level Forum on the Health Millennium Development Goals.
30. All of these considerations influence the next steps for the Global Fund. However, as noted above, rather than attempting to answer them all now, the Secretariat would propose considering them in the context of developing a recommendation on a process for reaching a consensus. There are essentially two possibilities for this process: either the Secretariat can actively engage partners (including ongoing initiatives such as the High-Level Forum on the Health Millennium Development Goals) or the Board can directly request partners to lead the process.
31. In the former, the Secretariat would envision playing a catalytic role in identifying and potentially assembling partners, and helping to define the scope of the work. In the latter, the partners would need to assume these responsibilities themselves (and would need to have sufficient resources to carry out the work).
32. Should the Board seek to ask partners to lead the process, the three most logical bodies would be UNAIDS, WHO, and the World Bank, all of which have considerable experience in working in and leading international processes. The first two are normative agencies, whereas the last shares with the Global Fund the role of a major financier of life-long therapy.
33. Certain key features would need to be present irrespective of who initiates the process. In particular, it would need to be open to the participation of all stakeholders in the fight against the three disease (particularly people living with HIV, tuberculosis, and malaria) and be thoroughly transparent. Further, it should promote harmonization, in HIV/AIDS particularly in the context of the "Three Ones" principles. Finally, it should also lead to the development of monitoring and evaluation processes aimed both at assessing the translation of policy into practice and at verifying the actual impact of the policies.

IV. Possible recommendations for decision points

34. Below are three draft recommendations to the Board, two of which have two options each and one of which has only one. Because of the nature of the original Board decision, the PMPC is not obliged to provide any recommendations at all, or it could make all three of these (as they are complementary rather than mutually exclusive).
35. The Eighth Board Meeting decision point on this topic included an explicit urging that this work be carried out "urgently." This is necessitated by the imminent need to start making decisions about Phase 2 renewals of proposals that contain treatment in general and more specifically life-long treatment. By the time that the Board meets in November, the first three proposals containing antiretroviral therapy will be due for a Phase 2 renewal decision, with nearly twenty more coming due between then and the next Board meeting in April.
36. Draft recommendation 1: There are two options on the development of internal mechanisms to address continuity of services through the Phase 2 process.

Option 1: The PMPC recommends that the Board adopt the following system for addressing continuity of services in the context of the Phase 2 renewal decision:

- a. A recipient whose Request for Continued Funding is not approved would be allowed to submit instead an Extra-ordinary Request for Continued Funding for Treatment.
- b. The Extra-ordinary Request would be limited to requesting financing for services directly related to the continuation of treatment (including medicines [which, in the case of discontinuation of antiretroviral therapy, includes drugs for HIV-related opportunistic infections], diagnostics, and, as appropriate, costs for medical staff and other personnel directly involved in care of the patients on treatment) for those people already placed on life-long treatment at the time of the Extra-ordinary Request.
- c. The Extra-ordinary Request would be limited to the amount required to provide services directly related to the continuation of treatment for one year from the date of submission of the Extra-ordinary Request, less the amount of the Phase 1 proposal not disbursed at the time of the Extra-ordinary Request.
- d. In addition to a budget, the Extra-ordinary Request would contain a description of the steps that are being taken to find sustainable sources of financing for the people on treatment.
- e. The Secretariat would review these plans for sustainable financing and the budget, and provide a recommendation to the Board on their appropriateness. The Extra-ordinary Request would not be subject to a performance-based review unless the Secretariat had pre-existing information to suggest that the approach to and/or quality of care was inadequate. The frequency and modality for the provision of the Secretariat's recommendations, and the mechanism by which funds are committed to the Extra-ordinary Requests would be in line with the decision that the Board adopts for the broader Phase 2 decision-making process.

Option 2: The PMPC recommends that the Board ask the Secretariat to further work to develop a system for addressing continuity of services in the context of the Phase 2 renewal decision and report back to PMPC in time for recommendations to be made to the Tenth Board Meeting.

37. Draft recommendation 2: As noted above, the topic of developing a distinct financing modality for life-long treatment was already addressed in the context of GF/B8/13, and the retreat on that discussion paper that is due to occur after the Ninth Board Meeting may address the issue. However, separately from this the PMPC could provide a recommendation to the Board on the subject:

The PMPC recommends that the Board ask the Secretariat to develop options for creating a financing modality that is tailored to the specific considerations of life-long therapy, and report back to the PMPC (and other committees as relevant).

38. Draft recommendation 3: The only draft recommendation on working with partners focuses on the process for developing an international consensus on ensuring continuity of services. In these draft recommendations, the focus has been on treatment, care and support, and prevention, in line with the Eighth Board Meeting decision that had a broad scope. Variations of the two options both could be developed that either narrow the scope of the process or delineate the possible outputs of the process.

Option 1: The PMPC recommends that the Board ask the Secretariat to actively engage with a broad range of partners (including ongoing initiatives such as the High-Level Forum on the Health Millennium Development Goals) to initiate a process that will result in an international consensus on ensuring continuity of treatment, care and support, and prevention services for HIV/AIDS, tuberculosis, and malaria.

Option 2: The PMPC recommends that the Board ask UNAIDS, WHO, and the World Bank to lead a process that will result in an international consensus on continuity of treatment, care and support, and prevention services for HIV/AIDS, tuberculosis, and malaria.

Annex: Budgetary implications

1. Draft recommendation 1, either option: There are no material budgetary implications of this recommendation (the costs of either option would be borne by existing staff).
2. Draft recommendation 2: The additional cost of implementing this recommendation is estimated at US\$25,000 (which is for professional fees for legal advice and for the hiring of a consultant to assist in researching approaches used by other financiers).
3. Draft recommendation 3: The additional cost of leading a process to develop an international consensus on ensuring continuity of treatment, care and support, and prevention services for HIV/AIDS, tuberculosis, and malaria is estimated at US\$300,000. This consists of two international meetings (one preparatory and one larger) and consultancy/short-term staff time to organize, facilitate, and report on the meeting. In Option 1, these costs would be allocated to the Secretariat. In Option 2, the bulk of the costs would be borne by partners. However, this total (or a proportion thereof) could still be allocated to the Secretariat to ensure that sufficient resources are available for the Global Fund to support the process.

DISCUSSION PAPER ON REPROGRAMMING IN THE LIGHT OF CHANGING SCIENTIFIC EVIDENCE

I. Background

1. At its Eighth Meeting, the Board of the Global Fund examined the question of how to address the implications for recipients of Global Fund financing of changing scientific evidence.
2. The issue arose with some urgency at the Eighth Board Meeting because of the emerging international consensus on the importance of the use of artemisinin-based combination therapy (ACT) for the prompt and effective treatment of malaria. A number of recipients of existing Global Fund grants for malaria wished to change from older, less effective anti-malarial drugs to ACT. However, a treatment course of ACT typically costs between 10 and 20 times as much as earlier anti-malarials, meaning that recipients who wished to switch lacked sufficient resources in their existing two-year budgets.
3. The Board addressed this problem by relying on the principles of the Phase 2 decision-making process, which allows for a decision on the transition from Phase 1 to Phase 2 to be taken before the typical 20 months. The Board thus “authorize[d] the Secretariat to commit as necessary up to USD 90 million for the projected costs of reprogramming 28 programs, which would be financed by utilizing resources from the Phase 2 renewal funding of these programs.”
4. While the shift in thinking around the use of ACT prompted this discussion, there is little doubt that the same issues will arise in the context of AIDS, tuberculosis and other aspects of malaria. Particularly for AIDS, the scientific knowledge of how to address the disease is advancing rapidly, meaning that it is only a matter of time before interventions or products that were deemed appropriate when the Technical Review Panel recommended a proposal will be considered outdated.
5. The Board therefore went on to request “PMPC to consider the issue of reprogramming in the context of changing scientific evidence, and report back to the Ninth Board Meeting.”
6. There are two distinct aspects of addressing reprogramming in the context of changing scientific evidence:
 - a. Determining where and when a shift should occur;
 - b. The financial commitment process that is used once reprogramming has been agreed upon.

II. Determining where and when reprogramming should occur

7. In the Global Fund's current business model, recipients – typically in the form of Country Coordinating Mechanisms – make determinations of the appropriate products and strategies needed for disease control in a given context. This approach is then reviewed by the Technical Review Panel, which assesses whether the proposed approach is technically-sound and makes a recommendation to the Board of the Global Fund. The Board's approval encompasses the full duration of a proposal (up to five years; see the Comprehensive Funding Policy, GF/B7/2, page 6). After a proposal is approved, there is currently no explicit provision for ad-hoc re-review of a proposal by the TRP or Board in the light of changing scientific evidence.
8. The most significant experience that the Global Fund has had with reprogramming to date is in the context of a shift to artemisinin-containing combination therapy for the treatment of malaria. The process adopted for that reprogramming – which involved the TRP and technical partners (particularly the Roll Back Malaria Partnership) in addition to the Secretariat – worked smoothly and efficiently.
9. Broadly, there are two approaches to determining where and when reprogramming as a result of changing scientific evidence could occur. The Global Fund can either develop a policy that would dictate that recipients change approaches if certain triggers were used, or it can rely on technical partners to disseminate information and encourage recipients to change voluntarily.
10. At the moment, there is little evidence to support the need for the development of a policy that would mandate reprogramming in the light of changing scientific evidence. Not only is there not another immediate issue that is likely to necessitate reprogramming on a large scale, but there is no suggestion that recipients will not be willing to change voluntarily. Indeed, the experience with the ACT reprogramming was that when recipients were presented with information on a changed scientific context, they were keen to shift to ACT and no external pressure was needed.
11. Instituting a system that would force recipients to use certain health products as a result of external judgments of scientific evidence would also run counter to existing Board policy, which allows recipients considerable latitude in determining which drugs to use, stating that recipients may procure “medicines which appear in current national, institutional or World Health Organization (WHO) standard treatment guidelines (STGs) or essential medicines lists (EMLs)” (GF/B4/2, page 22).
12. In lieu of a top-down approach, the Secretariat intends to develop further mechanisms that facilitate the bottom-up identification of changes in scientific evidence, building on the experience with ACT reprogramming. In particular, the Secretariat will be working closely with technical partners to ensure that new scientific thinking is disseminated to recipients rapidly and in a format that is conducive to decision-making. The Secretariat would propose using this approach and reporting back to the PMPC if any issues arise that require policy formulation.
13. To build a safeguard into this non-prescriptive approach, the Board could add a provision to address the fact that current policy allows recipients to willfully ignore changes in scientific evidence without any possibility of re-review by the TRP. This was not a problem in the ACT reprogramming because recipients were willing to change in the face of new scientific evidence, but the experience did reveal the lacuna in current policy. If a recipient had chosen to disregard evidence of extremely high levels of resistance to chloroquine or sulphadoxine-pyrimethamine, the current Board policy would permit this, as it provides recipients with considerable flexibility in determining which drugs to use, as the policy quoted above (paragraph 11) states. This raises significant concerns about the risk exposure of the Global Fund, both in terms of reputational concerns and for reasons of liability.

14. This could be addressed simply by adding a proviso to the Board's original approval of a proposal that the approval is subject to re-review. Doing this would continue to allow recipients to be the primary drivers of reprogramming, but would allow the Global Fund to have the ability to intervene should a situation arise in which a recipient was ignoring scientific evidence. It would also create a further incentive to recipients to engage more proactively with technical partners, rather than running the risk of a re-review.
15. Such an approach could be addressed with the following recommendation:
The PMPC recommends that the Board codify the ability of the Secretariat to ask the Technical Review Panel to re-review proposals in the course of implementation by adding the following words to the approval of proposals in Categories 1 and 2: "This approval is subject to re-review by the Technical Review Panel if, in the sole discretion of the Global Fund, changes in scientific evidence materially affect the proposal."

III. Financial commitment process

16. In the event that reprogramming is necessary to handle changes in scientific evidence, the reprogramming could lead to either the use of interventions that are cost-neutral (or even cost-saving) than the interventions for which Global Fund resources were originally requested, or the use of interventions that are more expensive.
17. In the first instance, no additional mechanisms would be needed. In this case recipients would be able to meet their original Board-approved targets simply through the sort of modifications of budgets and procurement and supply management plans that normally occur in the course of implementation.
18. This section, therefore, focuses on the scenarios in which a new intervention(s) dictated by changing scientific evidence is more expensive than the intervention(s) already covered by Global Fund financing, meaning that the original Board-approved targets for the coverage of key services cannot be met within the existing two-year financial commitments.
19. It could be argued that recipients should be restricted to receiving financing for only the interventions that they identified in their proposals, and therefore that recipients should have to reapply if they wish to significantly modify their implementation strategies. However, such an approach could force recipients to continue to use interventions that had been identified as inappropriate, thus endangering individual and public health. It would also undermine the Global Fund's emphasis on flexibility and on local ownership of program design and implementation. Simply insisting that recipients reapply has thus not been considered.
20. Instead, the below recognizes the need to develop mechanisms to provide recipients with the opportunity to access the financing needed to address changing scientific evidence. Three options for this are presented.
21. The first option to enable recipients to have access to sufficient resources to address changing scientific evidence would be based on the approach adopted by the Eighth Board Meeting for the ACT reprogramming and would use resources from Phase 2 to finance changes. The second option would be to supplement existing grants with the resources needed to finance the shift to a more effective intervention.
22. The third option, which involves more fundamental shifts to make Global Fund financing more flexible – and therefore more able to handle major reprogramming – was touched upon in GF/B8/13, "Discussion Paper on the Core Business Model of the Global Fund." This paper discussed the shift from the Global Fund using a "project mode" of funding to program financing, a

transition that could make Global Fund financing more responsible to changing contexts, without the need for new financing modalities.

A. Option One

23. The Phase 2 decision-making process approved by the Seventh Board Meeting allows recipients to move up the timeline for making the Phase 2 decision if they are accelerating implementation and therefore are exhausting Phase 1 resources more rapidly than originally anticipated (and in the case of severe exchange rate fluctuations). When considering the financial needs associated with the shift to artemisinin-based combination therapy at the Eighth Board Meeting, the Board recognized that reprogramming might also create the need for accelerated access to Phase 2 resources. It therefore “authorize[d] the Secretariat to commit as necessary up to USD 90 million for the projected costs of reprogramming 28 programs, which would be financed by utilizing resources from the Phase 2 renewal funding of these programs.”
24. This approach could become a standard part of the Phase 2 process if the current justifications for accelerating the decision-making process (accelerated implementation and severe exchange rate fluctuations) were broadened to include reprogramming. Recipients would be notified that should scientific evidence change and they wish to shift to new, more expensive interventions, they should prepare a Phase 2 renewal request in advance of the normal timeline.
25. The primary advantage of this approach would be that it would build upon the existing mechanism, reducing transaction costs for recipients and the Global Fund. This also means that it can be operationalized immediately. In comparison with the second option described below, this approach is likely to be more flexible and more rapid than waiting for a new commitment of resources from the Board. Finally, it does not require any amendment to the Comprehensive Funding Policy to determine the relative prioritization of the resources for such a shift vis-à-vis the priority accorded to renewals and new proposals.
26. The main disadvantage of this approach is the difficulty that it creates for the integrity of the Phase 2 decision process. In the current system, recipients submit a request for continued funding 18 months after the start of a program. This allows the development of a considerable base of performance data that enables decision-making. However, a recipient needing to accelerate the Phase 2 decision solely to access additional resources to finance a shift as a result of changing scientific evidence may not be able to provide sufficient performance data to justify the extension of a proposal. This could be partially addressed by qualifying any decision to extend a proposal as conditional (i.e., limiting approval to either category B1 or B2; see GF/B7/8 Annex 4, page 6), but it is still obviously less satisfactory than having a lengthier period over which to measure performance.¹
27. Another difficulty of this approach is that if some of the financing originally intended for the latter years of the full five year period is brought forward, a shortfall will occur towards the end of the five year period (e.g., if the fifth year budget is used to cover higher costs in years one – four, no resources will be left for year five), unless cost savings occur. Recipients would then be required to apply for a new proposal to compensate for the “loss” of the latter years of the earlier proposal.
28. If the change in scientific evidence requires a large shift in resources, it is also possible that the full five year amount will be insufficient to cover even the first two years of a program, as is the

¹ Another, somewhat more complicated approach to address this would be to create a new modality for accessing Phase 2 resources in which recipients are entitled to utilize in Phase 1 a portion of Phase 2 resources while keeping to the normal Phase 2 decision-making schedule. This “advance” against the Phase 2 resource envelope could be subject to review by the TRP but would otherwise not be linked to the normal Phase 2 performance review. Establishing such a system would be subject to many of the same challenges noted below in the second option (e.g., on eligibility criteria).

case for a number of recipients that are seeking to switch to ACT. A related problem is that if a change in scientific evidence occurs while a program is already in Phase 2, there are no additional resources to draw upon.

29. Finally, reprogramming using Phase 2 resources may force recipients to alter the balance contained in the original proposal between different parts of the program. In particular, if the resources needed to finance a shift as a result of changing scientific evidence are considerable and if the recipient is not able to apply in a subsequent Round of financing (or is unsuccessful), the recipient might need to move resources to treatment at the expensive of prevention (or vice versa).

B. Option Two

30. The second approach for addressing changing scientific evidence would create a new financing modality, a “top-up grant.” Such a grant would be available for the sole purpose of providing supplemental resources to a recipient in order to finance a shift to a new intervention that has been deemed necessary as a result of changing scientific evidence.
31. Adding a new financing modality to the current system would avoid many of the difficulties described above. However, doing so would require further work in a number of areas, particularly the eligibility criteria for top-ups, the review process for them, and the decision-making process for commitments. Preliminary analysis indicates that establishing a top-up system would not be a trivial exercise and would take some time to operationalize.
32. For example, eligibility for a top-up grant could be determined either on a case-by-case basis (i.e., when a recipient identifies a particular need and provides a rationale for the Global Fund), or based on a pre-determined set of changes in scientific evidence (i.e., the Global Fund would determine up front the conditions in which recipients could submit proposals for top-ups).
33. Either approach has considerable challenges. For the former, allowing recipients to apply for a top-up whenever they felt it appropriate runs the risk of establishing a system that could encourage recipients to seek top-ups regularly (particularly in a resource-constrained environment, when recipients will have a strong incentive to obtain top-up grants rather than having to compete in a new Round), with high transaction costs for all involved. On the other hand, developing a list of activities that would be covered by a top-up grant would potentially put the Global Fund in the position of having to determine *ex ante* all the possible types of changes in scientific evidence would be eligible for a top-up grant.²
34. A process for reviewing top-up grants would also need to be developed. Although the TRP is the obvious candidate for such work, this would significantly change its role, both in terms of mandate (which would be extended to reviewing issues arising in the course of implementation) and

² While there is an intuitive appeal of having a “white list” of changes in scientific evidence that would be eligible for a top-up, this would be difficult to operationalize, at least within current Board policy. One problem would be that this would cast the Global Fund as a normative body responsible for endorsing (or not) new approaches to disease control, a responsibility that is considerably outside the organization’s mandate. However, simply relying on other international organizations is complicated by existing Board policy. For example, one approach could be simply to deem eligible changes codified through amendments to WHO’s standard treatment guidelines (STGs) or Model Essential Medicines List (EML). However, as quoted above, Board policy gives recipients considerably more flexibility than this, allowing them to use Global Fund financing to procure medicines that are not on WHO’s STGs and EML. It would be inconsistent to allow initial financing of products not endorsed by WHO, but then later insist that recipients adhere to WHO norms if they wished to change. Relying solely on WHO documents might also have the negative externality of unduly politicizing the processes of updating the STGs and EML. Finally, WHO materials have their own revision timelines, potentially meaning that recipients that had strong scientific evidence supporting a change based on local research and/or conditions would be forced to delay while waiting for an update.

practicalities (the current structure is not well-suited to handling what could be a large volume of review work that would arrive at any point in the year).

35. Finally, the Board would need to establish a mechanism for making commitments for top-up grants. As with the TRP, this would involve practical difficulties of handling the approval of top-up grants on a rolling basis, despite the periodic nature of Board meetings. It would also involve policy-related challenges. An example of the latter is the need to modify the Comprehensive Funding Policy to determine the relative priority accorded to top-ups as compared to renewals and new proposals.

C. Option Three

36. A third approach to the challenge of reprogramming would be to situate it in the context of a broader attempt to make Global Fund financing both more flexible and more predictable. In particular, one of the key constraints that has been identified in the organization's core business model is that it is unduly "projectized" (i.e., the current model is too focused on standalone projects generated from periodic Global Fund-scheduled Calls for Proposals, rather than oriented around existing program structures). This has led Global Fund financing to be perceived as vertical, rather than the original vision of the organization's resources seamlessly integrating with existing financial flows targeting AIDS, tuberculosis and malaria.
37. These issues were covered in greater detail in GF/B8/13, "Discussion Paper on the Core Business Model of the Global Fund." Of particular relevance to the question of reprogramming is the idea of the Global Fund rewarding well-performing CCMs with access to longer-term streams of financing. This would move away from periodic Calls for Proposals to a more flexible and predictable source of financing, bolstering the ability of CCMs to handle revisions to program implementation strategies (such as those wrought by changing scientific evidence) without needing supplemental, one-off allocations.
38. Members of the Board are scheduled to consider such modifications to the Global Fund's core business model at a retreat following the Ninth Board Meeting. It is therefore difficult to anticipate the possible relevance of this approach for reprogramming. However, having identified the problem posed by reprogramming while the consideration of a shift to a program approach is still at an early stage allows the topic to be addressed as part of any broader work to develop a program approach. This would be an obvious improvement over trying to retrofit reprogramming into the current business model, as is required by the two options above.

D. Options for recommendations for decision points

39. Only the first of the three options above can be operationalized immediately. The soonest that a system based on either Option Two or Option Three could be developed and approved by the Board would be the Tenth Board Meeting in April 2005, meaning that there would be a considerable period of uncertainty if the Board decides only to adopt either of these approaches.
40. Therefore, when potential recommendations for the second and third options are presented below, they include a short-time solution based on option one and complete this with Option Two and Option Three, respectively.
41. There are therefore three draft recommendations to the Board:
 - a. The PMPC recommends that the Board expand the circumstances in which the Phase 2 decision-making process can be accelerated by modifying the existing decision on the Phase 2 process, as set forth in GF/B8/2, page 7, to read as follows: "The Phase 2 decisions will be taken 20 months after the start date for grant programs with

exceptions for *force majeure* situations. The decision may be taken earlier in cases of (i) accelerated implementation; (ii) severe exchange rate fluctuations; or (iii) additional financing needs resulting from changes in scientific evidence.”³

- b. The PMPC recommends that:
 - i. Until a different modality for addressing financial commitments for reprogramming is developed, the Board expand the circumstances in which the Phase 2 decision-making process can be accelerated by modifying the existing decision on the Phase 2 process, as set forth in GF/B8/2, page 7, to read as follows: “The Phase 2 decisions will be taken 20 months after the start date for grant programs with exceptions for *force majeure* situations. The decision may be taken earlier in cases of (i) accelerated implementation; (ii) severe exchange rate fluctuations; or (iii) additional financing needs resulting from changes in scientific evidence.”
 - ii. The Board ask the Secretariat to prepare options for the development of “top-up” grants to be used to finance changes in scientific evidence, and report back through PMPC to the Tenth Board Meeting.
- c. The PMPC recommends that:
 - i. Until a different modality for addressing financial commitments for reprogramming is developed, the Board expand the circumstances in which the Phase 2 decision-making process can be accelerated by modifying the existing decision on the Phase 2 process, as set forth in GF/B8/2, page 7, to read as follows: “The Phase 2 decisions will be taken 20 months after the start date for grant programs with exceptions for *force majeure* situations. The decision may be taken earlier in cases of (i) accelerated implementation; (ii) severe exchange rate fluctuations; or (iii) additional financing needs resulting from changes in scientific evidence.”
 - ii. The Board ask the Secretariat to include options for the financing of reprogramming in the light of changes in scientific evidence in the context of ongoing work as set out in GF/B8/13.

³ NB (not part of the recommendation text): The new wording here is “(iii) additional financing needs resulting from changes in scientific evidence.”

Annex: Budgetary implications

1. Recommendation in Section II: There are no material budgetary implications of this recommendation.
2. Recommendations in Section III:
 - a. Recommendation 1: There are no material budgetary implications of this recommendation.
 - b. Recommendation 2: The additional cost of implementing this recommendation is estimated at US\$25,000.
 - c. Recommendation 3: The budgetary implications of this recommendation would be addressed in the context of any budgetary implications needed to address recommendations arising from consideration of GF/B8/13.