



Investing in our future

The Global Fund

To Fight AIDS, Tuberculosis and Malaria

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Attachment 1

Section 1: Income Level and Cost-Sharing Eligibility Criteria for Proposals for Funding from the Global Fund

Section 2: Terms of Reference of the Technical Review Panel

Section 3: Terms of Reference for the Expert Review Panel for Providing Recommendations to the Global Fund on the Use of Selected Finished Pharmaceutical Products (FPPs)

Income Level and Cost-Sharing Eligibility Criteria for Proposals for Funding From the Global Fund¹

Part 1: Overview of Eligibility Criteria

1. As outlined in the Framework Document, the Global Fund's criteria for eligibility for funding from the Global Fund should take into account a number of factors such as disease burden, political commitment, the involvement of an inclusive Country Coordinating Mechanism and the income level of the country² in which activities will be implemented (as measured by appropriate economic indicators).
2. As such, the Global Fund makes eligibility determinations for proposals for funding based on three criteria. The first is in relation to Country Coordinating Mechanism (CCM) requirements as approved at the 9th Board Meeting. The other two are with respect to income level and cost sharing requirements. This document sets out income level and cost-sharing eligibility criteria that apply to new proposals for funding under the Rounds-Based and Rolling Continuation Channels. These eligibility criteria may also apply to proposals under future funding channels as and when determined by the Global Fund Board.
3. The eligibility criteria set out below have been designed to give the highest priority to those proposals from countries and regions with the greatest need, based on the highest burden of disease and the least ability to contribute financial resources to fight HIV/AIDs, Tuberculosis and Malaria.

Part 2: General Principles

1. The Global Fund assesses income level eligibility of a proposal based on the categorization of the countries in which activities will be implemented as published annually by the World Bank. Proposals for programs to be implemented in countries classified as "low income", "lower-middle income" and "upper-middle income" are eligible for funding from the Global Fund, but additional requirements must be met in the case of "lower-middle income" and "upper-middle income" countries. Proposals for programs to be implemented in countries classified as "high income" are not eligible for funding from the Global Fund.
2. The funding request should seek to cover identified needs based on a sound, costed national strategy to fighting HIV/AIDS, Tuberculosis and Malaria. In the absence of a costed national strategy, the Global Fund will consider funding grant proposals for specific interventions to fight the relevant disease. In order for a proposal to be eligible for funding, the applicant must demonstrate that the cost of funding the national program or interventions for the relevant disease is shared between the Global Fund, domestic resources in the country in which program activities will be implemented and contributions from other donors, as set out in Part 4, paragraph 2 below.

¹ Approved during the Sixteenth Board Meeting on 12-13 November 2007 in Kunming, China (Decision Point GF/B16/DP18, Document GF/B16/7 Revision 1, Attachment 1)

² References in this document to "country" refer to "economies" as classified by the World Bank.

3. A regional proposal that includes implementation in countries a majority of which are eligible for funding will be considered eligible.

Part 3: Income Level Eligibility

1. For proposals for programs to be implemented in countries classified as “lower-middle income”, the interventions for which funding is being requested must focus on poor or vulnerable populations.
2. For proposals for programs to be implemented in countries classified as “upper-middle income”, the following conditions apply:
 - a. The interventions for which funding is sought must be focused on poor and vulnerable populations; and
 - b. There must be a very high disease burden in the country in which activities will be implemented, defined as follows:

HIV/AIDS

- i. The epidemic in the country targeted in the proposal is of such magnitude that it has a measurable impact on population demographics such as life expectancy³, and significant additional external resources are required to adequately address the epidemic;

Or

- ii. The epidemic in a vulnerable population⁴ in the country targeted in the proposal is of such magnitude that there is risk of accelerated spread within that vulnerable population and significant additional external resources are required to adequately address the epidemic.

And

- iii. The country in which activities in the proposal are targeted must be included in the list of Official Development Assistance recipients, published by the Organization for Economic Cooperation and Development (OECD) Development Assistance Committee (DAC).

³ The Board notes that several studies have shown that HIV has a broad and measurable impact on population demographics such as life expectancy once HIV prevalence rate in adults 15-49 is equal to or more than 1 percent (UN Population Division “World Population Prospects 2004”, and US Census Bureau, Internal Programs Center “World Population Profile: 1996, 1998, 2000 and Global Population Profile 2002”). UNAIDS/WHO will provide a list of countries in which adult HIV prevalence is equal to or more than 1 percent. This list will be updated as new data becomes available.

⁴ HIV prevalence rates in adults is equal to or more than 5 percent in at least one identified vulnerable population. UNAIDS/WHO will provide a list of countries in which HIV prevalence is at least 5 percent in one or more vulnerable population. This list will be updated as new data becomes available.

Tuberculosis

- i. The country in which the proposal activities are targeted is included on the WHO list of high-burden countries or on the WHO list of countries that account for ~~95~~ 97 percent of all new cases attributable to HIV/AIDS .

Malaria

- i. The country experiences more than 1 death per 1000 due to malaria based on data provided by WHO.
3. Proposals from countries classified as “upper-middle income” are eligible to apply for funding if the applicant falls under the “small island economy” exception to the International Development Association lending eligibility requirements, regardless of national disease burden.
 4. The Secretariat will make income level eligibility determinations on an annual basis ~~at the time of the Call for Proposals under the Rounds-Based Channel~~ following the release of the World Bank Country Income Classifications in July of each year (or following the month of publication if different from July), to be reviewed by the Portfolio Committee at its next meeting. These income level eligibility determinations will be effective for all calls for applications to the Global Fund under all funding channels from 1 January to 31 December for the following calendar year. In cases where a country moves up from one income category to the next, a one-year grace period will apply, meaning that for the purposes of the next Call for Proposals, the determination of income level eligibility will be based on the earlier income level classification.
 5. In line with the general principle that high income countries are not eligible for Global Fund funding, the one-year grace period only applies to countries moving from the “low-income” category to the “lower-middle income” category and for countries moving from the “lower-middle income” category to the “upper-middle income” category. Those countries moving from “upper-middle income” to “high-income” are not eligible for funding.
 6. In order for the Global Fund to maintain its poverty focus, Global Fund funding for proposals for programs that will be implemented in “upper-middle income” countries will be limited to 10 percent. This ceiling allows for the possibility of increasing demand from “upper middle income” countries with a high burden of disease, such as South Africa.

Part 4: Cost Sharing Eligibility

1. The Global Fund may fund up to the proportion set out below of the cost of the national program as follows:
 - a. in “low-income” countries, up to 100 percent of the national disease program;
 - b. in “low-middle income” countries, up to 65 percent of the national disease program; and
 - c. in “upper-middle income” countries, up to 35 percent of the national disease program.

If there is no national program for the disease, references to the “national disease program” in this Part 4 will be deemed to be references to the specific interventions to fight the disease in the country.

2. The cost-sharing proportion is measured as follows:

A = Total Program Need for the period covered by the current funding request

B = Domestic Financing (national budget + domestic civil society and private sector contribution) for the period covered by the current funding request

C = Available or planned external resources (borrowing, including “soft loans”, grants and contributions from bilateral and multi-lateral donors) for the period covered by the current funding request

D1 = The total funding provided by the Global Fund through existing grants for the disease under previous rounds or under the Rolling Continuation Channel that overlaps with the period covered by the current funding request.

D2 = The amount of the current funding request which may be up to the full amount of the identified funding gap.

Funding Gap = A-B-C-D1

Cost Sharing Proportion = $(D1+D2)/A \times 100$

3. The Global Fund Board may permit some exceptions to the maximum cost-sharing thresholds specified above based on the particular country context, such as:
 - i. Severe economic shock leading to the temporary inability of the country to continue to contribute to the cost sharing element for the three diseases;
 - ii. Severe natural disaster requiring considerable diversion of national resources to address critical needs, thereby temporarily hampering the country's ability to contribute to the cost sharing element for the three diseases; or
 - iii. Where stigma associated with one of the three diseases lead to exclusion of the needs of specific vulnerable groups from the national program.
4. The cost-sharing requirement does not apply for proposals submitted by applicants that are not CCMs⁵.

⁵ The Framework Document states that the Global Fund will consider proposals from non-CCM applicants arising from partnerships in circumstances such as: i) countries without a legitimate government, ii) , countries in conflict or facing natural disaster, or iii) countries that suppress or have not established partnerships with civil society and non-governmental organizations.

TERMS OF REFERENCE OF THE TECHNICAL REVIEW PANEL

Part 1: Background

1. The Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) provides grants in support of technically sound and cost-effective interventions for the prevention of infection and the treatment, care and support of persons infected and directly affected by HIV/AIDS, tuberculosis and malaria.

2. The Technical Review Panel (TRP) is an independent, impartial team of experts appointed by the Global Fund Board to guarantee the integrity and consistency of an open and transparent proposal⁶ review process. The TRP, in its various formations outlined in paragraph 4 and 9 below, reviews:

- (a) proposals for financial support submitted through the rounds based channel (Rounds-based channel);
- (b) Requests for Phase 2 Continued Funding that are determined by the Secretariat's Phase 2 Panel to constitute a 'Revised Go' under the criteria specified in the Secretariat's Phase 2 Decision Making Policies and Procedures (Revised Go Requests) as may be amended from time to time;
- (c) proposals for the continuation of expiring grants submitted through the rolling continuation channel⁷ (Rolling Continuation Channel); and
- (d) other ad hoc requests by applicants to change implementation arrangements to such extent that the proposed changes are determined by the Secretariat to comprise a material reprogramming request in regard to a Global Fund Board approved proposal (a Reprogramming Request).

3. The TRP's review function is performed against technical criteria as set out in these terms of reference (TORs). Based on these criteria, the TRP makes:

- (a) funding recommendations to the Board of the Global Fund for final decision in respect of Rounds-based Channel and Rolling Continuation Channel proposals, and Revised Go Requests; and
- (b) a final decision to the Secretariat in respect of a Reprogramming Request.

⁶ The term 'proposal' refers to each separate component within an application for funding, whether HIV/AIDS, tuberculosis, malaria or such other component as may be approved by the Board from time to time.

⁷ Defined in Global Fund Board decision Global Fund/B14/DP9, as may be amended from time to time.

Part 2: TRP Membership

Definitions

4. In these TORs, a reference to:
 - (a) the **Permanent TRP** means the group of experts whose primary role is to review proposals through the Rounds-based channel, and **Permanent TRP Members** means those experts who primarily review such proposals;
 - (b) **Alternate Members** means those persons identified for each Round of proposal review, who may be requested by the TRP Chair to replace a Permanent TRP Member and serve on the TRP in the event a Permanent TRP Member is not available to review proposals for a specific Round;
 - (c) the **Support Group** means the pool of experts from which TRP membership is chosen and replenished from time to time;
 - (d) **Former TRP Members** means those TRP members whose term of service as a 'Permanent TRP Member' has expired and who may be requested to participate in review of Revised Go Requests and Rolling Continuation Channel proposals;
 - (e) the **TRP** means, collectively, each of the Permanent TRP Members, Alternate Members, the Support Group and Former TRP Members;
 - (f) the **TRP Chair** means the person selected by the Permanent TRP Members as chair of the TRP from time to time;
 - (g) the **TRP Vice Chair** means ~~the~~ a person selected by the Permanent TRP Members as vice chair of the TRP from time to time;
 - (h) a **Rolling Continuation Channel Panel** is a panel constituted to review proposals submitted under the Rolling Continuation Channel; and
 - (i) an **Ad Hoc Panel** is a panel constituted to review a Reprogramming Request or a Revised Go Request.

Composition of the TRP

5. The TRP membership shall:
 - (a) be representative of a wide array of expertise, both scientific and programmatic, with a preference for extensive program experiences;
 - (b) have geographically diverse experiences and include persons who work or have worked with a broad range of organizations in both developing and developed countries;
 - (c) include a balance of expertise in HIV/AIDS, tuberculosis and malaria prevention, care and treatment, as well as cross-cutting and health systems areas applicable to program implementation in resource-poor settings;
 - (d) include persons with extensive experience in the role of civil society/private sector in the field of HIV/AIDS, tuberculosis and/or malaria; and

- (e) include, all other matters being equal, geographically and ethnically diverse representation, and a significant number of women and people living with and/or affected by HIV/AIDS, tuberculosis and/or malaria.
6. TRP members serve in their personal capacities only.
7. Members of the Secretariat and employees of the United Nations and its specialized agencies are ineligible to serve as TRP members from Round 8. Board Members, Alternate Members, Focal Points and country coordinating mechanism⁸ members shall stand down from these roles if selected to serve on the TRP.
8. The names and curricula vitae of Permanent TRP Members (and Alternate Members or Support Group members selected to serve as a reviewer for a specific Round) shall be made public on the Global Fund website.
9. Size of TRP:
- (a) The **Permanent TRP** shall consist of a maximum of ~~37~~ **40** persons and, subject to this paragraph, be **generally** comprised of ~~maximum of:~~
- (i) eight HIV/AIDS experts;
 - (ii) six tuberculosis experts;
 - (iii) six malaria experts;
 - (iv) **16** ~~14~~ cross-cutting experts; and
 - (v) one additional Permanent TRP Member to replace the TRP Chair during the period that she or he is TRP Chair.

The TRP Chair and TRP Vice-Chair(s) may, at their discretion, adjust the number of experts across the different fields of expertise noted above, having regard to the needs of the TRP for a specific Round.

- (b) The **Alternate Member pool** shall consist of a maximum of 20 persons for each Round, apportioned between the relevant expertise groups as appropriate.
- (c) An **Ad Hoc Panel** or a **Rolling Continuation Channel Panel** shall consist of the TRP Chair and/or a Vice Chair and appropriate number of reviewers as determined by the Chair or Vice Chair.
- (d) The **Support Group pool** shall consist of a maximum of 80 persons at any one time (excluding Permanent TRP Members, Alternate Members and Former TRP Members), and respectively apportioned between the relevant expertise groups.

Part 3: Process of identification of TRP members

Formation and identification of Support Group

10. The Board of the Global Fund shall select Support Group members based upon recommendations of the Portfolio Committee and Executive Director of the Global Fund made in

⁸ The reference to country coordinating mechanism (CCM) includes regional coordinating mechanisms and sub-CCMs.

accordance with these TORs. Before making its recommendation, the Portfolio Committee and Executive Director shall agree to a ranking of the Support Group members.

11. Based on lessons learned, the TRP Chair and TRP Vice Chair(s) may identify perceived gaps in the minimum areas of expertise across the TRP, and provide such input to the Portfolio Committee for consideration in regard to the recruitment and selection processes for TRP membership.

12. Recruitment and selection of Support Group members:

- (a) will be undertaken typically every two years; and
- (b) may also be undertaken, as necessary to fill unexpected vacancies.

13. The recruitment and selection of Support Group members will be:

- (a) managed by the Portfolio Committee through an open, transparent and criteria based process; and
- (b) made through a public call for applications. On behalf of the Portfolio Committee, the Secretariat shall invite Board constituencies, lead technical partnerships (including UNAIDS, the Stop TB Partnership and the Roll Back Malaria Partnership), WHO's technical advisory clusters and programs, and TRP members to identify appropriately qualified and independent experts to receive an invitation to apply.

Identification of Permanent TRP Members and Alternate Members

14. After each Rounds-based review process, the TRP Chair and Vice Chairs shall identify persons they recommend as replacements for vacancies in Permanent TRP Members and Alternate Members from the Support Group and shall provide these recommendations to the Portfolio Committee and the Executive Director to consider and make recommendations to the Board, using criteria consistent with paragraph 5 above and based upon the following principles:

- (a) identified needs to ensure that the Permanent TRP maintains an appropriate mix of skills and competencies;
- (b) program and regional/in-country experiences and academic experiences are balanced amongst Permanent TRP Members; and
- (c) regard to the rankings of members of the Support Group.

Selection of the TRP Chair and TRP Vice Chair(s)

15. The TRP Chair and TRP Vice Chair shall be elected by the Permanent TRP Members from its membership as required to ensure that the position of TRP Chair and TRP Vice Chair are not vacant. The TRP may select a second Vice Chair to facilitate the sharing of TRP leadership responsibilities more broadly. It is anticipated that, typically, the TRP Vice Chair(s) will be confirmed by the Permanent TRP members as the incoming TRP Chair commencing immediately

after the completion of TRP clarifications for the final Rounds-based proposal review overseen by the outgoing TRP Chair. The TRP shall establish a voting procedure prior to such a selection.

Identification of TRP Members for non-Rounds-based channel reviews

16. The TRP Chair and Vice Chair(s) shall determine the size and composition of each Rolling Continuation Channel Panel based on the field of expertise of potential reviewers, and the content of the proposals. Such panels may include Permanent TRP Members, Former TRP Members and where necessary due to member unavailability, Alternate Members and Support Group members.

17. The TRP Chair and Vice Chair(s) shall determine the size and composition of each Ad Hoc Panel from Permanent TRP Members, and where necessary due to member unavailability, Alternate Members. The TRP Chair or a Vice Chair determines the size and composition of each panel depending on the particular reprogramming request submitted for review.

Maximum term of service for Permanent TRP Members

18. Permanent TRP Members may serve a term of up to four Rounds of proposal review. A Permanent TRP Member's term of service is not required to be completed over consecutive Rounds.

19. After completion of each Rounds-based proposal review, the TRP Chair and TRP Vice Chair(s) will report to the Portfolio Committee on its recommendations for Permanent TRP members.

20. The TRP Chair may serve as chair for no more than two Rounds. The maximum term of service of four Rounds of proposals for Permanent TRP Members referred to in paragraph 18 above is extendable for an additional two Rounds for the TRP Chair.

Conflicts of interests and confidentiality

21. Members of the TRP are covered by the requirements of the ['Policy on Ethics and Conflict of Interest for Global Fund Institutions'](#)⁹.

22. The TRP may set internal guidelines on how to comply with the 'Policy on Ethics and Conflict of Interest for Global Fund Institutions'.

23. Members of the TRP shall sign a confidentiality statement prepared in accordance with the TRP's internal guidelines on an annual basis if called upon to participate in the review of proposals.

Part 4: Scope of Work of the TRP

Review criteria and recommendations process

24. The TRP undertakes its review of Rounds-based channel proposals, Revised Go Requests, Rolling Continuation Channel proposals and Reprogramming Requests against the following technical criteria:

⁹ Report of the Third Board Meeting (GLOBAL FUND/B4/2, p.14) Annex 1 (Revision 1) to the Report of the Ethics Committee (GF/B18/8)

- (a) Soundness of approach;
- (b) Feasibility; and
- (c) Potential for sustainability and impact.

25. Detailed characteristics of the review criteria for proposals submitted after 5 July 2007 are set out in paragraph 24 above are attached as Attachment 1 to these TORs.

26. The TRP undertakes its review ensuring that each of the review criteria are equally considered (no one criterion overweighting any other), without consideration of the amount of resources available to the Global Fund or the income level or burden of disease of the economy targeted by proposal.

27. Primary and secondary reviewers may solicit ad hoc assistance from the Secretariat and technical partners, clarifying epidemiological information and/or policies or any aspects of implementation of previous financing concerning the proposal under review.

28. TRP recommendations are made by consensus in plenary¹⁰. If consensus cannot be reached, the Chair shall call for a decision by majority vote of those present.

29. Other than for Reprogramming Requests, the TRP shall provide its funding recommendations to the Board, as well as feedback to applicants regarding the technical quality of their proposal, in a document entitled 'TRP Review Form'. The TRP Review Form shall also specify any clarifications and/or adjustments that the TRP requires, or reasons why a proposal was not recommended for funding.

30. After a Board decision on funding (or, in the case of a Reprogramming Panel recommendation, the Secretariat's receipt of notice of the recommendation of the TRP¹¹), TRP Review Forms shall be provided to applicants.

Review and outcomes of proposals submitted through the Rounds-based channel

31. The TRP shall review eligible proposals submitted through the Rounds-based channel during an in-person meeting.

32. The TRP shall review each Rounds based proposal as a whole and not separately evaluate elements within a proposal and recommend some to the Board for funding and not others. The TRP can however recommend modification or even elimination of weak elements in an otherwise strong proposal where those weak elements are not a key or major aspect of the proposal. However, in reviewing a disease component which contains a cross-cutting HSS section, the TRP may recommend for funding either:

- a. The entire disease component, including the cross-cutting HSS section;
- b. The disease component excluding the cross-cutting HSS section; or
- c. Only the cross-cutting HSS section if the interventions in that section materially contribute to overcoming health systems constraints to improved HIV, tuberculosis and malaria outcomes.

¹⁰ In these TORs the term 'plenary' refers to all of the TRP members participating in the relevant review process (whether a Round, Continuation Channel wave, or an individual reprogramming request)

¹¹ Refer to paragraph 3 in part 1 above.

In addition, the TRP can recommend modification or even elimination of weak elements in an otherwise strong proposal where those weak elements are not a key or major aspect of the proposal.⁷

Commencing with Round 10, the TRP may recommend the approval of a Rounds based proposal conditional upon the removal of a limited set of elements of the proposal (which removal is not subject to a right of appeal).¹²

33. The TRP Chair and/or a TRP Vice Chair shall assign the primary and the secondary reviewers for each proposal. The primary reviewer is responsible for compiling the TRP Review Form and presenting the group's review comments to the plenary. The secondary reviewer supports the group's presentation at the plenary session.

34. The TRP Chair shall not serve as a reviewer of proposals, but facilitates the plenary discussions on a daily basis.

35. The TRP shall classify proposals according to the four categories set out in part 1 of **Attachment 2** to these TORs and presents its recommendations by category to the Board.

36. After each Rounds-based proposal review meeting, the TRP Chair and Vice Chair(s) shall prepare a report to the Board, which includes an analysis of the outcome of the review process as well as recommendations on lessons learned from that Round.

Review and outcomes of proposals submitted through the Rolling Continuation Channel

37. The TRP shall review eligible proposals submitted through the Rolling Continuation Channel. The TRP Chair shall determine the method of such review.

38. The TRP shall determine whether or not the Rolling Continuation Channel proposal is materially different in scope, as defined by the Secretariat¹³, compared to the scope of the grant it seeks to continue. If the Rolling Continuation Channel Panel determines that there is such a material difference, it shall reject the proposal under Category 4 specified in Part 2 of Annex 2 to these TORs (and will also provide information on any perceived main technical weaknesses in the proposal that the TRP has observed in making such determination). If the TRP determines that the proposal is not materially different, it shall continue to undertake a full review of the proposal for technical merit as specified in paragraph 24 above.

39. The TRP may recommend the approval of a Rolling Continuation Channel proposal conditional upon the removal of a limited set of elements of the proposal.

40. The TRP shall classify proposals according to the four categories set out in part 2 of **Attachment 2** to these TORs and presents its recommendations by category to the Board.

¹² Article 32 has been amended in line with Board Decision [GF/B17/DP5](#) and [GF/B18/DP14](#).

¹³ The Guidelines accompanying a Rolling Continuation Channel Proposal Form will define 'Materially different' for the purposes of the application.

Review and outcomes of Reprogramming Requests

41. At any stage after initial Board approval the Secretariat may request the TRP to review changes to the implementation plans for a grant on the basis that proposed changes are so significant that had they been known at the time that the original recommendation was made, may have resulted in a different TRP recommendation (Material Reprogramming).

42. The TRP Chair or a Vice Chair shall determine the method of review of Reprogramming Requests.

43. Where the TRP determines that the Reprogramming Request is Material Reprogramming, the TRP reviews the Reprogramming Request against the criteria set out in paragraph 24 above. If the TRP determines that the Reprogramming Request is not a Material Reprogramming, the TRP refers it back to the Secretariat. The decision of the TRP represents a final decision on the Reprogramming Request.

44. Where a Reprogramming Request is approved by the TRP, the TRP may request an applicant to provide clarifications or adjustments to the TRP within the certain timeframe prior to final approval. Such adjustments or clarifications must be completed, as evidenced by approval of the TRP Chair or a Vice Chair.

Review and outcomes of Revised Go Requests referred by the Phase 2 Decision Panel

45. The TRP shall review Revised Go requests and make recommendations to the Board using the Phase 2 decision making categories set out in part 3 to Attachment 2 to these TORs. Other than when a 'No Go' recommendation is made, the TRP also recommends an upper ceiling for the incremental funding amount for continued funding.

Part 5: Proposal Clarifications and Adjustments Process

46. The TRP's funding recommendations to the Board (or, for Reprogramming Requests approved by the TRP) may require clarifications and adjustments.

47. Board decisions for funding of Rounds-based channel proposals, Rolling Continuation Channel proposals and Revised Go Requests are subject to such clarifications and adjustments being finalized within the limited timeframes set out in Annex 2 to these TORs. The TRP clarifications process commences as soon as possible following a Board decision on funding.

48. The primary and secondary reviewers of a proposal or Revised Go Request shall evaluate information provided by the applicant in response to the clarifications and adjustments requested by the TRP. The TRP Chair and/or TRP Vice-Chair(s) shall give final approval of the proposal or the Revised Go Request based on consultations with the primary and secondary reviewers.

49. During the TRP clarifications process, there may be several iterations between the TRP and the applicant, which may result in budgetary reductions or changes to objectives and targets. The TRP may also set conditions to be fulfilled prior to funding and indicate matters for the Secretariat's attention during the grant negotiations.

50. Successful appeals are subject to the same clarification process as described in this part 5.

Appeal Process

51. Board decisions on the funding of Rounds-based channel and Rolling Continuation Channel proposals are made by reference to TRP recommendations, and may be subject to appeal consistent with the Appeal Policy.

Part 6: Logistics

52. TRP Members may receive an honorarium for their services, as approved by the Global Fund Secretariat, in addition to travel expenses and per diems.

53. The TRP is supported by the Secretariat to support and facilitate its activities, in particular with regard to the arrangements for the TRP meetings as well as provision of the relevant documentation for review.

Attachment 1 - Proposal Review Criteria

The TRP looks for proposals that demonstrate the following characteristics:

Soundness of approach:

- Use of interventions consistent with international best practices (as outlined in the Stop TB Strategy, the Roll Back Malaria Global Strategic Plan, the WHO Global Health-Sector Strategy for HIV/AIDS and other WHO and UNAIDS strategies and guidance) to increase service coverage for the region in which the interventions are proposed, and demonstrate a potential to achieve impact;
- Give due priority to groups and communities most affected and/or at risk, including by strengthening the participation of communities and people infected and affected by the three diseases in the development and implementation of proposals;
- Demonstrate that interventions chosen are evidence-based and represent good value for money;
- Involve a broad range of stakeholders in implementation, including strengthening partnerships between government, civil society, affected communities, and the private sector;
- Address issues of human rights and gender equality, including contributing to the elimination of stigmatization of and discrimination against those infected and affected by tuberculosis and HIV/AIDS, especially women, children, and other vulnerable groups; and
- Are consistent with national law and applicable international obligations, such as those arising under World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement), including the Doha Ministerial Declaration on the TRIPS Agreement and Public Health, and encourage efforts to make quality drugs and products available at the lowest possible prices for those in need while respecting the protection of intellectual property rights.

Feasibility:

- Provide strong evidence of the technical and programmatic feasibility of implementation arrangements relevant in the specific country context, including where appropriate, supporting decentralized interventions and/or participatory approaches (including those involving the public, private and non-government sectors, and communities affected by the diseases) to disease prevention and control;
- Build on, complement, and coordinate with existing programs (including those supported by existing Global Fund grants) in support of national policies, plans, priorities and partnerships, including National Health Sector Development Plans, Poverty Reduction Strategies and sector-wide approaches (where appropriate);
- Demonstrate successful implementation of programs previously funded by international donors (including the Global Fund), and, where relevant, efficient disbursement and use of funds. (For this purpose, the TRP will make use of Grant Score Cards, Grant Performance Reports and other documents related to previous grant(s) in respect of Global Fund supported programs);
- Utilize innovative approaches to scaling up programs, such as through the involvement of the private sector and/or affected communities as caregivers;
- Identify in respect of previous proposals for the same component submitted to the Global Fund through the Rounds-based channel but not approved, how this proposal addresses any weaknesses or matters for clarification that were raised by the TRP;

- Identify for proposals submitted through the Rolling Continuation Channel, how his proposal addresses the implementation challenges and sustainability issues identified by the Secretariat during the Rolling Continuation Channel qualification process;
- Focus on performance by linking resources (inputs) to the achievement of outputs (people reached with key services) and outcomes (longer term changes in the disease), as measured by qualitative and quantitative indicators;
- Demonstrate how the proposed interventions are appropriate to the stage of the epidemic and to the specific epidemiological situation in the country (including issues such as drug resistance);
- Build on and strengthen country impact measurement systems and processes to ensure effective performance based reporting and evaluation; and
- Identify and address potential gaps in technical and managerial capacities in relation to the implementation of the proposed activities through the provision of technical assistance and capacity building.

Potential for sustainability and impact:

- Strengthen and reflect high-level, sustained political involvement and commitment, including through an inclusive and well-governed CCM, Sub-CCM or RCM;
- Demonstrate that Global Fund financing will be additional to existing efforts to combat HIV/AIDS, tuberculosis, and malaria, rather than replacing them;
- Demonstrate the potential for the sustainability of the approach outlined, including addressing the capacity to absorb increased resources and the ability to absorb recurrent expenditures;
- Coordinate with multilateral and bilateral initiatives and partnerships (such as the WHO/UNAIDS “Universal Access” initiative, the Stop TB Partnership, the Roll Back Malaria Partnership, the “Three Ones” principles¹⁴ and UNICEF’s “Unite for Children. Unite against AIDS” campaign) towards the achievement of outcomes targeted by National Health Sector Development Plans (where they exist);
- Demonstrate that the proposal will contribute to reducing overall disease, prevalence, incidence, morbidity and/or mortality; and
- Demonstrate how the proposal will contribute to strengthening the national health system in its different components (e.g., human resources, service delivery, infrastructure, procurement and supply management).

¹⁴ One agreed HIV/AIDS action framework that provides the basis for coordinating the work of all partners, one national AIDS coordinating authority with a broad-based multi-sectoral mandate, and one agreed country-level monitoring and evaluation system. See www.unaids.org for more information. Proposals addressing HIV/AIDS should indicate how these principles are put into practice.

Attachment 2: Recommendation Categories of the TRP

Part 1 - Recommendation categories relevant to Rounds-based channel proposals

Category	Description of Recommendation
1	Recommended for funding with no or only minor clarifications, to be met within four eight ¹⁵ weeks of receipt of notice to the applicant of the Board decision on funding, as evidenced by the documented final approval of the TRP Chair or TRP Vice-Chair.
2	Recommended for funding provided that adjustments and clarifications are met within a limited timeframe, as evidenced by the documented final approval of the TRP Chair or TRP Vice Chair (based on consultations with the primary and secondary reviewer). The applicable timeframe is that the initial reply to any clarifications or adjustments must be received by the Global Fund within six weeks of the applicant's receipt of notice the Board decision on funding, and any further adjustments and clarifications should be completed within three months of the Global Fund's receipt of the initial reply from the applicant. <i>As a subset of Recommended Category 2 Proposals, 'Recommended Category 2B Proposals' - Proposals identified at the request of the Board to allow for a situation in which there are insufficient funds to meet the commitments required to fund all of the Recommended Category 1 Proposals and Recommended Category 2 Proposals. Recommended Category 2B Proposals are relatively weak 'Recommended Category 2 Proposals', on grounds of technical merit and/or issues of feasibility and likelihood of effective implementation. The same timeframe for clarifications applies to these proposals as for Recommended Category 2 Proposals</i>
3	Not recommended for funding in its present form but encouraged to resubmit a revised version of the same proposal, taking into account the issues raised by the TRP, for consideration in the next round of proposals following major revision ¹⁶ .
4	Rejected.

¹⁵ The deadline for Category 1 proposals have been extended from four to eight weeks in line with the Board Decision GF/B18/DP14

¹⁶ Amended in line with the Board Decision GF/B18/DP19 (applicable commencing with Round 10)

Part 2 - Recommendation categories relevant to Rolling Continuation Channel proposals

Category	Description of Recommendation
1	Recommended for funding with no clarifications.
2	Recommended for funding provided that adjustments and clarifications are met within a limited timeframe, as evidenced by the documented final approval of the TRP Chair or TRP Vice Chair (based on consultations with the primary and secondary reviewer). The applicable timeframe is that the initial reply to any clarifications or adjustments must be received by the Global Fund within four weeks of the applicant's receipt of notice the Board decision on funding, and any further adjustments and clarifications should be completed within two months of the Global Fund's receipt of the initial reply from the applicant.
3A ¹⁰⁻¹⁷ (Applicable only upon initial submission)	Not recommended for funding based on technical merit but strongly encouraged to resubmit a revised proposal, taking into account the issues raised by the TRP, for consideration in the next wave of Rolling Continuation Channel proposals.
3B (Applicable only upon re-submission)	Not recommended for funding based on technical merit but encouraged to resubmit through the Rounds-Based Channel following major revision.
4	Materially different and rejected as a Rolling Continuation Channel proposal.

^{17 40} Category 3 relevant to Rolling Continuation Channel proposals has been divided into two categories, 3A and 3B, in line with Board Decision GF/B18/DP8

Part 3 - Recommendation categories during the Phase 2 Revised Go Request review process

Category	Description of Recommendation
Go	Recommended commitment of additional resources.
Conditional Go	Recommended commitment of additional resources provided that certain time bound conditions are met, or provided that adjustments to the Revised Go Request for Continued Funding are provided within a limited timeframe set by the TRP as evidenced by final approval of the TRP Chair or TRP Vice Chair.
No Go	Recommended discontinuation of funding.

**Terms of Reference for the Expert Review Panel
for providing recommendations to the Global Fund on the use of selected Finished
Pharmaceutical Products**

PART 1: BACKGROUND

1.1 At its Eighteenth Meeting in November 2008, the Global Fund Board approved a revised Quality Assurance Policy for Pharmaceutical Products ("QA Policy"). The QA Policy shall come into effect on 1 July 2009 and shall replace the Global Fund's previous policy for the quality assurance of pharmaceutical products.

1.2 The QA Policy provides that Global Fund grant funds may only be used to procure antiretrovirals, anti-tuberculosis and anti-malarial finished pharmaceutical products (FPPs) that meet the following standards:

- i. Prequalified by the WHO Prequalification Program or authorized for use by a Stringent Drug Regulatory Authority (SRA); or
- ii. Recommended for use by an Expert Review Panel (ERP).

1.3 The Board has authorized the Secretariat to request the World Health Organization (WHO) to host the ERP and to conclude the necessary arrangements with WHO.

1.4 This document sets out the terms of reference for the ERP and will be subject to final approval following a review by the Global Fund Board Portfolio Committee (PC) at its 11th Meeting in March/April 2009.

PART 2: PURPOSE OF THE ERP

2.1 As defined in the QA Policy, the ERP will be an independent technical body hosted by WHO Department of Essential Medicines and Pharmaceutical Policies that is composed of external technical experts.

2.2 The purpose of the ERP is to review the potential risks/benefits associated with the use of FPPs that are not yet WHO-prequalified or SRA-authorized. The ERP will make recommendations to the Global Fund on whether to allow grant funds to be used to procure such FPPs.

PART 3: DIVISION OF FUNCTIONS BETWEEN GLOBAL FUND SECRETARIAT AND THE ERP

3.1 The Global Fund Secretariat will be responsible for:

- i. inviting manufacturers of selected medicines to submit an Expression of Interest (EoI) to have FPPs reviewed by the ERP;
- ii. publishing on its website guidelines on the application process for ERP review;
- iii. managing the receipt of product dossiers sent by manufacturers according to the EoI requirements and guidelines;
- iv. providing product dossiers to the ERP Coordinator at WHO for ERP review;

- v. notifying manufacturers of the outcome of the ERP's review of their respective product dossiers; and
- vi. maintaining on its website an up-to-date list of all FPPs that have been recommended for use by the ERP.

3.2 The WHO Department of Essential Medicines and Pharmaceutical Policies will be responsible for:

- i. hosting the ERP;
- ii. establishing rules of procedure and criteria for ERP reviews in line with those established for the WHO Prequalification Program;
- ii. nominating an ERP Coordinator to be responsible for managing the selecting ERP members, ensuring that ERP members remain current with latest SRA guidelines and ensuring timely review of the dossiers received from the Global Fund Secretariat.

3.3 The ERP will be responsible for:

- i. timely review of product dossiers with a particular focus on the technical information described in Part 6 below; and
- ii. delivering to the Global Fund a report detailing the findings of each such review, including recommendations on whether to allow grant funds to be used to procure the FPP in question, within the timeline agreed with the Global Fund

PART 4: ERP MEMBERSHIP

4.1 The ERP shall consist of a pool of at least 15 senior experts who may be called upon , to participate in the review of product dossiers. Out of that pool, a maximum of seven experts will be selected to participate in each panel meeting to conduct and finalize the specific dossier reviews.

4.2 ERP membership shall be representative of a wide range of expertise in the pharmaceutical and medical fields and preferably include at least two members with recent work experience in a SRA. Each ERP Member shall have work experience in a national medicines regulatory authority and extensive professional experience in at least one of the following technical areas: (i) quality assurance of pharmaceuticals; (ii) quality control of pharmaceuticals; (iii) pharmaceutical regulatory affairs; (iv) disease control; (v) pharmaceutical manufacturing; (vi) clinical and/or biopharmaceutics/pharmacokinetics

4.3 ERP Members shall serve in their personal capacities only (that is, they shall not represent their employers or other organizations when serving as ERP members). The names and curricula vitae of ERP members shall be made available to the public.

4.4 ERP members are covered by the requirements of the Global Fund's Policy on Ethics and Conflict of Interest for Global Fund Institutions ("Ethics Policy"). Accordingly, each member shall be required to complete and submit declaration of interest forms to the Global Fund's Ethics Official in accordance with the requirements set out in the Ethics Policy.

4.5 ERP members shall treat all information to which they gain access during the review process as confidential and shall sign statement modeled after the WHO Prequalification Program guidelines.

PART 5: SCOPE OF WORK OF THE ERP

5.1 As requested by the Global Fund, the ERP shall assess the quality of FPPs that meet the following eligibility criteria:

- (i) (a) the manufacturer of the FPP has submitted an application for pre-qualification of the product by the WHO Prequalification Program and it has been accepted by WHO for review; OR
- (b) the manufacturer of the FPP has submitted an application for marketing authorization to an SRA, and it has been accepted for review by the SRA,

AND

- (ii) the FPP is manufactured at a site that is compliant with the standards of Good Manufacturing Practice (GMP) that apply for the relevant Product Formulation, as verified after inspection by:
 - (a) the WHO Prequalification Program; OR
 - (b) an SRA; OR
 - (c) a regulatory authority participating to the Pharmaceutical Inspection Cooperation Scheme (PIC/S).

5.2 For each such assessment, the ERP shall review selected parts of the product dossier that have been sent to the ERP Coordinator from the Global Fund. The ERP assessment shall focus on the technical areas specified in Part 6 below.

5.3 The ERP shall prepare and submit a report to the Global Fund, which outlines the key findings of its review and provides a recommendation on whether the Global Fund should allow the FPP to be procured with grant funds.

5.4 The ERP review process should be conducted in close collaboration with the WHO Prequalification and WHO disease programmes.

PART 6: TECHNICAL AREAS OF ERP REVIEW

6.1 The ERP will review a product dossier, focusing on the following technical areas:

- i. product registration information;
- ii. regulatory (licensing) status of the FPP and manufacturing facility (including GMP status);
- iii. finished product specifications and information regarding compliance with international pharmacopoeia standards, if available;
- iv. stability testing data (both accelerated and real time studies) as per ICH and/or WHO Guidelines;
- v. product labeling information;
- vi. active pharmaceutical ingredient (API) characteristics, including specifications, test methods and any certifications;
- vii. Integrity of supply chains; and
- viii. Safety and efficacy data or human bioequivalence data.

PART 7: VALIDITY OF THE ERP RECOMMENDATIONS

7.1 As specified in the QA Policy, if the ERP recommends the use of an FPP, the ERP's recommendation shall be valid for a period of no more than 12 months ("ERP Recommendation Period"), or until the FPP is WHO-prequalified or SRA-authorized¹⁸, whichever is the earlier.

¹⁸ Or approved or subject to a positive opinion under the Canada S.C. 2004, c. 23 (Bill C-9) procedure, or Art. 58 of European Union Regulation (EC) No. 726/2004 or United States FDA tentative approval.

However, the Global Fund may, in its sole discretion, request the ERP to consider extending the ERP recommendation period for up to an additional 12 months if the FPP is not yet WHO-prequalified or SRA-authorized within the ERP Recommendation Period. The extension review would include an assessment of progress with WHO prequalification or SRA approval. The Global Fund may refer more than one request for such an extension to the ERP

PART 8: TRANSPARENCY

8.1 Guidelines on the application process for ERP reviews will be made publicly available on the Global Fund website. All FPPs recommended for use by the ERP will also be made publicly available.

PART 9: LOGISTICS

9.1 ERP members may receive an honorarium for their services, as approved by the Global Fund, in addition to travel expenses and per diems.

9.2 The ERP is supported by the Secretariat to facilitate its activities, in particular with regards to the arrangements for the ERP sessions as well as provision of the relevant documentation for review.

PART 10: EVALUATION OF THE ERP

10.1 No later than 18 months after the establishment of the ERP, the Global Fund will evaluate the performance of the ERP against the indicators that will be set forth in the contract between the Global Fund and the WHO.



Investing in our future

The Global Fund

To Fight AIDS, Tuberculosis and Malaria

Nineteenth Board Meeting
Geneva, 5 - 6 May 2009

GF/B19/5
Attachment 2

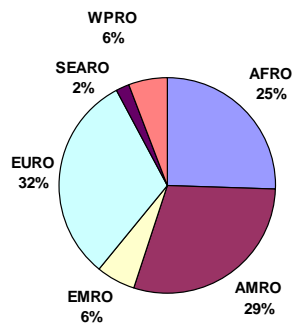
PC Sub-working Group on TRP Replenishment and Round 9 TRP Membership

1. Further to the PC Report (GF/B18/5 part 3, paragraph 3), the PC requested the Secretariat to conduct a partial replenishment of up to five new cross-cutting experts with a particular focus on gender and issues facing sexual minorities to join the TRP Support Group.
2. At their 11th Meeting in March 2009, the PC decided to convene a Sub-Working Group to select the new TRP Support Group members in time for these newly recruited gender experts to be considered in the Round 9 TRP membership.¹
3. A Sub-working Group on the TRP partial replenishment and on Round 9 TRP membership meeting was held on 4 May 2009. The meeting was chaired by the Chair and Vice-Chair of the PC. The following Sub-Working Group members attended the meeting:
 - i. UK/Australia Representative to the PC: Dr Tim Poletti
 - ii. Developing Country Non-Governmental Representative to the PC: Dr Karlo Boras
 - iii. Representatives from WHO:
 - a. Dr Leopold Blanc, Medical Officer, Stop TB
 - b. Dr Ying-Ru Lo, Coordinator, HIV/AIDS, TB, Malaria and Neglected Tropical Diseases
 - iv. UNAIDS: Mr Pradeep Kakkattil, Chief, Technical Support Division
 - v. World Bank: Dr Armin Fidler, Legal Adviser, Health Policy and Strategy Human
 - vi. TRP Chair and Vice Chairs: Drs Peter Godfrey-Faussett, Indrani Gupta and Bola Oyeledun
4. The composition of the Sub-working Group is based on Board policy for TRP selection which requires the input of partner organizations in their respective areas of expertise.
5. The Sub-working Group deliberated on a short list of twenty-two candidates. Ensuring an appropriate focus on expertise in the field of gender and sexual minorities, the Sub-Working Group unanimously selected five candidates to recommend to the Board.
6. In addition, the Sub-working Group discussed Round 9 TRP Membership. The PC received and endorsed the recommendations of the TRP Chair and Vice-Chairs. The proposed membership for the TRP for Round 9 and the alternates for 2009 is detailed in the Annex to this Attachment 2.

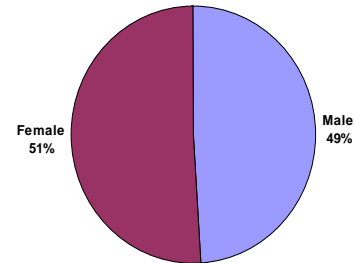
¹ GF/B19/5 part 4, paragraph 2.

7. The proposed TRP Members for Round 9 include three of the new five gender experts. In addition, female representation in the TRP increases from 43% to 51% and strong representation of experts working in countries in most need is maintained. The gender and geographic breakdown of the TRP as proposed by the PC is shown in the figures below.

Regional Balance by country of nationality



Gender Balance



8. Based on the results of these deliberations, the PC recommends the following decision point to the Board.

Decision Point:

The Board approves the appointment of the following:

- (a) *To strengthen the TRP's cross-cutting expertise with a focus on gender and sexual minorities, Drs Ondina Leal, Tim Brown, Sarah Hawkes, Mabel Bianco and Katya Burns as members of the TRP Support Group;*
- (b) *Dr Tim Brown (HIV), Dr Daphne Toupozis (HIV), Ms Nomathemba Mazelani (HIV), Ms Hanem Zaher (Tuberculosis), Dr Ondina Leal (Cross-Cutting), Dr Mabel Bianco (Cross-Cutting), Dr George Gotsadze (Cross-Cutting) and Mr Tore Rose (Cross-Cutting) as Permanent Members of the TRP to serve up to four Rounds commencing from Round 9;*
- (c) *In respect of calls for proposals made in 2009, the twelve (12) persons identified as Alternate Members in GF/B19/5 Revision 1.*

each of whom have been recommended by the Portfolio Committee and the Executive Director upon consideration of required technical expertise, as well as geographical distribution and gender balance.

There are no material budgetary implications for this decision.

Technical Review Panel (TRP) Round 9 Membership

Category	No.	Surname	First name	Gender	Nationality	Rounds served									
						1	2	3	4	5	6	7	8		
HIV/AIDS (TBD) Members	1	Sikipa	Godfrey	M	Zimbabwe										
	2	Tregnago Barcellos	Nemora	F	Brazil										
	3	Bobrik	Alexey	M	Russia										
	4	Kornfield	Ruth	F	USA										
	5	Lauria	Lilian de Mello	F	Brazil										
	6	Brown	Tim	M	USA										
	7	Toupozis	Daphne	F	USA/Greece										
	8	Mazelani	Nomathemba	F	South Africa										
Alternates	1	Nyenwa	Jabulani	M	Zimbabwe										
	2	Melen Lemos	Cinthia	F	Belgium										
	3	Mazelani	Nomathemba	F	South Africa										
	4	Darby	Eileen	F	Australia/Ireland										
Malaria (TBD) Members	1	Genton	Blaise	M	Switzerland										
	2	Rojas De Arias	Gladys Antonieta	F	Paraguay										
	3	Burkot	Thomas	M	USA										
	4	Talisuna	Ambrose	M	Uganda										
	5	Adeel Abdel-Hameed	Ahmed Awad	M	Sudan										
	6	Lyimo	Edith	F	Tanzania										
Alternates	1	Wiseman	Virginia	F	Australia										
Tuberculosis (TBD) Members	1	El Sony	Asma	F	Sudan										
	2	Hanson	Christy	F	USA										
	3	Bah-Sow	Oumou Younoussa	F	Guinea										
	4	Hamid Salim	Abdul	M	Bangladesh										
	5	Kimerling	Michael	M	USA										
	6	Zaher	Hanem	F	Egypt										
Alternates	1	Ticona	Eduardo	M	Peru										
Cross Cutting (TBD) Members	1	Decosas	Josef	M	Germany										
	2	Alilio	Martin S.	M	Tanzania										
	3	Nuyens	Yvo	M	Belgium										
	4	McKenzie	Andrew	M	South Africa										
	5	Boillot	Francois	M	France										
	6	Brandrup-Lukanow	Assia	F	Germany										
	7	Barron	Peter	M	South Africa										
	8	Okedi	William	M	Kenya										
	9	Baker	Shawn Kaye	M	USA										
	10	Ghandhi	Delna	F	UK										
	11	Ayala-Oström	Beatriz	F	Mexico/UK										
	12	Murindwa	Grace	M	Uganda										
	13	Heywood	Alison	F	Australia										
	14	Le Franc	Elsie	F	Jamaica										
	15	Oyeledun	Boia (Chair)	F	Nigeria										
	16	Tore	Rose	M	Norway										
	17	Gotsadze	George	M	Georgia										
	18	Bianco	Mabel	F	Argentina										
	19	Leal	Ondina	F	Brazil										
Alternates	1	Rabeneck	Sonya	F	Ireland/Canada										
	2	Herbert-Jones	Sarah	F	UK										
	3	Hadley	Mary	F	UK										
	4	Bosch Capblanch	Xavier	M	Spain										
	5	Donnard	Jean-Francois	M	France										
	6	Dusseljee	Jos	M	Netherlands										

Key:

Permanent TRP Members	Rounds served
GAVI IRC members selected for proposal reviews called in 2008	Rounds not served
Alternate Members	