Twentieth Board Meeting
Addis Ababa, Ethiopia 9-11 November 2009

GF/B20/5
Decision

REPORT OF THE PORTFOLIO AND IMPLEMENTATION COMMITTEE

OUTLINE:

1. This report summarizes the deliberations of the Portfolio and Implementation Committee (PIC) at its meeting on 16-17 September 2009 including its recommendations to the Twentieth Board Meeting.

PART 1: INTRODUCTION

1.1 The Portfolio and Implementation Committee (PIC) met in Geneva on 16-17 September 2009. Dr. Joseph Andrè Tiendrebeogo and Mr. William Parr served as Acting Chair and Acting Vice-Chair, respectively.

1.2 This report contains the following sections:

Part 2: Country Coordinating Mechanism (CCM) Matters
Part 3: Quality Assurance Policy for Pharmaceutical Products
Part 4: Information Items

PART 2: COUNTRY COORDINATING MECHANISM MATTERS

2.1 At its Nineteenth Meeting[1], the Board adopted in principle the proposed new funding model for CCMs which allowed increased funding and flexible modalities to enable CCMs to undertake their core functions. The Board delegated the authority to approve the revised funding policy for CCMs to the Portfolio Committee (now the Portfolio and Implementation Committee).

2.2 In addition, the Board also requested the Secretariat to conduct a review of the CCM Guidelines[2] to clarify the role of CCMs and recommend necessary amendments in time for the Twentieth Board Meeting in November 2009.

Revised CCM Funding Policy[3]

2.3 Following the Board decision, the Secretariat further developed the revised CCM funding model. The revised model ("expanded funding") presented to the PIC allows CCMs[4] to access amounts greater than US$ 50,000 per year based on a two-year work plan with measurable targets. However, the current model ("basic funding") will be maintained for CCMs with lower capacities for organization and governance but with the ceiling amount raised from US$ 43,000 to US$ 50,000. It is expected that the basic funding model will be phased-out within three years as CCMs develop capacity and/or face increasing workloads and switch to the expanded funding model.

2.4 The advantages of the expanded funding model are as follows:

i. Responds to Board's request for stronger and more transparent performance using targets and workplans. Sample performance indicators for CCMs have been developed by the Secretariat through broad-based consultations;
ii. Adopts simple processes that are light to implement;
iii. Allows flexibility and adapts to country context in terms of cost structures and targets;
iv. Promotes strategic focus by CCMs on oversight, constituency engagement and CCM alignment;

[1] GF/B19/DP20. Country Coordinating Mechanism (CCM) Funding Policy
[2] GF/B16/7, Revision 1, Attachment 1
[3] GF/PIC01/05 Country Coordinating Mechanism (CCM) Funding Alternatives
[4] Or, other national bodies that meet the minimum CCM eligibility requirements and have taken on the roles and functions of the CCM.

v. Improves transparency and measurability of CCM performance to promote partners' confidence and support;

vi. Links performance information to targeted technical support for areas of weaknesses; and

vii. Strengthens CCMs which is a strategic investment in better grant performance.

2.5 The PIC approved the revised funding model and requested the Secretariat to finalize the list of performance indicators and other operational features in time for implementation in January 2010. The revised policy will require an increase of US$1.6 million in the CCM budget for 2010 which includes allocation for two additional staff. This will be subject to the regular budget review process.

PIC Decision Point: Approval of the CCM Funding Policy

The Portfolio and Implementation Committee, with delegated authority from the Board:

(i) Deletes Part 7 of the "Guidelines on the Purpose, Structure, Composition and funding of Country Coordinating Mechanisms and Requirements for Grant Eligibility" and renames it "Guidelines and Requirements for Country Coordinating Mechanisms";

(ii) Approves the revised CCM Funding Policy as outlined in Annex 2 of GF/B20/5; and

(iii) Requests the Secretariat to work with partners to conduct an evaluation of the revised CCM Funding Policy following two years of implementation, and to present the results to the Portfolio and Implementation Committee in 2012.

The budgetary implications of this decision point in 2010 amount to US$ 1.6 million.

Review of CCM Guidelines[5]

2.6 Following on the Board request in May 2009, the Secretariat reviewed the CCM roles and responsibilities in the CCM Guidelines and developed initial amendments to the guidelines. These are based on the recommendations of the Five-Year evaluation, lessons learned and best practices from case studies, experience gained through CCM eligibility screening and key informant inputs including from Secretariat staff.

2.7 The Secretariat proposed to finalize CCM Guideline amendments by November 2010 in order to reflect the results of critical activities that are planned for completion in 2009-2010. These include, among others, the analysis of impact of the new grant architecture and National Strategy Applications on CCM roles, the review of CCM eligibility screening practices, the research of Regional Coordinating Mechanism issues, the study of alignment questions in particular with respect to National AIDS Councils, and an analysis of country-level feedback on the new Global Fund strategies and CCM tools.

2.8 The PIC agreed with the initial recommendations of the Secretariat and provided the following guidance:

i. Focus on lessons learned and avoid unnecessary prescriptions;

ii. Promote use of existing structures. The use of sub-CCMs and non-CCMs should be further studied;

[5] GF/PIC01/06 Review of Country Coordinating Mechanism (CCM) Roles and Responsibilities Reflected in the CCM Guidelines

iii. Ensure broad consultations but align with other consultations so that stakeholders are not overburdened.

2.9 The PIC endorsed the proposed timeline for completing the review process and agreed to request delegated authority from the Board to approve the final amendments to the CCM Guidelines.

Decision Point 1: Review of the CCM Guidelines

The Board delegates authority to the Portfolio and Implementation Committee (PIC) to approve changes to the "Guidelines and Requirements for Country Coordinating Mechanisms".

This decision does not have material budgetary implications.

PART 3: QUALITY ASSURANCE POLICY FOR PHARMACEUTICAL PRODUCTS

3.1 The revised Quality Assurance Policy for Pharmaceutical Products (QA Policy) was approved at the Eighteenth Board Meeting. The revised policy was successfully launched on 1 July 2009 with all necessary tools and systems in place including the Expert Review Panel (ERP).

3.2 The ERP completed its first set of reviews in May 2009 recommending 28 (out of 63) finished pharmaceutical products (FPPs) to be procured with Global Fund grants for a time-limited period and according to selection criteria set out in the QA Policy. The second set of reviews is scheduled in October 2009.

3.3 The revised QA Policy requires that Global Fund financing may only be used to procure antiretroviral, anti-tuberculosis and anti-malarial FPPs that are (i) prequalified by the WHO Prequalification Program or authorized for use by a Stringent Regulatory Authority (SRA), OR (ii) recommended for use by the ERP. FPPs are eligible for review by the ERP if the following conditions are met:

i. the manufacturer of the FPP has submitted an application for pre-qualification of the product by the WHO Pre-qualification Program and it has been accepted by the WHO for review; OR

   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 that apply for the relevant product formulation as verified after inspection by (i) the WHO Prequalification Program, or (ii) an SRA, or (iii) a regulatory authority participating in the Pharmaceutical Inspection Cooperation Scheme.

3.4 As originally anticipated during the development of the QA Policy, the requirements of the revised QA Policy are posing challenges in the supply of some essential and long-established pharmaceutical products that are in line with WHO and/or national Standard Treatment Guidelines. Following the effective date of the QA Policy, two particular areas have been brought to the attention of the Global Fund by concerned technical partners

with regard to treatment for malaria and tuberculosis (see below). Since implementation of the QA Policy is still in its early days, it is expected that other challenges may be identified in the near future[6].

i. There is a challenge in identifying products needed for the treatment of severe malaria cases or for the treatment of *plasmodium vivax* malaria that meet the QA policy requirements. These products include non-artemisinin based formulations containing quinine, sulfadoxine+pyrimethamine, chloroquine and primaquine. These products are long-established treatments for malaria that were previously eligible for procurement with Global Fund grants as they were 'multi-source'[7]. However, there is a limited number of FPPs for these product formulations registered for use by SRAs and/or prequalified by WHO. Since these products are 'multi-source' and, in most cases, are not listed on the WHO Prequalification Program's expression of interest, there is little incentive or likelihood of applications being made for SRA registration or WHO prequalification. Therefore, none of these products was eligible for review by the ERP and no product dossiers for these products have been submitted for ERP review.

ii. Similar challenges apply to first line treatment regimens for tuberculosis. These products were previously eligible for procurement with Global Fund grant funds as they were 'multi-source.' However, these medicines are not listed in the invitation to submit an expression of interest under the WHO Prequalification Program. Therefore, there is little likelihood of applications for WHO prequalification. In addition, there is also little incentive or likelihood of applications for SRA authorization because these products are locally manufactured for national use. The primary example for this case is the product formulations used in the first line anti-TB regimen in India.

3.5 The PIC considered the options presented by the Secretariat and agreed[8] to recommend a change in the eligibility criteria for the ERP review to allow a risk/benefit review for 'multi-source' products that do not meet the first criterion (i.e., submission for WHO Prequalification or SRA authorization) but meet the second criterion (i.e., manufacture in a GMP compliant site) [see paragraph 3.3]. The PIC noted that this will not compromise the quality assurance standards of the QA Policy since the products would still need to be recommended by the ERP in order to be eligible for purchase with grant funds. Annex 3 contains the QA Policy with the amendments proposed by the PIC.

3.6 The PIC, likewise, endorsed the proposed transitional provisions while dossiers for the 'multi-source' FPPs are prepared and reviewed by the ERP.

3.7 The PIC recommendation was reached considering possible risks of stock-outs and/or treatment disruptions for programs supported by at least 43 Global Fund grants if the Global Fund were not able to continue to fund such essential and long-established pharmaceutical products. The proposed approach is also consistent with the approaches of partners such as the UNICEF and WHO.

[6] For some artemisinin-based formulations for malaria (DHA piperaquine, and artemisinin-based injectables and suppositories), there is currently no WHO pre-qualified, SRA-authorized or ERP-recommended FPP. Product dossiers for these product formulations are expected to be submitted to the ERP for review in October 2009.

[7] Multi-source product means a pharmaceutical product for which the monograph of the finished dosage form was published in the International, U.S. or U.K. Pharmacopeia before 10 October 2002. This is therefore a closed list of products.

[8] One constituency did not support the proposed expansion of the ERP review.

3.8 The Market Dynamics and Commodities Ad Hoc Committee (MDC) met after the PIC Meeting (on 3 October 2009). As part of their agenda and terms of reference, they reviewed the recommendations of the PIC to the Board on the QA Policy. The MDC plans to propose amendments to the decision point as contained in its report GF/B20/8. The MDC amendments are intended to be "friendly" to clarify the policy and decision point and not alter the work of the PIC on the issue. The final text of the decision point will be presented to the Board by the PIC, following usual procedures for amendments to Committee- recommended decision points (in this case, consultations with PIC members on the MDC proposals).

Decision Point 2: Quality Assurance Policy for Pharmaceutical Products

The Board recognizes that, as described in the Portfolio and Implementation Committee's Report to the Board (GF/B20/05), there are challenges with identifying sources for certain essential and long-established multi-source treatments that meet the requirements of the Global Fund's revised Quality Assurance Policy for Pharmaceutical Products ("QA Policy"). In order to avoid disruption to treatment of patients, the Board therefore decides to revise the QA Policy to expand the eligibility criteria for a risk/benefit review of products by the Expert Review Panel (ERP) by adding the following provision at the end of paragraph 13 of the QA Policy:

> *"Provided that the criterion in paragraph (ii) above is met, multi-source [8] FPPs that are not WHO prequalified or SRA authorized are also eligible for review by the ERP for associated potential risks/benefits in accordance with paragraph 10 of this Policy.*
>
> *Footnote 8: For these purposes, "multi-source" means a pharmaceutical product for which the monograph of the finished dosage form was published in the International, U.S. or U.K. Pharmacopeia before 10 October 2002"*

The Board notes that it will take some time for dossiers for these multi-source FPPs to be prepared and submitted to the next set of ERP reviews and that an interim exception is necessary to avoid disruption in essential treatment. The Board decides that, on an exceptional basis and for the period up to 30 June 2010 only, grant funds may be used to procure multi-source FPPs, provided that:

- *(a) there are no other FPPs for that product formulation available (as defined in the QA Policy) that are WHO-prequalified or SRA-authorized or ERP-recommended;*
- *(b) the site at which such FPP is being manufactured must, at the time of the procurement, be in compliance with the relevant GMP standards as verified by the WHO Prequalification Program, or an SRA or a regulatory authority participating in PIC/S;*
- *(c) the FPP has been selected for procurement by relevant UN procurement agencies; and*
- *(d) the notification/confirmation and testing processes described in paragraphs 9 and 31 of the QA Policy will apply to such procurement.*

This decision does not have material budgetary implications.

PART 4: INFORMATION ITEMS

Operations Update

4.1 The PIC encouraged the Secretariat to continue with an in-depth presentation of portfolio status and implementation issues. The PIC suggested possible topics that the Secretariat should also cover in the next PIC meeting, such as the quality of programs, region-specific strategies, implementation of the National Strategy Applications and the new Global Fund architecture, implementation of the gender and sexual orientation strategies, technical assistance, implementation of the PMTCT framework of action, and updates on stock-outs and treatment disruption. The operations update should cover all items in the PIC terms of reference requiring oversight including all aspects of the grant cycle from applying for funding to grant closure.

Managing Tension Between Supply and Demand

4.2 The PIC noted the initial recommendations of the Demand and Supply Working Group and endorsed the proposal to amend the pre-notification period and resubmission of category 3 proposals for Round 9 proposals.

Preventing Stock-outs and Treatment Interruptions in Global Fund Grants[9]

4.3 Preventing stock-outs and treatment interruptions is a high priority and a shared responsibility among the Global Fund and its partners. The PIC endorsed the Secretariat proposed action plan for enhancing work with partners in dealing with stock-outs and treatment disruptions for anti-retroviral drugs. The Committee also requested to expand the initial analysis to cover tuberculosis and malaria with more emphasis on treatment disruption. The analysis should also cover country health systems (including warehousing, delivery, buffer stocks and overstocks), and the availability of technical assistance to improve these systems. Stock-outs and treatment disruptions will be a standing agenda item of the PIC and the Secretariat will report on its analysis in the next PIC meeting.

Enhancing the Global Fund's Response to HIV/AIDS: Addressing Sub-optimal PMTCT services

4.4 The PIC endorsed the Secretariat's proposed framework of action to accelerate the transition to more efficacious ARV regimens for effective prevention of mother-to-child transmission (PMTCT). The PIC also provided a range of comments for consideration by the Secretariat in implementing the framework including the following:

i. Ensure linkages and integrated approach with other health services, especially maternal and child health services at primary health care level;

ii. Involve countries in undertaking more in-depth country level analysis to assess political will, readiness for transition and service delivery systems (both health systems and community systems) to ensure that proposed solutions are context-specific;

iii. Focus on the four pillars of PMTCT as stated in the WHO guidelines when defining PMTCT service delivery area, linking this work with the Gender Equality Strategy, and increasing the involvement of men;

iv. Address pediatric HIV care as requested in the Board decision.

[9] GF/PIC01/03: Preventing Stock-outs and Treatment Interruptions in Global Fund Grants

4.5 The PIC requested an update on the implementation of the framework in its next meeting.

Technical Review Panel Matters[10]

4.6 The PIC noted the Secretariat's progress in implementing the recommendations from the Round 8 TRP Report. It also endorsed the proposed approach and timeline for the TRP full replenishment and stressed the need to consider lessons learned from previous replenishment exercises. The PIC suggested that once the new PIC membership is formed, a Sub-committee will be established to oversee and ensure an open and transparent process for the full replenishment.

Income Level Eligibility[11]

4.7 The PIC endorsed the list of income level classifications for all funding channels in 2010 which will be released after the Twentieth Board Meeting. The Committee, likewise, endorsed the proposed approach and timeline for the review of income level and cost-sharing eligibility criteria. The PIC suggested that once the new PIC membership is formed, a Sub-committee on Review of Income Eligibility will be established to provide oversight and ensure broad consultations during the review process.

Quality Assurance Status for Diagnostics[12]

4.8 The PIC endorsed the framework for developing a quality assurance policy for diagnostics proposed by the Technical Advisory Group on Quality Assurance for Diagnostic Products. The PIC emphasized that a consultative approach should be taken in developing the policy similar to the one adopted for the QA policy for pharmaceutical products. A proposed QA policy for diagnostics will be presented to the Board at its last meeting in 2010.

Quality Assurance Status for Pharmaceutical Products other than Antiretrovirals, Anti-tuberculosis and Anti-malaria (non-ATMs)[13]

4.9 The first phase of the study established that quality assurance for all non-ATM medicines is a cause of concern. The PIC endorsed the Secretariat's proposal to proceed with the next phase of the study to explore the possibility of establishing quality requirements for non-ATMs. The mandate of the Technical Advisory Group for Pharmaceutical Products will be expanded to propose quality requirements for non-ATMs. Partners should be consulted on the proposed recommendations prior to their finalization. A proposed QA policy for non-ATMs will be presented to the Board at its last meeting in 2010 through an amendment of the QA Policy for pharmaceutical products.

Voluntary Pooled Procurement[14]

4.10 The VPP is already operational since April 2009 with two procurement service agents already engaged while the service providers for the capacity building and supply chain management assistance are being contracted. Twenty countries have already registered for participation in the VPP with additional 20 countries engaged in various stages of the

[10] GF/PIC01/07: Technical Review Panel Matters
[11] GF/PIC01/08: Income Level Eligibility Criteria
[12] GF/PIC01/09: Quality Assurance and Procurement Matters
[13] ibid
[14] ibid

consultation process to join VPP. The PIC requested the Secretariat to include an early analysis of the value-added of VPP in its next update.

Coordination between PIC and MDC

4.11 In view of the late establishment of the membership of the MDC and with the aim of ensuring a smooth transition in relation to market dynamics matters, the PIC took the primary role in the review and oversight of the procurement matters outlined in Part 3 and in paragraphs 4.8 to 4.10 above in preparation for the Twentieth Board Meeting. Following the re-constitution of the PIC after the Board Meeting, the leadership of the PIC and MDC, facilitated by the Secretariat, will coordinate to clarify the on-going roles of the PIC and MDC on quality assurance and procurement matters.

Annex 1

GUIDANCE ON LOCATION OF FURTHER INFORMATION

The below table indicates where further information on items dealt with in this report can be found:

Where indicated documents are available on the PIC password-protected website:
http://extranet.theglobalfund.org/cme/default.aspx

Item:	**Further information available:**
1. Country Coordinating Mechanism Matters	GF/PIC01/05: CCM Funding Alternatives GF/PIC01/06: Review of CCM Roles and Responsibilities contained in the CCM Guidelines Annex 2 of this document
2. Quality Assurance Policy For Pharmaceutical Products	GF/PIC01/09: Procurement and Quality Assurance Matters Annex 3 of this document
3. Information Items	GF/PIC01/03: Preventing Stock-outs and Treatment Disruptions in Global Fund Grants GF/PIC01/07: Technical Review Panel Matters GF/PIC01/08: Income Level Eligibility Matters GF/PIC01/09: Procurement and Quality Assurance Matters

Annex 2

Country Coordinating Mechanism (CCM)[1] Funding Policy

Overview of CCM Funding

1. The purpose of the CCM Funding Policy is to enable CCMs to meet their intended purpose and role as defined in the "Guidelines and Requirements for Country Coordinating Mechanisms."[2]

2. The Global Fund recognizes the important role of CCMs in the Global Fund architecture (including their central role in proposal development and submission and grant oversight) as outlined in the Global Fund's Framework Document. In order to fulfill their responsibilities, CCMs inevitably incur administrative costs and may not have the independent resources to cover these costs.

3. The Global Fund has established a separate pool of funds to finance CCM costs through a direct line item in the Secretariat's budget. CCMs may not draw directly from approved grant funds to support CCM costs except in the situation where the CCM's request for funding for administrative costs for up to two years was approved by the Global Fund Secretariat prior to 13 November 2007. Such CCMs may continue to use grant funds to support CCM costs until the end of the approved term of such CCM funding and may then apply for continued funding to begin upon expiry of the approved term.

4. The CCM Funding Policy will be administered by the Secretariat under the oversight of the Portfolio and Implementation Committee.

Parameters for CCM Funding

5. CCMs (or other national bodies that meet the minimum CCM eligibility requirements and have taken on the role and function of the CCM) may receive funding as long as there is at least one active grant under implementation. A grant is considered active through to the end of grant closure.

6. CCM funding requests may be classified as "Basic" or "Expanded" CCM funding:
    i. Basic funding requests will cover eligible costs for a single year period, and are limited to a maximum amount of US$ 50,000;
    ii. Expanded funding requests will cover eligible costs for a two-year period, and may exceed US$ 50,000 per year. For amounts exceeding US$ 100,000 per year, the CCM must demonstrate that it has mobilized 20% of the amount exceeding US$ 100,000 from sources other than the Global Fund for the same CCM budget period.

7. Funding requests may be submitted annually under Basic funding, and biennially under Expanded funding. There is no limit to the number of times that a CCM may apply for funding.

1. For the purposes of this policy, the term Country Coordinating Mechanisms or "CCMs" includes regional CCMs and sub-CCMs. Regional Coordinating Mechanisms ("RCMs") and Sub-CCMs will be treated as separate from the CCM for the country or countries in which they operate for the purposes of applying for, receiving and using CCM funding.
2. GF/B16/7, Revision 1, Attachment 1

8. The period covered by a new funding request shall not overlap with periods for which the Global Fund is already providing CCM funding support.

9. In reviewing a request for CCM funding, the Global Fund Secretariat will take into consideration whether the costs to be supported are consistent with national salary scales and local operating costs.

10. CCMs using the CCM funding policy for Expanded funding must submit the following documents to the Secretariat:

    a. As part of the CCM funding application:

        i. a detailed two-year budget outlining costs to be supported and planned expenditure as part of the application. Budgets must be classified by cost category, as well as by the following CCM functional areas: oversight, constituency engagement, alignment with country structures and processes, capacity building, other.

        ii. a two-year work plan consistent with the budget, and including defined activities and performance targets measurable using the core set of CCM indicators provided by the Secretariat.

    b. During implementation at the tenth month point, and at the twenty second month point of the CCM funding period:

        i. an expenditure report with costs broken down by financial cost category (salaries, administration, meetings, consultations, communications, translation, program oversight and others) as well as CCM functional area;

        ii. a performance report describing progress towards planned targets.

11. CCMs using the CCM funding policy for Basic funding must submit the following documents to the Secretariat:

    a. As part of the CCM funding application: a detailed budget outlining costs to be supported and planned expenditure. Budgets must be classified by cost category, as well as CCM functional area, as detailed in para.10.a.i.

    b. During implementation at the tenth month point of the CCM funding period: an expenditure report with costs broken down by financial cost category as well as CCM functional area, as detailed in para.10. a.i

12. Under either funding model, the Secretariat may request the CCM to complete the CCM self-assessment questionnaire as needed.

13. Eligible costs may include the following items:

        i. **Salary of CCM secretariat staff**. CCM funding shall not be used for the salary of CCM members.

        ii. **CCM consultancy fees.** Consultancy fees may be used for technical support for core CCM functions such as civil society participation, program oversight and alignment with other national bodies. CCM funding cannot be used for hiring consultants to write proposals for Global Fund financing. Terms of reference for consultants hired by the CCM must include a specific clause prohibiting the writing of proposals by the consultant hired.

iii. **Office expenses** including rent, equipment and supplies, excluding vehicle purchase or long term lease.

iv. **CCM meeting expenses**, including travel costs for members (and non-members invited by the CCM) to attend CCM meetings and/or oversight visits.

v. **Communication and information dissemination** (e.g., call for proposals, periodic reports of implementation status, minutes of meetings, establishing and updating a website or newsletter and translation of key information).

vi. **Organization and facilitation of meetings** and workshops on CCM capacity building, or topics related to CCM core functions. This includes facilitation of constituency consultation (e.g. civil society) and processes to promote and improve the quality of stakeholder participation, including travel costs for civil society participation.

Application Process

14. A CCM that wishes to receive funding support may submit an application for funding to the Secretariat at any time, supported by the documents listed in paragraphs 10 and 11 above, as applicable.

15. In order to ensure the transparency and accountability of funding flows to all stakeholders, all CCM constituencies should participate in the development of the budget and work plan and all members must sign the funding request. This sign-off will be considered demonstration that all stakeholders have had meaningful input into the budgetary needs of the CCM and to testify that they are in accord with how CCM funding streams will meet their needs. For added transparency, the Secretariat will post the costed CCM work plan on the Global Fund website.

16. A CCM using the previous funding policy (US$ 43,000 limit) may request to terminate the funding agreement before its end date, to reapply for Basic or Expanded CCM funding. If the request is approved by the Secretariat, unspent funds from the terminated agreement will be transferred to the new funding agreement.

Implementation, Reporting and Oversight

17. The Global Fund and the CCM will consult to identify a suitable disbursement arrangement that i) is accountable, transparent and verifiable, including by the LFA and ii) facilitates access to eligible CCM funding by civil society members of the CCM (as specified in paragraph 13).

18. CCMs must commit to use Global Fund funding solely for the purposes described in the funding request and in accordance with the approved budget. Material changes to the budget will require Global Fund approval.

19. In cases where the CCM is not an incorporated body or separate legal entity, the CCM should nominate another entity to provide the commitment referred to in paragraph 18 above, and to be accountable for the use of the CCM funding and the management of the funds as described in paragraph 17 above. This commitment will be documented in a short agreement and be signed by an authorized representative of the CCM.

20. Disbursement and activity reports of CCM funding (including reporting by the CCM on access to CCM funding by civil society and other NGO stakeholders) must be provided

to the Global Fund on an agreed periodic basis as described in paragraph 10 and 11 above. These reports will be subject to LFA review and verification.

21. When necessary, CCM funding policy processes will be adapted by the Secretariat to facilitate implementation and simplify processes, while ensuring that the main concepts and principles of the policy are maintained.

Annex 3

GLOBAL FUND QUALITY ASSURANCE POLICY FOR PHARMACEUTICAL PRODUCTS

BASIC PRINCIPLE

1. Global Fund grant funds may only be used to procure finished pharmaceutical products (FPP) in accordance with the standards prescribed in this policy.

GLOSSARY

2. Capitalized terms and acronyms used in this policy shall have the meaning given to them below.

Common Technical Document for the Registration of Pharmaceutical Products for Human Use (CTD) means a common format for the submission of information to regulatory authorities in ICH member countries.

Finished Pharmaceutical Product (FPP) means a medicine presented in its finished dosage form that has undergone all stages of production, including packaging in its final container and labeling.

Fixed Dose Combination (FDC) means a combination of two or more active pharmaceutical ingredients in a fixed ratio of doses.

Good Manufacturing Practices (GMP) means the practices, which ensure that pharmaceutical products are consistently produced and controlled according to quality standards appropriate to their intended use and as required by marketing authorization.

International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) is an initiative involving regulatory bodies and pharmaceutical industry experts that was established to make recommendations on ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration. ICH member countries are specified on its website: http://www.ich.org.

Pharmaceutical Inspection Cooperation Scheme (PIC/S) means the Swiss association of inspectorates which provides a forum for GMP training. The PIC/S is not subject to any international or domestic regulations. PIC/S member countries are specified on its website: www.picscheme.org.

Product Formulation means an active pharmaceutical ingredient (or combination of ingredients), dosage form and strength. Note: different FPPs may exist for the same Product Formulation.

Quality Control means all measures taken, including the setting of specification sampling, testing and analytical clearance, to ensure that starting material, intermediate, packaging material and FPPs conform with established specifications for identity, strength, purity and other characteristics.

Stringent Drug Regulatory Authority (SRA) means a regulatory authority which is (a) a member of the ICH (as specified on its website:); or (b) an ICH Observer, being the European Free Trade Association (EFTA) as represented by Swiss Medic, Health Canada and World Health Organization (WHO) (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally binding mutual recognition agreement including Australia, Norway, Iceland and Liechtenstein (as may be updated from time to time).

National Drug Regulatory Authority (NDRA) means the official drug regulatory authority of a country.

NDRA Recognized Laboratories means quality control laboratories for pharmaceutical products selected by NDRAs according to their standards to conduct their quality control testing for pharmaceutical products.

Medicine means an active pharmaceutical ingredient that is intended for human use.

WHO Prequalification Programme means the programme managed by WHO which prequalifies (a) medicines that are considered to be acceptable for procurement by the United Nations and specialized agencies; and (b) quality control laboratories for medicines.

CLINICAL STANDARDS

Compliance with Standard Treatment Guidelines and Essential Medicines Lists

3. Global Fund grant funds may only be used to procure medicines that appear in current national or institutional standard treatment guidelines or essential medicines list ("National or Institutional STGs or EML"), or the World Health Organization (WHO) standard treatment guidelines or essential medicines list ("WHO STG or EML").

4. When submitting grant proposals to the Global Fund, applicants must ensure that they include a list of the medicines that they intend to procure with grant funds, together with a copy of the relevant National or Institutional STG or EML or the WHO STG or EML. If an applicant intends to procure medicine that is included in the relevant National or Institutional STG/EML, but not included in the WHO STG or EML, or vice versa, the applicant is requested to provide a detailed technical justification for the selection of that medicine, which will be reviewed by the Technical Review Panel (TRP).

5. A Principal Recipient (PR) must submit a technical justification to the Global Fund if it would like to procure a medicine that (i) was not specified in the grant proposal approved by the Global Fund; and (ii) is included in the relevant National or Institutional STG/EML, but not included in the WHO STG or EML, or vice versa. The Secretariat may, if it deems necessary, refer that technical justification to the TRP for review.

Adherence, Drug Resistance and Monitoring Adverse Effects

6. It is strongly recommended that PRs implement mechanisms to encourage adherence to treatment regimens (including but not limited to providing medicines in FDCs, once-a-day formulations and/or blister packs, and providing peer education and support), to monitor and contain resistance, and to monitor adverse drug reactions

according to existing international guidelines[1]. The cost of implementing such mechanisms may be included in the budget for the relevant Global Fund grant. To help contain resistance to second-line TB medicines and consistent with the policies of other international funding sources, all procurement of FPPs to treat Multi Drug Resistant Tuberculosis (MDR-TB) must be conducted through the Green Light Committee of the Stop TB Partnership hosted by the WHO (GLC). [2]

PROCUREMENT OF ANTIRETROVIRALS, ANTI-TUBERCULOSIS AND ANTI- MALARIAL FPPS

Quality Standards

7. Global Fund grant funds may only be used to procure antiretrovirals, anti-tuberculosis and anti-malarial FPPs that meet the following standards and, in accordance with the selection process described in Sections 8 and 9 below:

(i) Prequalified by the WHO Prequalification Programme or authorized for use by a Stringent Drug Regulatory Authority (SRA)[3].or

(ii) Recommended for use by an Expert Review Panel (ERP), as described in Section 10 below.

Selection Process

8. If there are two or more FPPs available[4] for the same Product Formulation that meet the quality standards set out in Section 7(i), the PR may only use Global Fund resources to procure an FPP that meets either of those standards.

9. However, if a PR determines that there is only one or no FPP available[5] that meets either of the quality standards set out in Section 7(i) and it wishes to use Global Fund resources to procure an alternate FPP, it must request confirmation from the Global Fund that the PR's determination is accurate and that the alternate FPP meets the standard specified in Section 7(ii).

Expert Review Panel

10. Upon the Global Fund's request, an independent Expert Review Panel (ERP) composed of external technical experts will review the potential risks/ benefits associated with the use of an FPP that is not yet WHO-prequalified or SRA-authorized[6] and will make recommendation to the Global Fund.

11. The Global Fund will maintain an up-to-date list of all FPPs that have been recommended by the ERP. This list will be made publicly available on the Global Fund's website. If, pursuant to Section 9, a PR requests to procure an FPP that does not appear on the list, the Global Fund shall request the ERP to review the relevant FPP.

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[1] E.g. WHO, The Uppsala Monitoring Centre. The Importance of Pharmacovigilance. Safety Monitoring of medicinal products. Geneva: World Health Organization, 2002, available at http://www.who.int/medicinedocs/en/d/Js4893e/. Safety of Medicines. A guide to detecting and reporting adverse drug reactions. Geneva: World Health Organization, WHO/EDM/QSM/2002.2, available at http://www.who.int/medicinedocs/en/d/Jh2992e/

[2] http://www.who.int/gtb/policyrd/DOTSplus.htm

[3] 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.

[4] "Available" means the manufacture can supply the requested quantity of the FPP within not less than 90 days of the requested delivery date.

[5] Refer to footnote 4.

[6] Refer to footnote 3.

12. The Global Fund will also make the terms of reference and rules of procedure for the ERP publicly available.

Eligibility Criteria for ERP Review

13. FPPs are eligible for review by the ERP if the following conditions have been met:

(i)
- (a) the manufacturer of the FPP has submitted an application for pre-qualification of the product by the WHO Prequalification Programme 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 Programme; OR
- (b) an SRA; OR
- (c) a regulatory authority participating to the Pharmaceutical Inspection Cooperation Scheme (PIC/S).[7]

Provided that the criterion in paragraph (ii) above is met, multi-source[8] *FPPs that are not WHO prequalified or SRA authorized are also eligible for review by the ERP for associated potential risks/benefits in accordance with paragraph 10 of this Policy.*

Time Limitation

14. 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-authorized[9], whichever is the earlier.

15. In accordance with Section 9, the PR may enter into a contract with a supplier for the procurement of an FPP recommended for use by the ERP at any time until the expiry of the ERP Recommendation Period, but the term of the contract must not exceed 12 months (that is, the PR cannot place an order for FPPs under the contract more than 12 months after it is executed).

16. 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[10] within the ERP Recommendation Period. The Global Fund may refer more than one request for such an extension to the ERP.

[7] List of PIC/S members is available on the PIC/S website: www.picscheme.org
[8] For these purposes, "multi-source" means a pharmaceutical product for which the monograph of the finished dosage form was published in the International, U.S. or U.K. Pharmacopeia before 10 October 2002.
[9] Refer to footnote 3.
[10] Refer to footnote 3.

PROCUREMENT OF ALL OTHER FPPs

Quality Standards

17. All FPPs, other than antiretrovirals, anti-tuberculosis and anti-malarial FPPs, need only to comply with the relevant quality standards that are established by the National Drug Regulatory Authority (NDRA) in the country of use.

Selection Process

18. PRs must select FPPs, other than antiretrovirals, anti-tuberculosis or anti-malarial FPPs, in accordance with NDRA requirements.

NATIONAL DRUG REGULATORY AUTHORITY AUTHORIZATION

19. Global Fund resources may only be used to procure FPPs that have been authorized for use by the NDRA in the country where they will be used in accordance with its standard practices for drug registration or other forms of authorization (such as authorizations for marketing or importation).

20. For FPPs that have been prequalified by the WHO Prequalification Programme, NDRAs are encouraged to expedite the process for authorizing the use of such FPPs by accepting the prequalification approval letter and supporting documentation, including WHO prequalification report and the manufacturer's summary of information relating to the quality, safety and efficacy of the FPP, together with all necessary information to perform quality control testing of products and necessary reference standards.

21. For FPPs that have been authorized for use by an SRA[11], NDRAs are encouraged to expedite the process for authorizing the use of such FPPs in the relevant country by accepting the executive summary of the Common Technical Document for the Registration of Pharmaceutical Products for Human Use (CTD) or sections of the CTD relating to the quality, safety and efficacy of the FPP, together with all necessary information to perform quality control testing of products and necessary reference standards, to fulfill national requirements.

PROCUREMENT PRACTICES TO ASSURE QUALITY

22. In addition to the Global Fund's existing polices for procurement practices, PRs must ensure that all FPPs are procured in accordance with principles set forth in the Interagency Guidelines: A Model Quality Assurance System for Procurement Agencies[12] (as amended from time to time).

23. PRs are responsible for monitoring the performance of suppliers with respect to product and supply chain quality, and must submit information to the Global Fund on supplier performance as defined by the Global Fund.

[11] Refer to footnote 3.

[12] A model quality assurance system for procurement agencies (Recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products). Annex 6. In: *WHO Expert Committee on Specifications for Pharmaceutical Preparations*, Fortieth report, Geneva, World Health Organization, 2006, (WHO Technical Report Series, No 937), and Interagency Publication by WHO, UNICEF, UNIDO, UNDP and World Bank WHO/PSM/PAR/2007.3.

MONITORING PRODUCT QUALITY

24. The quality of FPPs procured with Global Fund grant funds must be monitored. The cost of conducting quality control activities may be budgeted for in the Global Fund grant. PRs must submit to the Global Fund the results of quality control tests, which may be made publicly available by the Global Fund.

For All FPPs

25. In collaboration with NDRAs, PRs must ensure that random samples of FPPs are obtained at different points in the supply chain - from initial receipt of the FPPs in-country to delivery to end-users/patients - for the purpose of monitoring the quality of such FPPs (including quality control testing).

26. Such samples must be sent to NDRA laboratories or NDRA Recognized Laboratories or WHO Prequalified Laboratories or Global Fund contracted laboratory(ies) for quality control testing.

27. To ensure the NDRA Laboratories or NDRA Recognized Laboratories have adequate capacity for full pharmacopoeial testing, they must meet one of the following criteria:

(i) Prequalified by WHO Pre-qualification Programme, or
(ii) Accredited in accordance with ISO17025.

28. The Global Fund will, based on the advice of WHO, provide protocols and standard operating procedures that may be used for quality control testing and reporting of results.

29. The Global Fund will request Local Fund Agents to verify whether PRs have complied with the process described in Sections 25 and 26.

30. Technical assistance aimed at strengthening NDRA Laboratories or NDRA Recognized Laboratories may be included in Global Fund proposals.

For FPPs Recommended for Use by the ERP

31. When a PR procures an FPP that has been recommended for use by the ERP, the Global Fund will make the necessary arrangements for randomly selected samples of the FPP to be tested for quality control purposes, in accordance with advice provided by the ERP, prior to the delivery of that FPP by the manufacturer to the PR or other designated recipient. The PR will ensure that its contract with the manufacturer affords the Global Fund and its authorized agents with access rights that would allow for such sampling to be undertaken. The cost of the sampling and testing of the FPP will be borne by the Global Fund.

TRANSITIONAL PROVISIONS

32. If a PR entered into a contract with a supplier on or before 30 June 2009 for the procurement of FPPs that complied with the Global Fund's previous QA Policy, but do not comply with this policy, the PR must notify the Global Fund of the details of this contract. The Global Fund may, after consultation with the PR, require the PR to take reasonable steps to discontinue procurement of FPPs under such contract, with a view to making a smooth transition to compliance with this policy at the earliest opportunity. In any event, the PR may not seek to extend or renew such a contract after 30 June 2009.