



Investing in our future

The Global Fund

To Fight AIDS, Tuberculosis and Malaria

Twenty-First Board Meeting
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GF/B21/8 (Revision 1)

Decision

REPORT OF THE MARKET DYNAMICS AND COMMODITIES AD HOC COMMITTEE

OUTLINE:

1. This report summarizes the deliberations of the Market Dynamics and Commodities Ad-hoc Committee (MDC) at its Second Meeting on 4-5 March 2010. It includes the MDC's recommendation on contingency plans for life-saving anti-malarials to the Twenty-First Board Meeting.

PART 1: INTRODUCTION

1.1 The Market Dynamics and Commodities Ad Hoc Committee (MDC) held its Second Meeting on 4 and 5 March 2010 in Geneva. The Chair was Mr. Dai Ellis. The Vice-Chair, Ms. Shanelle Hall, sent her apologies for not being able to attend the meeting due to an urgent family matter.

1.2 This report contains the following topics:

i. Items for Board Decision (Part 2):

- Contingency plan to prevent disruption in the supply of life-saving anti-malarial medicines;

ii. Items for information (Part 3):

- Implementation of the Voluntary Pooled Procurement Mechanism;
- Implementation of the Price and Quality Reporting Mechanism;
- Progress Update on Quality Assurance Matters for Health Products;
- Overview of Corporate Risk assigned to MDC Oversight; and
- Prioritization of Areas for Further Study and Action.

1.3 The Terms of Reference for the MDC approved by the Board at its Nineteenth Meeting include:

- i. Operational oversight of the core existing Global Fund mechanisms and policies related to the procurement of health products; and
- ii. Further development of the Global Fund's strategic approach to influencing market dynamics.

The Committee has emphasized that its primary focus should be on the latter priority, although it will continue to fulfill its oversight responsibilities.

1.4 Overall, the Committee determined that the Global Fund should pursue a strategy and corresponding operational mechanisms that enable it to better leverage its central role in global health financing to improve the market dynamics of essential health products. This approach of acting as a more deliberate "market shaper" (as opposed to a more passive "market taker") is in line with the analysis and recommendations presented by the Policy and Strategy Committee at the Fourteenth Board Meeting. The Committee identified a number of ways to pursue this broader strategic objective, including optimizing essential existing mechanisms such as the Voluntary Pooled Procurement Mechanism and the Price and Quality Reporting Mechanism as well as exploring entirely new approaches. In the latter area, the Committee has identified two priorities that will be the initial focus of its deliberations:

- i. Improving the efficiency of commodity budgeting and spending as part of the Global Fund's overall focus on "value for money"; and
- ii. Identifying and developing appropriate solutions to critical market dynamics challenges (e.g., high prices, supply constraints, etc.) for certain product areas (e.g., LLINs, 2nd line ARVs, etc.).

The MDC identified a series of next steps to develop strategic options in these areas and will seek to bring relevant recommendations to the Board in the next year.

1.5 Guidance on the location of further information is provided at the end of this report (Annex 5).

PART 2: CONTINGENCY PLAN TO PREVENT DISRUPTION IN THE SUPPLY OF LIFE-SAVING ANTIMALARIAL MEDICINES Decision

2.1 At its Twentieth Meeting¹, the Board requested the MDC “to consider, as a matter of urgency, contingency plans regarding the recently notified disruption of funding for certain life-saving anti-malarial medicines” which do not comply with the requirements of the Global Fund’s Quality Assurance Policy for Pharmaceuticals (“QA Policy”) (Annex 1). The following medicines are concerned: dihydroartemisinin-piperaquine (DHA-PPQ) tablets, artemether injectable, artesunate injectable and artesunate rectocaps.

2.2 Due to the urgent requirement to define a contingency plan, MDC members held a teleconference on 28 January 2010. Consultations on this issue continued until the time of the Second MDC Meeting.

2.3 Three options were proposed for a contingency plan, which in summary were as follows:

- i. Option 1: To prohibit the relevant medicines from being eligible for procurement with Global Fund funding as they do not meet the requirements of the QA Policy (Annex 1);
- ii. Option 2: To restate the interim exception to the QA Policy (Annex 2) to permit the procurement of the relevant anti-malarial medicines until 31 December 2010; or
- iii. Option 3: To delegate authority to the MDC to consider requests by the Secretariat to determine on a case-by-case basis whether to permit the procurement of the relevant anti-malarial medicines through Global Fund grants, as prompted by fact-based proposals from the Secretariat that draw on technical input from WHO.

2.4 Eight of the ten MDC members who participated in the teleconference indicated a preference for Option 2. The other two participants were in favor of a modified Option 1, under which interim exceptions to the QA Policy would be considered, and made, on a case-by-case basis.

2.5 The MDC requested the Secretariat to explore modifications to Option 2 to address the following concerns:

- i. Inherent risks of funding products which do not meet the quality standards of the QA Policy with Global Fund finance;
- ii. Risk that available products on the market will still not have progressed to meeting the quality standards of the QA Policy after the time-limited exception has expired; and
- iii. Risk of deploying DHA-PPQ in the private sector in Cambodia under AMFm².

2.6 The Secretariat consulted with the Chair and Vice Chair of the AMFm Committee, and provided to the MDC an analysis of risks and benefits of deploying DHA-PPQ, especially in the private sector, through AMFm in Cambodia³.

¹ Decision Point GF/B20/DP13

² In order for a product to be eligible for co-payment under the AMFm initiative, it must meet the requirements set out in the Global Fund QA Policy. Oversight of the QA Policy and consideration of amendments and exceptions to the QA Policy are the responsibility of the MDC.

³ Annex 3 to Background Paper GF/MDC02/05

2.7 In response to the MDC's request, WHO⁴ provided clarifications on the Expert Review Panel (ERP) review process and outcomes (see Part 3, Paragraph 3.21). WHO clarified that the ERP performs quality risk assessments which do not take into account the clinical risk of ineffective or no treatment. WHO stated that - in cases where no adequate alternative medicines exist in a given situation - the ERP could potentially develop a process to incorporate input from the relevant WHO disease programme to weigh quality risks against the clinical risk of providing ineffective or no treatment at all. There was general agreement among the MDC members that such an assessment based on the circumstances of a specific country situation could be part of a longer-term solution for dealing with contingency situations.

2.8 WHO⁵ described the circumstances requiring the urgent provision of these life-saving anti-malarial medicines as follows:

- i. DHA-PPQ is required in Cambodia, based on WHO published guidelines as well as national treatment guidelines. Cambodia was included in the AMFm pilot phase specifically because of the urgent need to address concerns regarding artemisinin resistance. It is estimated that 60-70% of patients in Cambodia seek treatment in the private sector; and
- ii. Injectable artemisinin-based anti-malarials (which have widely replaced three-times daily injectable quinine) and rectal artesunate are life-saving treatments for patients with severe malaria.

A summary of the therapeutic benefits and the quality status of these medicines is provided in Annex 3.

2.9 The MDC consulted with the RBM Partnership in relation to the three options referred to in Paragraph 2.3 above. The RBM Partnership indicated support for Option 2 to restate the interim exception (Annex 2), and confirmed that, in its view, funding for these life-saving anti-malarial medicines is urgently required.

2.10 The MDC also considered the risks of permitting DHA-PPQ to be procured in the private sector in Cambodia through AMFm. Some MDC members expressed concerns that the private sector in Cambodia was not adequately regulated and controlled, which increases the risks of using a product that does not meet the quality requirements of the QA Policy. The MDC considered alternatives to the three options referred to in Paragraph 2.3 above, such as limiting the sale of DHA-PPQ under the AMFm in Cambodia to the public sector until such time as the ERP considered the risk of ineffective or no treatment under the specific circumstances in Cambodia and provided advice permitting the procurement of DHA-PPQ. However, given the short timeline for implementing AMFm Phase 1, the delays associated with such an ERP review is very likely to severely affect the implementation of AMFm Phase 1, and would likely curb the benefits of AMFm in Cambodia. Many MDC members expressed their strong reservations about the MDC making a decision on this issue with the limited information available to the MDC. In response to these reservations, the Secretariat provided further clarifications about:

- i. The obligation for suppliers to comply with detailed minimum packaging requirements designed to permit tracking and ensure proper use;

⁴ WHO is hosting the Expert Review Panel (ERP) described in the QA Policy, as requested by the Board (Decision Point GF/B18/DP11).

⁵ WHO Global Malaria Programme

- ii. Training campaigns to promote proper use, focusing on the private sector;
- iii. Support to develop the pharmacovigilance system; and
- iv. The fact that Cambodia has submitted a plan for quality control at country level.

2.11 Beyond the deployment of DHA-PPQ in Cambodia, MDC members expressed concerns about the use of grant funds to procure medicines not advised by the ERP to be eligible for procurement, and about the possibility that the products might still not be available when the proposed extension to the time-limited interim exception expires. There was also concern that an extension to the time-limited interim exception may not encourage some manufacturers to meet the requirements of the QA policy.

2.12 Following an extensive and robust exchange of views, the MDC:

- i. recognized the absence of eligible alternative anti-malarial products;
- ii. noted that some manufacturers are committed to resubmit dossiers to the ERP⁶ while seeking prequalification by the WHO Prequalification Programme;
- iii. recognized the urgency of adopting a contingency plan for the relevant medicines to avoid treatment disruptions; and
- iv. recommended to work towards a longer term approach to procuring life-saving treatment in situations where no products
- v. meet the criteria of the QA Policy, by ensuring that when assessing medicines for which there are no alternatives in a given situation, the ERP's advice also considers the clinical risk of providing ineffective or no treatment, as identified by the relevant WHO disease programmes.

2.13 Considering the concerns described in Paragraphs 2.10 and 2.11 above, the Private Sector constituency did not support the above proposed Decision Point, and the United States Government (USG) constituency did not support the use of DHA-PPQ in the private sector in Cambodia.

2.14 During the finalization of the draft MDC report to the Board, the USG Constituency proposed a number of amendments to the Decision Point as agreed to at the 2nd MDC Meeting. The Chair circulated the proposed amendments to all MDC committee members, who responded by providing their comments. A consensus agreement on an amended Decision Point was reached prior to the Twenty-First Board Meeting as reflected in this revised report.

⁶ The next ERP review is in May 2010 (with an April deadline for submission of dossiers).

2.15 The MDC recommends the following amended Decision Point to the Board.

Decision Point 1: Interim Exception to the Global Fund's Quality Assurance Policy for Pharmaceuticals
~~Pharmaceutical Products~~

1. ~~The Board approves a restatement of the interim exception to the Global Fund's Quality Assurance Policy for Pharmaceuticals Pharmaceutical Products as set out in Annex 4, to include certain life-saving artemisinin-based anti-malarial medicines only for use in a given region or country where there is no viable alternative medicine as advised by the World Health Organization (WHO).~~ the MDC Report to the Board (GF/B21/8, Annex 4). This interim exception expires on 31 December 2010.

2. ~~The Board requests the Secretariat to work on an urgent basis with WHO to establish a process for the Expert Review Panel (ERP) to include, in specifically consider and assist to deal with exceptional cases where no adequate therapeutic alternatives exist for a finished pharmaceutical product, in the future. Such exceptional cases would be limited to situations in which financing provided by the Global Fund would be used to procure a Finished Pharmaceutical Product (FPP) of a formulation for which:~~

- (i) no **available**⁷ FPP complies with the quality standards of the Global Fund's Quality Assurance Policy; and
- (ii) WHO has made a determination, based on the available information, that no therapeutic alternatives exist that would be adequate for the specific country or region of intended use.

In such exceptional cases, ERP review should include an assessment of the clinical risk of providing ineffective or no treatment, in addition to a quality risk analysis. If necessary, the Terms of Reference of the ERP shall be revised accordingly.

This decision does not have material budgetary implications.

⁷ "Available" means that the manufacturer can supply the requested quantity of the FPP within not less than 90 days of the requested delivery date.

Implementation of the Global Fund's Market Dynamics Strategy (Voluntary Pooled Procurement, Price and Quality Reporting)

3.1 The MDC recognized the progress made on implementing the Voluntary Pooled Procurement (VPP) strategy in its first six months of operations. It has achieved procurement of large quantities of certain types of health products at favourable prices. The Global Fund's Procurement Support Services initiative also helps to facilitate access to in-country Capacity-Building Services (CBS).

3.2 The Office of the Inspector General (OIG) updated the MDC on the objectives and progress of the ongoing OIG review of the new VPP initiative in line with the OIG annual audit approach document adopted by the Board at its Twentieth Meeting. The review has been delayed due to other urgent assignments of the OIG; a first draft of the OIG report is expected to be shared with the Secretariat by the end of the second quarter of 2010. The scope of the OIG review includes the following:

- i. Compliance of VPP policies and procedures with the those of the Global Fund;
- ii. Ways to encourage participation, and Global Fund capacities in place to handle this;
- iii. Procurement of health products over time;
- iv. Mechanisms of detecting and flagging problems; and
- v. Country experiences.

3.3 The Secretariat also identified a number of challenges that have impeded the ability of the VPP to broadly impact market dynamics to date. These included:

- i. Operational impediments (e.g., difficulty in forecasting demand among participating countries) to adopting techniques (e.g. minimum volume guarantees to suppliers) that could lead to greater impact on market dynamics;
- ii. Growing but still limited country participation in the mechanism and therefore insufficient aggregated demand to negotiate improved prices and other conditions for certain product categories (e.g. ARVs);
- iii. Disproportionately large number of transactions for some low-value product categories;
- iv. Misalignment in the timing of countries' joining the VPP and placement of orders;
- v. Limited capacity within the Secretariat to implement all of the aspects of the mechanism alongside other priorities

3.4 Partly as a result of these challenges, the Secretariat described that it has largely not been able to pool orders across countries thus far. The Secretariat outlined a number of operational steps that it will take to continue enhancing the VPP, but also noted that greater strategic clarity from the Committee and Board could assist effective implementation and increase market impact.

3.5 In the long term, broader participation will enable the VPP to assist the consolidation of procurement orders to improve the predictability of demand and to achieve economies of scale. The MDC considered that implementation of the decision taken at the Fifteenth Board Meeting, envisaging mandatory participation for countries with inadequate procurement capacity⁸, may need to be reinforced.

3.6 Long-Lasting Insecticide-treated Nets (LLINs) have to date been the most prominent product in the operations of the VPP in value terms. Specific challenges encountered in supporting the procurement of LLINs to meet the 2010 universal coverage targets through both the VPP and normal grants include:

- i. Product specification and fragmentation of demand;
- ii. Unpredictability of demand;
- iii. Risk of constraints in production capacity, with limited incentives for production expansion if high demand is not subsequently sustained ; and
- iv. Supply chain and distribution challenges.

3.7 Approaches were discussed for the Secretariat to implement “value-for-money” strategies for LLINs. It was suggested that the life span, effectiveness and cost of LLINs should be considered in making procurement decisions. However, there are currently no studies on the cost-effectiveness or determination of life span of LLINs. The Secretariat will work with WHO⁹, other relevant technical partners and communities, to establish evidence and guidance to help buyers achieve the best available pricing and other terms, when procuring LLINs.

Operational Next Steps

3.8 The MDC endorsed the Secretariat’s plan to develop, and report against, a high-level framework of performance indicators related to the objectives of the VPP mechanism set by the Board.

3.9 MDC members recognized the importance of allocating adequate resources to the Secretariat to enable it to continue effective implementation and realize the strategic potential of the VPP.

Strategic Next Steps

3.10 The MDC recognized that the VPP represents one of the principal means through which the Global Fund can increase its impact on key market dynamics outcomes. Yet the VPP’s full potential to impact market dynamics has not yet been realized, which is understandable given the early stage of VPP implementation. The MDC accordingly determined that guiding and supporting the optimization of the mechanism, particularly in relation to its strategic approaches to influencing market dynamics, will be a priority for the Committee.

⁸ GF/B15/DP15: Use of the Pooled Service shall be voluntary except for PRs that, in the determination of the Secretariat, have demonstrated inadequate capacity to procure effectively and efficiently, which the Secretariat, if appropriate, may in each case require to procure through the Pooled Service.

⁹ Global Malaria Programme

3.11 In response to the Secretariat's briefing, the MDC requested the Secretariat to lead an analysis of additional strategies to enhance the impact on market dynamics for target product categories, including LLINs. This analysis should build on, and be complementary to, the OIG's review (see Paragraph 3.2 above). The MDC will review this analysis at its Third Meeting and determine whether to recommend any of the strategic options presented to help increase the impact of the VPP.

3.12 During its discussion of the VPP, the MDC questioned whether the VPP should devote its limited capacity to procuring common products such as condoms for which there is small or no potential to impact market dynamics. Some MDC members also expressed concern about the use of remote consultants to provide capacity building support to countries and questioned whether alternative models were possible. These issues may be revisited by the MDC at its subsequent meetings.

Implementation of the Price and Quality Reporting Mechanism

3.13 The Secretariat updated the MDC on the implementation of the Price and Quality Reporting (PQR) mechanism. As at 22nd February 2010, the PQR contains reported data on procurement to the value of 345 million USD from 102 countries¹⁰.

3.14 The Secretariat described the main challenges experienced with the PQR system, including:

- i. Data entry errors e.g. inconsistent use of units of measurement or Incoterms;
- ii. No segregation in the database of entries not yet verified by LFA;
- iii. Inconsistent nomenclature, hindering meaningful data aggregation; and
- iv. Absence of a systematic link between Procurement and Supply Management (PSM) Plans and PQR data, needed to calculate the percentage of procurement reported.

3.15 PQR data and the extent of their verification by the Local Fund Agent (LFA) are being examined as part of Phase 2 reviews. The Secretariat informed the Committee that entry of data into the PQR is a mandatory requirement for Phase 2 review and that it was emphasizing the enforcement of this measure.

Operational Next Steps

3.16 The MDC commended the Secretariat for the progress made in implementing the PQR and welcomed the Secretariat's high level plan to increase data validity and completeness further in cooperation with PRs and partners. The MDC requested the Secretariat to provide an update on its plans to further develop key aspects of PQR functionality which can inform decision-making, such as forecasts, price references, price comparisons and benchmarking.

3.17 The MDC requested the Secretariat to develop and regularly report on a set of standard indicators for tracking the performance of the PQR. The Committee noted that a particularly valuable indicator would be to determine the proportion of overall Global Fund-financed orders captured in the PQR.

¹⁰ As at 22 February, excluding outliers (defined as entries showing a per unit price of less than 25% or greater than 250% of the median)

Strategic Next Steps

3.18 The MDC emphasized that the PQR is central to the Global Fund's ability to monitor and impact market dynamics and achieve other major corporate priorities, notably improving the value achieved with its resources ("value for money"). Because the information contained in the PQR is essential to diagnosing market dynamics challenges and identifying opportunities for improvement—and therefore to the rest of the MDC's work—the MDC sees the enhancement of the PQR as a particularly urgent priority (even relative to other priorities adopted by the MDC). The MDC asked the Secretariat to make PQR improvements a top priority for the remainder of the year.

3.19 Since the Secretariat is already making strong progress on improving operational aspects of the PQR, the MDC will increasingly focus on monitoring those improvements and helping identify ways to translate the improvements into greater extraction of value and insights from PQR data.

Progress Update on Quality Assurance Matters for Health Products

3.20 The Secretariat updated the MDC on progress and challenges with implementing the revised Quality Assurance Policy for Pharmaceuticals (QA Policy) (Annex 1), and the interim exception (Annex 2). The MDC commended the Secretariat for its successful implementation of the QA policy and expressed particular interest in progress made with mandatory in-country quality monitoring, including random Quality Control testing of products. The MDC recognized the positive impact which the QA Policy has had to provide an incentive to manufacturers to have their products WHO-prequalified or authorized by a stringent regulatory authority. The MDC noted the greatly increased availability of antiretroviral products which meet the requirements of the QA Policy, and the remaining challenges for artemisinin-based antimalarials.

3.21 WHO¹¹ gave an update on the ERP review process and outcomes of the first two rounds of review of product dossiers (see also Paragraph 2.7 above). An important clarification was that the ERP has not to date considered therapeutic benefits alongside the quality risk analysis in its review of products, but that it would be possible for the ERP to do so by collaborating with relevant WHO disease programmes if requested by the Global Fund.

Operational Next Steps

3.22 The MDC acknowledged the progress made in developing a QA policy for diagnostic products and for medicines other than antimalarials, anti-TB products and antiretrovirals ('non-ATM medicines'). It recognized the scarcity of reported procurement data for these products, and highlighted the need to consider the implications for grant recipients and local industry when designing these policies. The MDC plans to define its recommendations for QA policies for diagnostics and non-ATM medicines to the Board at its Third and Fourth MDC Meeting respectively.

3.23 The MDC emphasized that it will be important to develop a process for resolving ad hoc challenges with the non-availability of medicines meeting the requirements of the QA Policy (see recommended Decision Point in Paragraph 2.13 above).

¹¹ See Footnote 4

Overview of Corporate Risk assigned to MDC Oversight

3.24 The Secretariat presented an overview of the key corporate risk of “Poor quality pharmaceutical products” contained in the Global Fund’s Corporate Risk Register. Board oversight of that key corporate risk and the measures implemented to manage this risk was delegated by the Board to the MDC.

3.25 Following an exchange of views, the MDC:

- i. recognized the effectiveness of the QA Policy to limit the likelihood of poor quality pharmaceutical products being used in grant-funded programmes; and
- ii. requested an update on the Global Fund’s approach of balancing this risk against that of treatment disruptions due to supply challenges.

3.26 The MDC recommended maintaining the current rating of the risk as “medium”.

3.27 The Finance and Audit Committee, in its report to the Board, will summarize all of the Committees’ discussions on the overarching issues relating to the corporate risk register.

Prioritization of Areas for Further Study and Action

3.28 The MDC spent a substantial portion of its meeting understanding the Global Fund’s current approaches to market dynamics and procurement issues and discussing specific ways in which its strategy on in these areas can and should evolve.

3.29 As a result of these discussions, the MDC identified five broad priority themes that it could explore further to enhance the Global Fund’s impact on market dynamics. These include:

- i. Monitor and appropriately respond to acute market dynamics problems and/or high impact opportunities in specific product niches, drawing on the experience of the VPP and the work of other partners (e.g. Unitaid). Examples might include but would not be limited to:
 - a. Demand, supply or price fluctuations (e.g. artemisinin supply chain, LLINs); and
 - b. Excessively high prices (e.g. MDR-TB drugs, 2nd line ARVs).
- ii. Improve the efficiency of commodity budgeting and spending. Initial specific opportunities in this area that were raised by the Committee and Secretariat include:
 - a. Facilitate budgeting in line with international reference prices, e.g. through facilitated benchmarking analyses;
 - b. Review and optimize proposed health budgets before Board approval;
 - c. Expand post-grant signature activities to monitor performance against PSM plans, respond to challenges encountered, and incorporate performance into decisions about continued funding; and
 - d. Encourage the use of intellectual property rights flexibilities to procure the most affordable products among equivalent options.
- iii. Accelerate uptake of new products (e.g. point of care diagnostics, second line ARV treatments, fixed-dose anti-malarial combinations¹²). The Committee acknowledged the Global Fund’s important contributions in this area on an ad hoc basis to date,

¹² NB. The Board, at its 19th Meeting, requested its Chair “to delegate to the relevant committee(s) the task of identifying and considering options for the Global Fund, within its mandate as a financing institution, to support countries in expediting the transition to FDCs, taking into consideration the implications for quality, supply, pricing and appropriate use of ACTs, and to report back to the Board at its Twentieth meeting.”

- including the shift to ACTs as first-line malaria treatment in 2004 and more recent facilitation of changes to PMTCT regimens. The Committee will explore if there are means of incorporating these types of contributions into core Global Fund systems;
- iv. Supporting country ownership and strengthening local capacity on procurement-related matters, including medicines regulation; and
 - v. Local manufacturing and implications for market dynamics.

3.30 The Committee agreed that the first two areas (monitoring and responding to market dynamics and efficiency of commodity budgeting and spending) should be the initial priorities for its strategic work and it accordingly spent additional time discussing options in these areas

3.31 For the second priority, the MDC acknowledged current measures used by the Secretariat to ensure reasonable commodity budgeting prior to grant signature, particularly through the development of Procurement and Supply Management plans. The MDC welcomed the fact that an increasing emphasis on retrospective reviews of spending against the budgets within those PSM plans will inform Phase 2 reviews of and evaluations of grant performance.

3.32 The Secretariat agreed on the importance of engaging actively on market dynamics issues but also pointed to its limited resources to take on additional work.

Strategic Next Steps

3.33 The MDC agreed that an important next step for its market dynamics monitoring priority would be to identify product areas where there are opportunities to work with partners to conduct necessary analysis. It was agreed that the Chair and Vice Chair will work with the Secretariat to appropriately pursue this step before the Third MDC Meeting.

3.34 To further inform its deliberations on spending and budgeting efficiency, the MDC requested the Secretariat to share at the Third MDC Meeting an analysis of change in commodity budget between different phases of grant preparation, including proposals, their TRP reviews and the Secretariat's approval of the corresponding PSM plan.

3.35 The MDC also asked the Secretariat to present at the Third MDC Meeting a range of suggested actions to improve commodity budgeting and spending across the Global Fund grant life-cycle, connected with the other activities being pursued to enhance the "value for money" strategy.

3.36 The MDC will discuss the outcomes of analyses mentioned in Paragraph 3.33 above, and the related strategic analysis of the VPP (see Paragraph 3.11 above) at its Third Meeting with the aim of progressing towards appropriate strategic recommendations.

3.37 The MDC will discuss these approaches in more detail based on the strategic analysis of the VPP (see Paragraph 3.11 above) at its Third Meeting, and will coordinate its work on value for money with that of the Portfolio and Implementation Committee (PIC).

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

GLOBAL FUND QUALITY ASSURANCE POLICY FOR PHARMACEUTICAL PRODUCTS¹

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.

¹ Including amendment as per Decision Point GF/B20/DP13

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 NDRA 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

guidelines². 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).³

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)⁴; 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 available⁵ 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 available⁶ 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-authorized⁷ and will make recommendation to the Global Fund.

² 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/>

³ <http://www.who.int/tb/strategy/en/>

⁴ 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.

⁵ "Available" means the manufacture can supply the requested quantity of the FPP within not less than 90 days of the requested delivery date.

⁶ Refer to footnote 4.

⁷ Refer to footnote 3.

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.

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).⁸

Provided that the criterion in paragraph (ii) above is met, certain multi-source⁹ FPPs for malaria and first-line tuberculosis treatment that do not meet the criteria in paragraph (i) above are also eligible for review by the ERP for associated potential risks/benefits in accordance with paragraph 10 of this Policy. The list of ERP-recommended FPPs that is made publicly available will indicate which of the ERP-recommended FPPs were eligible for review as a result of this paragraph.

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-authorized¹⁰, 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

⁸ List of PIC/S members is available on the PIC/S website: www.picscheme.org.

⁹ 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.

¹⁰ Refer to footnote 3.

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-authorized¹¹ within the ERP Recommendation Period. The Global Fund may refer more than one request for such an extension to the ERP.

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 antimalarial 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 SRA¹², 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 policies 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 Agencies¹³ (as amended from time to time).

¹¹ Refer to footnote 3.

¹² Refer to footnote 3.

¹³ 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.

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.

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.

QUALITY ASSURANCE POLICY FOR PHARMACEUTICAL PRODUCTS:

INTERIM EXCEPTION

(EXTRACT OF DECISION POINT GF/B20/DP13)

....

The Board decides that, on an exceptional basis and for the period up to 31 December 2010 only, grant funds may be used to procure certain multi-source FPPs for malaria and first-line tuberculosis treatment, 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.

The Board requests the MDC to consider, as a matter of urgency, contingency plans regarding the recently notified disruption of funding for certain life-saving medicines (e.g. artemisinin intra-rectal and injectable medicines) in situations where no FPPs for such medicines meet the criteria in paragraph 7 of the QA Policy and to make recommendations to the Board at the earliest opportunity.

This decision does not have material budgetary implications.

SUMMARY OF QUALITY ASSURANCE STATUS OF FOUR LIFE-SAVING ANTI-MALARIAL MEDICINES

Manufacturer ¹ , presentation(s)	Quality status as per Global Fund's QA Policy			Requirements for Interim Exception (GF/B20/DP13)		
	SRA registration	WHO pre-qualification	ERP review	GMP compliance	Procured by UN agency	Covered
Dihydroartemisinin-piperaquine: According to WHO Global Malaria Programme, most adequate medicine to contain artemisinin resistance in Cambodia						
Sigma-Tau (Italy): 40/320 mg capsules, not yet marketed.	Submitted to EMEA in July 2009	In process	ERP review October 2009 → not recommended.	Yes	WHO: For Cambodia Zone 1	Yes
Holley Cotec (China): 40/320 mg tablets Manufactured by Zhejiang Holley Nanhu Pharmaceutical Co. Ltd; supplied by Beijing Holley-Cotec Pharmaceuticals Co. Ltd	Not submitted	In process (accepted for review in March 2009)	ERP review, May and October 2009 → not recommended.	Yes	MSF: For use within operational research framework in Myanmar	Yes
Artemether i.m. oily injection: Life-saving in severe <i>P. falciparum</i> malaria; reverting to 3 times daily par-enteral quinine is not realistic in treatment programmes according to WHO Global Malaria Programme						
Paluther, Sanofi (originator product): For compassionate use in the European Region						
Dafra Pharma (Belgium). Paediatric (40 mg/ml), and adult (80 mg/ml) formulation Manufactured by Rotexmedica, Germany; supplied by Dafra.	Not submitted	In process	ERP review, May and October 2009 → not recommended.	Yes	MSF (paed. formulation) Unicef: For Global Fund PRs in Liberia, Chad and Sudan IDA: For Global Fund, PMI, and other buyers	Yes
Strides Arcolab Limited (India): 80mg/ml formulation.	Not submitted	In process	ERP review May 2009 → not recommended	Yes	Unicef: for Global Fund PRs in Liberia, Chad and Sudan	Yes
Artesunate i.v. or i.m.: Life-saving in severe <i>P. falciparum</i> malaria, preferred in adults; reverting to 3 times daily quinine is not realistic in treatment programmes according to WHO Global Malaria Programme						
Guilin (China): Artesunate 60 mg powder for injection	Not submitted	In process	Submitted to the first ERP review April 2009 → not eligible for ERP review (not GMP compliant)	No. Re-inspection by WHO re-scheduled Feb 2010	None currently	Not yet
Artesunate rectal capsules: Life-saving in children with severe malaria; reduces the risk of death and permanent disability in young children of less than 5 years of age ⁷ , especially for pre-referral use						
Mepha (Switzerland): 50 mg and 200 mg rectal capsules	Not submitted	Submitted to WHO PQ before Oct. 2006: dossier was eventually rejected.	ERP review May 2009 → not recommended. Not eligible for re-submission (no longer under WHO PQ assessment)	Yes	Unicef, MSF, IDA	Yes

¹ Other companies are marketing the product, but there are no data available about them.

**INTERIM EXCEPTION TO THE GLOBAL FUND'S QUALITY ASSURANCE POLICY FOR
PHARMACEUTICAL PRODUCTS**

(RESTATED, INCLUDING RELEVANT CONTENT OF DECISION POINT GF/B20/DP13)

The Global Fund recognizes the challenges associated with identifying sources for certain essential medicines that meet the requirements of the Quality Assurance Policy for Pharmaceutical Products ("QA Policy").

To avoid disruption to treatment of patients, without compromising the fundamental quality assurance principles of the QA Policy, on an exceptional basis and for the period up to 31 December 2010 only, grant funds may be used to procure certain FPPs for malaria and first-line tuberculosis treatment as defined under Paragraphs 1. and 2. below, provided that:

- a. there are no other FPPs for that product formulation available that are WHO-prequalified or SRA-authorized or ERP-recommended;
- b. the site at which such FPP is 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 a United Nations procurement agency; and
- d. the notification, confirmation and testing processes described in Paragraphs 9 and 31 of the QA Policy will apply to such procurement.

Products which can be funded under these provisions include:

1. Certain multi-source anti-malarial and first-line anti-TB medicines, where "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; and

2. The following life-saving artemisinin-based anti-malarial medicines: dihydroartemisinin-piperaquine ~~tab-let~~, artemether injectable, artesunate injectable, and artesunate rectocaps, ~~only for use in a given region or country where there is no viable alternative medicine, as advised by the World Health Organization (WHO).~~ provided that:

i. the applicable medicine appears in:

(A) the current national standard treatment guidelines; or if these guidelines do not exist, the current institutional standard treatment guidelines; and

(B) the current WHO standard treatment guidelines;

ii. WHO has advised that there is evidence to demonstrate better efficacy or safety of the medicine in comparison to alternative medicines for the specific country or region of intended use; and

iii. the Secretariat has consulted with its expert advisers and obtained representations and warranties from one or more relevant governmental authorities approving the distribution and use, including over-the-counter distribution and use as applicable, of the medicine in the specific country or region.

Terms defined in the QA Policy have the same meaning in this Interim Exception.

GUIDANCE ON LOCATION OF FURTHER INFORMATION

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

Where indicated by an asterisk [*] documents are available on the MDC password-protected website:

<http://extranet.theglobalfund.org/cme/MDC/default.aspx>

Item:	Further information available:
1. Contingency plan to prevent supply disruption of life-saving anti-malarial medicines	“Contingency plan to prevent supply disruption of life-saving anti-malarial medicines” (GF/MDC02/05) [*]
2. Items for information:	
<ul style="list-style-type: none"> • Implementation of Global Fund’s market dynamics strategy 	<p>“Discussion paper: Progress update on the implementation of the Voluntary Pooled Procurement” (GF/MDC02/0) [*]</p> <p>“Challenges in product procurement: Long Lasting Insecticide treated Nets (LLIN)” (GF/MDC02/07) [*]</p> <p>“Update on the price and quality reporting (PQR) system” (GF/MDC02/02) [*]</p>
<ul style="list-style-type: none"> • Implementation of Global Fund’s QA Policy for health products 	“Quality assurance for health products matters (GF/MDC02/04)” [*]
<ul style="list-style-type: none"> • Oversight of corporate risk 	“Overview of corporate risks assigned to MDC oversight” (GF/MDC02/03) [*]
<ul style="list-style-type: none"> • Prioritization of areas for further study and action 	