



Investing in our future

The Global Fund

To Fight AIDS, Tuberculosis and Malaria

Eleventh Board Meeting
Geneva, 28-30 September 2005

GF/B11/9

REPORT OF THE FINANCE AND AUDIT COMMITTEE

Outline: This report from the Finance and Audit Committee (FAC) summarizes the deliberations of the FAC meeting on 6-7 July 2005 and recommends the points listed below for decision by the Board.

Summary of Decision Points

- 1 The Board approves an addition to the 2005 budget of US\$ 380,000 for the estimated costs of implementing the quality assurance policy for single and limited source pharmaceutical products. This amount is an upper limit pending experience of the extent to which random testing is required.

FAC notes that the Secretariat will continue to engage with WHO and other partners in order to optimize the process. FAC shall review the 2006 cost estimates in conjunction with the 2006 Secretariat budget process, and shall review the actual costs of implementation towards the end of 2006 and adjust the budget accordingly if warranted.

- 2 The Secretariat shall focus on the current move to rented offices (BIBC) with a view to expanding within, while continuing to pursue the Swiss (FIPOI) loan option and to explore low cost commercial financing alternatives for Secretariat office premises, with no immediate commitment to rent elsewhere or to purchase.
- 3 (A decision point regarding the appointment of the Inspector General may be recommended to the Board by means of the annex to this report that will be sent to the Board after 19 September, as mentioned at 7.12.)

Part 1: Adoption of Agenda

1. The draft agenda (Attachment 1) was adopted with the addition of an item concerning the identification of 'soft indicators' of performance arising from the replenishment conference and with the sequence of agenda items altered to facilitate consideration of the Office of the Inspector General item after the delayed arrival of the US delegate.

Part 2: FAC Workplan and Working Methods

1. The Chair expressed the desire for a co-chairing environment between Chair and Vice-Chair and encouraged all present at meetings to feel free to contribute.
2. There was recognition of the need for effective inter-committee communication through interaction with Chairs and Vice-Chairs of other committees. This could be facilitated by a 'news flash' style summary report, issued quickly after each meeting and highlighting cross-cutting matters.
3. It was agreed that video- and teleconferencing should be used wherever feasible, in order to make more effective use of committee members' time and save costs.
4. The draft work plan through April 2006 (GF/FAC1/02) was approved; the date of FAC meeting proposed for October 2005 was fixed for 7 September to be followed by a videoconference to consider the 2006 budget on 19 October 2005.

Part 3: Currency Risk Management

1. The Secretariat presented an update on currency risk exposure as at 31 May 2005. At that date, all grant liabilities were in US dollars and 92% of assets were held in US dollars. The option of switching grant currency when applying for continued funding for Phase 2 was exercised for the first time with a grant renewal (in Euro) approved in June 2005. Some Round 5 proposals were denominated in Euro and, if approved at the Eleventh Board meeting, would give rise to Euro grants being entered into in the subsequent months.
2. The Tenth Board meeting had approved transitional policies for currency risk management and had asked FAC to present a full recommendation on policies and parameters to the Eleventh Board meeting, unless insufficient experience warrants extension to the twelfth Board meeting. FAC concluded that there was insufficient experience to date on which to base further recommendations to the Board at this time and recognized that this may still be the case even by the Twelfth Board meeting. FAC will continue to keep this under review.

Information Point

FAC notes that there is insufficient experience to date on which to base further recommendations to the Board regarding currency risk management at this time and will review the matter again prior to the Twelfth Board meeting.

Part 4: 2006 Budget Framework

1. The Secretariat outlined the proposed timeframe for compiling the draft budget for 2006 and for review by FAC to enable its recommendation to the Twelfth Board meeting. The budget for 2006 will be presented with indicative amounts for 2007 and 2008.
2. FAC endorsed the proposed timetable, whereby FAC will discuss the budget by videoconference on 19 October, allowing adequate time for finalization prior to circulation of Twelfth Board papers on 18 November.
3. FAC concurred with the earlier recommendation of MEFA that the 2006 budget should focus on incremental needs in 2006 beyond the level required to continue activities funded in 2005 and that this should be backed by high level priorities consistent with the performance measures set for the Executive Director, rather than by very detailed work plans.
4. It was recognized that the outcome of the replenishment process, which would determine the Fund's grant-making capacity in 2006 & 2007, and the magnitude of Round 5 would have a major impact on operating expenses in 2006 – 2008. Any changes to the Fund's current business model that might emerge from the strategic planning process would also affect budgetary assumptions for these years; hence it was considered important to maintain close communication with the Policy and Strategy Committee regarding any proposed changes to the model that are known prior to finalization of the draft budget.
5. The possibility of an increased efficiency target for 2006 was discussed. The Secretariat reported that improvements in the manner of LFA contracting that would yield efficiencies in 2005 would be factored into the 2006 budget, leaving little scope for large additional efficiency gains in the near term. FAC observed that the scale of grant activity was likely to increase significantly in 2006 – 2008 if the projected needs for 2006 -2007 (\$7.1 billion) were fully financed through the replenishment process.
6. FAC agreed, in response to the Secretariat's request, to provide guidance on budgetary scenarios in the light of the replenishment outcome when FAC meets on 7 September, immediately after the London session of the Replenishment Conference.

Part 5: 2005 Operating Expenses Review (GF/FAC1/07)

1. The Secretariat presented details of operating expenses for the first five months of 2005 which were 32% of the budget for the year, and 23% less than the portion of the year's budget attributed to the five-month period. The lower-than-budget spending was due to consuming less LFA services than planned (mainly on Round 4 grants), lower-than-budgeted LFA rates and some Secretariat activities occurring later in the year than was reflected by the five-months' budget.
2. The outlook for the whole year (2005) is for LFA fees to be less than budgeted and normal Secretariat expenses to be in line with budget. However, the Secretariat office relocation, which had been planned for 2006, will now occur in 2005 and was budgeted for in 2006 rather than 2005. The resultant unbudgeted costs will be in the range of \$1.3 – \$1.8 million; much of this can be covered from the contingency and, possibly, from savings on other Secretariat expenses. If necessary, the Secretariat may seek permission to use part of the anticipated savings on LFA fees (as was allowed in 2004) to cover any remaining part of this exceptional item, so that total costs would still remain within the total budget for 2005. The Secretariat will report further to FAC later in 2005.
3. FAC reviewed the budgetary implications of Board mandated tasks since approval of the 2005 budget amounting to US\$422,000 for 2005.

Information Point

FAC notes that amounts totaling US\$ 422,000 have been approved for addition to the 2005 budget in respect of tasks mandated by the Board subsequent to approval of the original 2005 budget.

Part 6: Budgetary Implications of Tenth Board Decision on Quality Assurance

1. The Secretariat outlined the budgetary implications of implementing the policy on quality assurance for limited and single source pharmaceutical products. These had been estimated at US\$450,000 per year when the Board approved the policy and asked FAC to review the accuracy of the estimate (Tenth Board).

2. Key implementation aspects include:

- Likely evolution from a first phase of random testing, for which a Quality Control Agency will be directly contracted by Global Fund, to a more holistic approach involving close cooperation with key partners who are already undertaking their own drugs testing or interested in developing a common platform for increasing Quality Assurance, including the testing and sharing of test results.
- The process of this longer term initiative will include a competitive bidding process for the selection of an independent third party to act as Quality Control Agency, to be conducted by October 2005 for implementation by January 2006.
- WHO has provided guidance with regard to sampling and testing methodology and rules and has helped in developing the terms of reference for the Quality Control Agency

3. The budget required will be a function of the price of the tests and the total number of tests, plus set-up and running costs. It is not yet possible to make an accurate prediction of the total number of required tests and the following key assumptions underlie the cost estimates:

- 4,000 drug orders per annum, of which 21% to 29% are procured pursuant to Options Ci or Cii of the policy (giving minimum and maximum scenarios)
- A random testing rate of 18% of all Ci and Cii drug orders
- An average cost for sampling and testing of \$2,100 per test, based on information provided by partners and others.

Based on these assumptions and taking account of set-up and running costs, the costs of implementing the policy were estimated by the Secretariat at \$320,000 to \$380,000 in 2005 (which had not been provided for in the approved budget for that year), and \$400,000 to \$520,000 per year subsequently.

4. FAC noted that in advance of experience of implementing the policy and of the extent to which random testing will be required, uncertainties are inevitable in the budgetary estimates. In these circumstances, FAC agreed to recommend a budgetary provision of \$380,000 for 2005 as an upper limit, cognizant that actual costs may be lower than this. For 2006, FAC will review the cost estimates as part of the overall budgetary process and keep this under review in the course of that year.

5. FAC encouraged the Secretariat to continue to collaborate closely with WHO and other partners towards optimizing the process.

Decision Point 1

The Board approves an addition to the 2005 budget of US\$ 380,000 for the estimated costs of implementing the quality assurance policy for single and limited source pharmaceutical products. This amount is an upper limit pending experience of the extent to which random testing is required.

FAC notes that the Secretariat will continue to engage with WHO and other partners in order to optimize the process. FAC shall review the 2006 cost estimates in conjunction with the 2006 Secretariat budget process, and shall review the actual costs of implementation towards the end of 2006 and adjust the budget accordingly if warranted.

The budgetary implications of this decision are as stated in the decision text.

Part 7: Establishment of Office of the Inspector General (GF/FAC1/03)

1. Representatives of DLA Piper Rudnick Gray Cary US LLP (“DLA Piper”) presented their recommendations regarding the terms of reference and establishment plan for the Office of the Inspector General (OIG), including the selection of an Inspector General. The recommendations included that a sub-group of FAC be established to oversee the selection of candidates for recommendation to the Board.

Timeframe

2. There was considerable discussion of the urgent timetable required to enable selection of a candidate in advance of the 11th Board meeting in September, so as to fulfill US legislative requirements to enable full payment of the US contribution government for 2005. Failure to satisfy these requirements would result in 25% of the contribution being withheld.

3. Much concern was expressed regarding the short period of time available in which to advertise, interview and select recommended candidate(s). This process could commence only following Board approval of the terms of reference and establishment plan (late July) and would have to be completed by early September, for communication to the Board in advance of its meeting on 28-30 September. The feasibility of finding a suitable candidate within that period was questioned, especially since the advertising of the vacancy and the deadline for applications would occur during a peak holiday period.

4. FAC agreed to continue working towards the goal of recommending a candidate to the September Board meeting, with the overriding objective of finding the right person for the job. The outcome of the (initial) candidate search would determine whether more time would be required and the sub-group should decide by end of August whether such was necessary.

Terms of Reference of the OIG

5. FAC reviewed the recommended terms of reference for the OIG, noting the following:
- The Inspector General should report direct to the Board, rather than through FAC, although it may inform FAC
 - Compiling an annual work plan (in advance) may be impractical, though a report on the preceding year’s work should be issued. Scope should be allowed for organic growth of tasks as OIG experience develops.
 - It was important to clarify the relationships of the OIG with the Secretariat, TERG, the Fund’s external auditors, FAC, the Ethics Committee, etc.
 - OIG should be independent but not isolated or remote; its role should relate both to investigation and prevention

- The 'single audit' principle applied by UN and other organizations (including the World Bank, WHO and UNDP) will require the OIG to work through the comparable office in such entities (rather than having a right of access to their records)
- Consideration of disclosure policy was important, having regard to the interests of informants and others, and may necessitate private communications with the Board in some instances

6. When asked, the Secretariat's legal counsel advised that:

- No modification of the Global Fund bye-laws was required as a consequence of establishing the OIG, but the bye-laws could be modified to acknowledge the Office if such was desired for symbolic purposes (which the Policy and Strategy Committee may wish to consider).
- The WHO Rules did not preclude the Global Fund from establishing the OIG. (N.B. see clarification provided to FAC on September 26, 2005, attached as Annex 3) The existing delegation of authority from WHO to the Executive Director of the Fund would require a sub-delegation to the Inspector General in the interest of independence.

7. A sub-group of FAC (France, Point Seven (as Chair), United States) was mandated by FAC to finalise the terms of reference of the OIG for circulation to the Board by 15 July for email approval by 25 July. DLA Piper offered to work with the sub-group in the following days to facilitate this process. This sub-group will also oversee the selection of candidates.

Candidate Selection

8. Following consideration of the DLA Piper analysis of the proposals received from a number of executive search firms and having regard to proposal content and cost, FAC agreed to appoint Heidrick and Struggles to conduct the candidate search.

9. FAC considered it important that the candidate search should be far reaching, extending beyond the Anglo-Saxon community; to this end, the search firm should ensure that the position is advertised in English, French and Spanish language publications.

10. In considering the desired profile of the Inspector General, the sub-group will need to develop selection criteria and distinguish between essential and desired characteristics. DLA Piper offered to provide guidance to the sub-group in this regard.

Overall

11. FAC gratefully accepted the offer of DLA Piper to work closely with the sub-group in finalizing the terms of reference and in the candidate selection process. FAC thanked DLA Piper for their substantial ongoing pro-bono work that is enabling the OIG process to proceed with high quality and within a demanding timeframe.

Post-meeting update:

12. The terms of reference and establishment plan for the Office of the Inspector General were approved by the Board (by email process) on 27 July 2005 and advertisements for the IG position appeared in print media from 29 July. Short-listed candidates will be interviewed in Geneva on 19 September and the resultant FAC recommendations will be communicated to the Board shortly after that date (as Annex to this report).

Part 8: Potential Purchase of Secretariat Building (GF/FAC1/09)

1. The Secretariat presented various options for fulfilling its future office accommodation needs ranging from remaining in the new rented premises (the BIBC building) into which the Secretariat would move in July 2005, to pursuing an interest-free loan from the Swiss authorities (or a low-interest commercial loan) in order to purchase office premises.
2. It was explained that the Swiss agency (FIPOI) that supports the accommodation needs of international organizations currently had a five-year waiting list for its interest-free loans and that it made sense to be in the queue, without incurring any obligation to proceed, in order to have the option of such a facility in the future.
3. FAC, conscious that the Fund does not currently have a sufficiently long perspective to warrant a long-term loan commitment, concluded that the Secretariat should focus on its current move into new rented premises, which offered possibilities for expansion, while continuing to explore, without commitment, preferential loan options for the longer term.

Decision Point 2

The Secretariat shall focus on the current move to rented offices (BIBC) with a view to expanding within, while continuing to pursue the Swiss (FIPOI) loan option and to explore low cost commercial financing alternatives for a Secretariat office premises, with no immediate commitment to rent elsewhere or to purchase.

There are no material budgetary implications of this decision

Part 9: Fiscal Management Study (GF/FAC1/04)

1. The Secretariat summarised the report of the Board-commissioned study that was performed pro-bono by PricewaterhouseCoopers (PwC) who had presented their findings and recommendations in a briefing session on the day before the Tenth Board meeting. Key recommendations were:

- Comprehensive funding policy: Overall objective should be to reinforce reputation for prudent risk management, hence the policy should not be altered at present, but kept under review
- Long-term financial strategy: After the first voluntary replenishment mechanism is completed, the Board should formulate a long-term financial strategy for the Fund
- Investment strategy: Premature to consider any change, continue with current (conservative) risk/return profile
- Investment manager: FAC & Board should avail themselves of at least one additional investment manager
- Investment Committee: The Board should establish an Investment Committee that includes individuals with significant experience of hedging and multi-class asset portfolios
- Currency risk: FAC & Secretariat encouraged to consider simpler, practical procedures for managing currency mismatches

2. FAC was conscious that any shortfall in funding for Round 5 would re-focus attention on the comprehensive funding policy. By the conclusion of the September replenishment meeting, both the amount of TRP-recommended proposals and the funding available should be clear. If at that time a funding shortfall is evident, FAC, in its meeting immediately

following the replenishment conference, will consider the implications with regard to the comprehensive funding policy.

3. FAC discussed the PwC recommendation for the appointment of an additional investment manager (in addition to the Trustee), seen by many organizations as a best practice that facilitates comparison of managers' performance. The Secretariat was requested to obtain proposals, including presentations of historic rates of return, from a selection of investment managers for consideration by FAC.

4. Regarding the recommendation for the establishment of an investment committee, the Trustee suggested that FAC should have available to it a number of advisors with suitable expertise, who would be 'on call' to advise FAC on investment matters. FAC agreed that this approach was likely to be preferable to the establishment of an additional committee.

5. Currency risk management will be kept under review by FAC (as noted at 3 above) and the PwC recommendations will be borne in mind.

Information Point

FAC draws the attention of the Board to the recommendations of the PwC study. FAC will keep these recommendations under review and report further to the Board as necessary.

Part 10: Replenishment Process

1. The replenishment process was identified by FAC as a crosscutting matter, where both PSC and FAC have responsibilities and their relative roles require coordination with the Chair and Vice-Chair of PSC; the FAC Chair will confer accordingly.

'Soft indicators' (of performance)

2. FAC noted the discussions at the Rome replenishment meeting (20-21 June) regarding the desirability of identifying some 'soft indicators' of performance. The Secretariat informed FAC that a meeting of interested parties had been convened for 25 July in Geneva.

3. FAC noted that many indicators were already in place and that the Board had mandated TERG to report to it regarding performance of the Global Fund; however, this did not preclude the addition of further indicators.

4. The Vice-Chair and some other members of FAC will be attending the 25 July meeting and it was agreed that these members will report back to FAC.

Part 11: Next Meetings of FAC

1. FAC agreed to have a one-day meeting in London on 7 September 2005 (immediately after Replenishment Conference) to discuss:

For potential briefing to Eleventh Board meeting (28-30 September):

- Funding available for Round 5, in the light of replenishment discussions and the quantum of TRP-recommended Round 5 proposals,

In preparation for the Twelfth Board meeting (15-16 December 2005):

- Update on establishment of the Office of the Inspector General
- Report back on 'soft indicators' meeting

- Review of 2005 operating expenses and performance (January – June 2005)
- Transition plan to a fully independent entity (status report)
- Currency risk management (if sufficient experience by then)

2. A video-conference was fixed for 19 October to discuss in preparation for Twelfth Board meeting (in December):

- The 2006 draft budget
- Transition plan to a fully independent entity

Part 12: Annexes

The documents presented to the meeting are as listed below and may be consulted on the Global Fund website in the (password protected) section for committee papers.

Those papers which relate to proposed decision points are reproduced as annexes to this report, as indicated below.

Document No.	Document Title	
GF/FAC1/01	Draft Agenda	
GF/FAC1/02	FAC Workplan	
GF/FAC1/03	Proposed Terms of Reference and Establishment Plan for the Office of the Inspector General	
GF/FAC1/04	Independent Study of the Global Fund's Fiscal Management Structure and Processes	
GF/FAC1/05	Currency Risk Management Review	
GF/FAC1/06	2006 Budget Framework	
GF/FAC1/07	2005 Operating Expenses Review	
GF/FAC1/08	Budgetary Implications of Quality Assurance Policy for Single and Limited Source Pharmaceutical Products	Annex 1
GF/FAC1/09	Potential Purchase of Secretariat Office Accommodation	Annex 2
(For information)	FAC Terms of Reference	

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.

1ST FINANCE AND AUDIT COMMITTEE MEETING, GENEVA, 6-7 JULY 2005

AGENDA

Wednesday, 6 July 2005

19:00 – 21:30 **Dinner**
Introduction of Committee members

Thursday, 7 July 2005

8:30 – 9:00 **Welcome coffee**

9:00 – 9:30 **Approval of the Agenda**

9:30 – 10:15 **FAC Workplan and Working Methods**
(Potentially discussed at dinner on preceding evening)

10:15 – 10:30 **Break**

10:30 – 12:30 **Office of the Inspector General (Bartolomeo Migone)**
- Terms of reference
- Establishment plan, including recruitment of IG

12.30 – 13:30 **Lunch**

13:30 – 14:15 **Fiscal Management Study (John Burke)**
- Consideration of PwC report

14:15 – 14:45 **Currency Risk Management (Barry Greene)**
- Review experience to date

14:45 – 15.30 **Secretariat Financial Matters (Barry Greene)**
- Review of 2005 Operating Expenses
- Budgetary implications of 10th Board decision on quality assurance of limited and single source pharmaceutical products
- Budget 2006 framework

15:30 – 15:45 **Break**

15:45 – 16:30 **Potential Purchase of Secretariat Building (John Burke)**
- Consideration of the options available

16:30 – 17:00 **Close of meeting**

1ST FINANCE AND AUDIT COMMITTEE MEETING, GENEVA, 6-7 JULY 2005

ATTENDANCE LIST

Committee Members

Constituency	FAC Member	Attendee
European Commission (Chair)	Lieve Fransen	Lieve Fransen
Western Pacific Region (Vice-Chair)	Ren Minghui	Ren Minghui
Developed Country NGO	Peter van Rooijen	Peter van Rooijen
European Commission	Paul Avontroodt	Paul Avontroodt
Eastern and Mediterranean	Hassan Sadiq	<i>No attendee</i>
France	Sophie de Castelnau	<i>Madeleine Leloup</i>
Japan	Tamotsu Ikezaki	<i>Takako Tsujisaka</i>
Point Seven	Jerry O'Dwyer	Jerry O'Dwyer
World Bank	Kyung Hee Kim	Kyung Hee Kim
USA	To be named	<i>Peggy Hoyle</i>

Others

Observer Representing the Board Chair or Vice-Chair	Sabrina Guerard
Global Fund Secretariat	
FAC Focal Point, Chief Financial Officer	Barry Greene
Deputy Executive Director	Helen Evans
Chief Administrative Officer	John Burke
Legal Counsel	Bart Migone
Note Taking	David Ball
Individual Presentations	Steen Stottrup Daniel Low-Beer
Invited Consultants/Advisors	
Representing DLA Piper Rudnick Gray Cary US LLP	Sheldon Krantz Rachel Tausend

BUDGETARY IMPLICATIONS OF QUALITY ASSURANCE POLICY FOR SINGLE AND LIMITED SOURCE PHARMACEUTICAL PRODUCTS

Outline: This paper sets out to validate the budgetary implications of the Tenth Board Meeting decision to implement random quality control analysis of products being procured pursuant Option Ci and Cii in the new and amended Quality Assurance Guideline. At the time of the decision the budgetary impact was estimated to be up to USD 450,000 per year for possible staffing and contracting costs.

The Board mandated the Finance and Audit Committee to review the accuracy of this estimate and the need for additional funds beyond the approved total 2005 budget at its first meeting.

Attachments:

- Attachment 1 – Text of the Tenth Board meeting decision on quality assurance policy
- Attachment 2 – Estimation of the required number of quality tests
- Attachment 3 – Graphics showing the expected expenditure on testing and the first year projected implementation rate of the expenditure.
- Attachment 4 – List of countries with stringent regulatory authorities

Part 1: Background

1.1 The Tenth Board meeting approved new guidelines for procurement of single- and limited-source pharmaceutical products (the Board decision is attached as Appendix 1). Under very specific circumstances PRs are allowed to procure pharmaceutical products from (Ci) suppliers that have submitted the product for review to the WHO or to a stringent regulatory authority (see Annex 4) and which manufacture the product at a GMP compliant site or (Cii) suppliers which just manufacturer the product at a GMP-compliant site.

1.2 The Global Fund has been required to contract an independent third-party to conduct random quality analysis of products being procured pursuant criteria (Ci) or (Cii)

1.3 At the time of the Board decision the budgetary impact was estimated to be up to USD 450,000 per year for possible staffing and contracting costs. The Board asked FAC to review the accuracy of this estimate and the need for additional funds beyond the approved total 2005 budget. The objective of this paper is to validate the accuracy of the estimate.

Part 2: Implementation

2.1 The implementation of the Board decision will likely evolve from a first phase of random testing, directly contracted by TGF to a Quality Control Agency to a more holistic approach involving close cooperation with key partners who are already undertaking their

own drugs testing or interested in developing a common platform for increasing Quality Assurance, including the testing and sharing of test results.

2.2 The process of this longer term initiative will include a competitive bidding process for the selection of an independent third party to act as Quality Control Agency. It is envisaged that such a process would be conducted by October 2005 for implementation by January 2006.

2.3 WHO has provided guidance with regard to sampling and testing methodology and rules and has helped in developing the terms of reference for the Quality Control Agency.

2.4 Several companies have been contacted in the process of validating the budget and contracting the Quality Control Agent. SGS Nederland B.V, Trade Assurance Services and IDA HIV/AIDS Group were invited to quote for the activity. The Clinton Foundation and UNICEF were contacted in order to obtain a benchmark costing of the sampling and testing.

2.5 SGS has been able to make a rough quote but IDA is hesitant to quote because of a real or perceived conflict of interest and the length of the contract.

Part 3: Budget assumptions

3.1.1 The total expenditure for The Global fund .

3.2 Final quotes for the sampling and testing have not been obtained yet so the validation of the estimate is based on one rough quote and two sets of benchmarks.

3.3 At the present time it is not possible to make an accurate prediction of the total number of required tests because The Global Fund does not have an overview of the expected number of cases where the Principal Recipient will and because data on past experience is not yet available. Therefore the best possible estimate has to be based on the following assumptions:

- \$ 400M spend on drugs (\$ 600M including commodities)
- Average order size of approx. \$ 100,000
- Test 18% of all orders for any given product
- Volume procured by product is evenly distributed across the portfolio
- Cost of sampling and testing of USD 2,100 has been estimated based on rough quote from SGS and benchmark costs from The Clinton Foundation and UNICEF. Testing = USD 1,300 and Sampling USD 800 if the sampling is done in a country with existing representation.

3.4 Under these assumptions the estimated number of tests would be between 153 and 210 tests yearly and the total cost of tests and sampling would be between USD 321,300 and USD 441,000 (Cost per test x number of tests). A more detailed break down of the assumptions used to calculate this estimate is attached as Appendix 2.

3.5 It is intended to make a 6-month contract with a company, which allows The Global Fund to implement the Board decision. The contract will be covering the period until a long term solution – based on competitive bidding – can be implemented in January 2006.

3.6 The graphs in Appendix 3 show the predicted annual expenditure as well as the expected 6 month expenditure for testing and sampling. The expenditure in the initial 6 month is expected to be lower than half the annual expenditure because the implementation rate is expected to be lower in this initial period – largely due to the speed with which the PR's will adopt and comply with the policy.

Part 4: Budget

	2nd half 2005 (6month)	Full year 2006 (12)	
Maximum scenario			
210 checks (Annually) x USD 2,100 **)	199,500		441000
One time cost with (USD 1500 per produc 66 products	99,000		
Salary (USD 151,264 annually) 100% of FTE	75,632	50% of FTE	75,632
Travel	3,000		3,000
Total	<u>377,132</u>		<u>519,632</u>

Minimum scenario

153 checks (Annually) x USD 2,100 **)	140700		321,300
One time cost with (USD 1500 per produc 66 products	99,000		
Salary (USD 151,264 annually) *) 100% of FTE	75,632	50% of FTE	75,632
Travel	3,000		3,000
Total	<u>318,332</u>		<u>399,932</u>

*) Note: In the start-up phase (July 2005 - December 2005) the work load is expected to be higher (100%) than in 2006. The initial phase includes areas such as process development, vendor selection, contract agreement etc. which will not be done in 2006. In 2006 the workload is expected to be 50% of an FTE in order to monitor performance, improve processes and manage issues with suppliers, products or agent.

**) The implementation rate will be lower in the beginning. Consequently it is expected that only between 67 and 95 tests (Respectively minimum and maximum scenario) will be conducted the initial 6 month.

Part 5: Sensitivity of budget

5.1 As outlined at 3 above, assumptions regarding the volume of tests required significantly impact the budget, hence actual costs in 2005 may (or may not) be considerably less than the 'maximum scenario' cost estimates allowed for in the proposed Board decision point, following the methodology described.

5.2 It is also worth noting that there is some flexibility in the budget in the sense that the random coverage (18% of all orders for each product) can – if necessary - be reduced, thereby reducing the impact on the overall budget. If the random coverage were to be reduced to 16% the total annual cost in 2006 would be between USD 346,000 and USD 446,000. Prior to implementing the long term solution a competitive bidding process will be conducted and this will further allow for fine tuning of the budget and/or the level of coverage.

5.3 When the long term solution will be established the Secretariat will have 3-4 month of experience with the policy and therefore be in a better position to evaluate the degree to which PRs are choosing suppliers pursuant Option Ci and Cii. This will also allow for further fine tuning of the expected expenditure.

5.4 The Board-approved budget for 2005 does not include any provision for these costs.

OPS/ss

29-Jun-05, revised 25 Jul 05

Attachment 1: Decision of Tenth Board meeting

Quality Assurance of Limited and Single Source Pharmaceutical Products

Decision Point:

The Board decides to change its policy on quality assurance approved at the Third Board Meeting on "option (c)" by replacing the decision on Agenda Item 10(B)(4)(b)(c) with the following and eliminating the last sentence of that decision on the "option (c)" time limit:

- Once there are two or more equivalent pharmaceutical products that meet the standards in Option (a) or Option (b), then Option (c) is not applicable. Contracts entered into on or before April 30, 2005 with suppliers for products that qualified for purchase under Option (c) may be honoured by the Principal Recipient until they expire. No new purchase contracts or contract extensions for such products will be allowed after April 30, 2005.
- If the Principal Recipient determines that there is only one or no equivalent pharmaceutical product that meets the standards in Option (a) or Option (b) OR if the Principal Recipient determines that the products that meet these standards are unavailable² and represents the same to the Global Fund Secretariat, and the Secretariat does not object, then Global Fund resources may be used to procure other equivalent pharmaceutical products, provided that the products are selected in accordance with the following, in order of priority:
 - (i) the manufacturer has submitted an application for product approval to the WHO Prequalification Program or a stringent regulatory authority AND is manufactured at a site that is compliant with standards of Good Manufacturing Practice (GMP), as certified after inspection by the WHO or a stringent regulatory authority;
 - (ii) the product is manufactured at a GMP-compliant manufacturing site as certified after inspection by the WHO or a stringent regulatory authority.

A Principal Recipient shall inform the Global Fund Secretariat if it procures under provisions (i) or (ii), after having followed the above process. In turn, the Secretariat, working with technical partners, shall contract an independent third-party to conduct random quality analysis of products being procured

according to these criteria to ensure their quality in the absence of the Option (a) or Option (b) standard.

In the event that (a) the submitted application for product approval is no longer under consideration; or (b) the independent third party finds the quality of the product to be unacceptable, then the Principal Recipient shall promptly terminate the contract with the supplying manufacturer.

- In all cases, products purchased with Global Fund resources are subject to the monitoring product quality standards prescribed by the Fund as specified in Section 6 of the Report of the Third Board Meeting.
- Procurement of products according to criteria (i) or (ii) should be time limited and Principal Recipients should defer to Options (a) or (b) as soon as possible.

The Secretariat will monitor implementation of this decision and report to the Board at the Fourteenth Board meeting.

The budgetary implications are in the amount of up to US\$450,000 per year for possible staffing and contracting costs associated with implementation of the decision above. The accuracy of this estimate and the need for additional funds beyond the approved total 2005 budget will be reviewed by the Finance and Audit Committee at its next meeting.

Attachment 2: Estimation of the required number of quality tests

Product over view

	Column 1 Total products	Column 2 > 2 A/B	Column 3 < 2 A/B	Column 4 # with A or B	Column 5 No A/B	Column 6 No Ci/Cii
HIV	50	11	39	36	3	17
TB	8	0	8	4	4	4
Malaria	2	0	2	1	1	1
Total	60	11	49	41	8	22

60	100% Products	Column 1
-11	-18% > 2 A/B	Column 2
-22	-37% No Ci/Cii	Column 6
-10	-16% 50% will chose A/B if it exists	(Column 4 - Column 6) x 50%
18	29% of products	

Assumption \$ 600 M spend on drugs and commodities => \$ 400M on drugs
Average order size \$ 100,000 *) => 4000 orders per year
Random coverage = 18%
Cost per test = USD 2100

Maximum scenario

29% of orders =	1167 orders/year and	583 for 6 month
18% random =	210 tests/year and	105 for 6 month
Total test-cost = \$	441000 USD/year and	220500 for 6 month

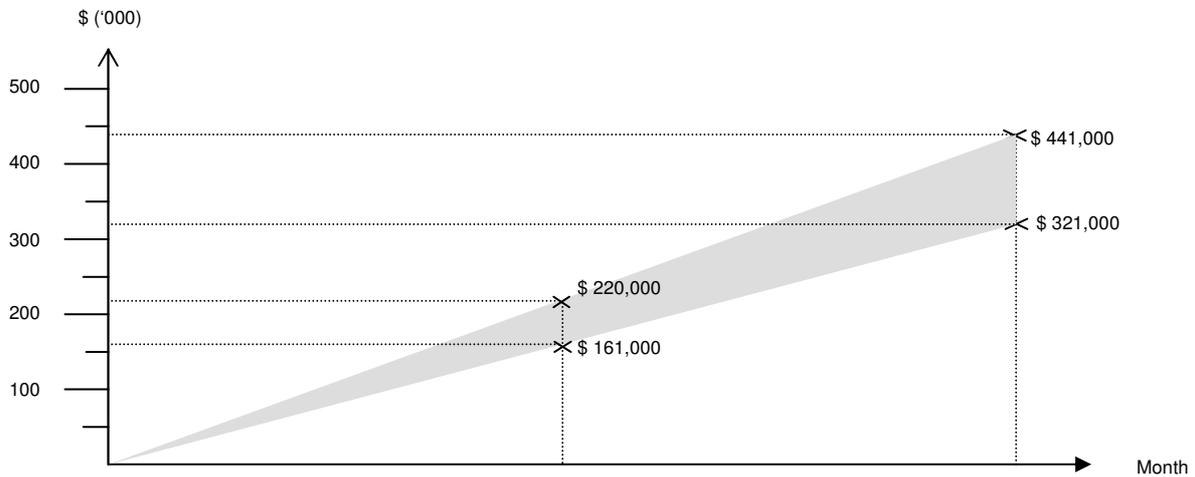
Minimum scenario:

8 products with no A/B	13% of all products	
25% will chose C if only one A/B and minimum one C exists		
5 products =	8% of all products	
21% of orders =	850 tests/year and	425 for 6 month
18% random =	153 tests/year and	77 for 6 month
Total test-cost = \$	321300 USD/year and	160650 for 6 month

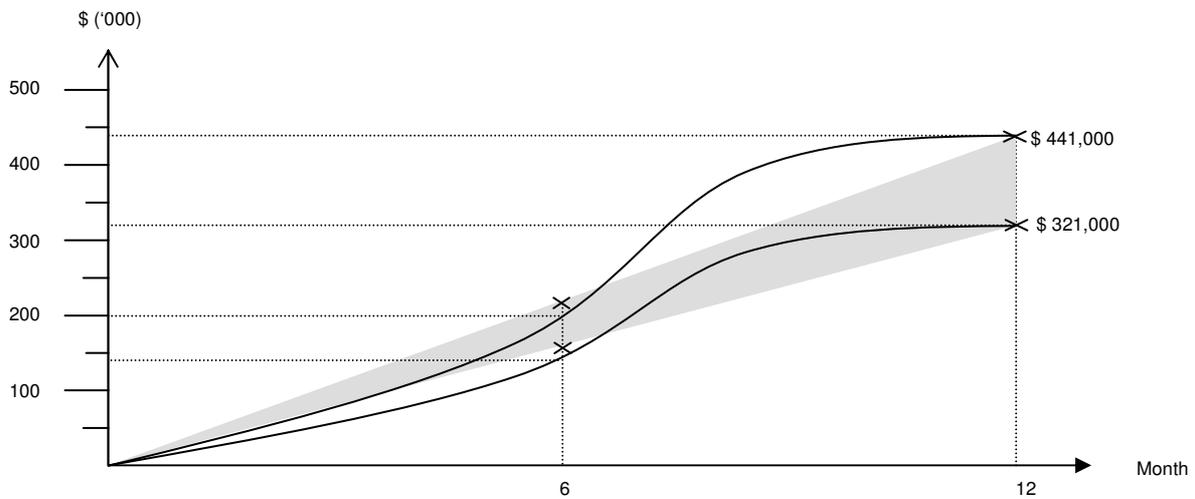
*) Note: The average order size has been increased from 48,000 to 100,000 due to the following reasons:
- In the Price Reporting Mechanism the sample size is only \$ 15M and the few countries (22) would indicate that it is not representative
- It is not possible to identify whether the orders in the sample represents only actual full orders or also "Call-off" within a tender

Attachment 3: Graphics showing the expected expenditure on testing and sampling and the first year projected implementation rate of this expenditure.

Graphic overview of estimated expenditure



Note: Cost is estimated to be between \$ 321K and \$ 441K annually. The 6-month period is between \$ 161K and \$ 220K



Note: The implementation rate would most probably be slower in the beginning. Consequently the cost in the initial 6 month would likely be between \$ 140k and \$200k

Attachment 4: Countries with stringent regulatory authorities

Pharmaceutical Inspection Cooperation Scheme (PIC/S) participating regulatory authorities:

Australia	Malaysia
Austria	Netherlands
Belgium	Norway
Canada	Portugal
Czech Republic	Romania
Denmark	Slovak Republic
Finland	Spain
France	Sweden
Germany	Switzerland
Greece	United Kingdom
Hungary	United States
Iceland	
Ireland	
Italy	
Liechtenstein	

International Conference on Harmonization (ICH) participating regulatory authorities:

European Union member states
Japan
United States

POTENTIAL PURCHASE OF SECRETARIAT OFFICE ACCOMMODATION

Outline: This paper outlines the most recent developments regarding Secretariat office accommodation and in particular reexamines the merits and risks of the potential purchase of a property in the Geneva area to house the Secretariat longer-term. It lays out several options for the Finance and Audit Committee to consider and recommends a way forward.

Part 1: Background

1. To cope with accelerating workload, the Global Fund Secretariat has expanded steadily. From around 90 staff in mid-2004, the 2005 approved budget authorized a rise to 150 staff, which, if temporaries, short-term staff, interns and consultants are included, requires a potential space need for 170 – 180 work stations. The 2005 budget projections envisaged headcount (permanent staff) leveling off at close to 200 in 2006 – 07, implying an overall minimum space need for 250 + work stations.

2. During late 2004, a range of alternate accommodation options were explored to establish short term and longer term potential solutions. The Secretariat worked with “FIPOI” (la Fondation immobilière pour les organisations internationales), whose primary role is to work with international organizations to help them solve their office space needs. Inter alia, FIPOI provides free or marginal cost consulting and advisory services, and guides and facilitates discussions with lawyers, real estate agents, government departments, etc.

3. A request for proposals was launched across the Geneva region. 10 offers were received and analyzed and a short-list of leading options defined. One of these has since provided the immediate solution to Secretariat space. As of mid-July 2005 the Secretariat will move from its current 8 locations spread over 2 buildings, to the Blandonnet International Business Centre (BIBC), equally close to Geneva airport. This move secures over 50% more space on 2 connecting floors, at a lower overall cost per square metre than current premises. The rental is on a 3 year renewable lease.

4. The FIPOI research also identified several potential purchase options. The most attractive of these – located in an excellent location (Versoix, reasonably close to the airport), has a good all round package of facilities and is for sale at an indicative price of \$ 50 million. Time from commitment to completion would be up to 3 years, suggesting a possible entry date of mid-2008.

5. To encourage and support international organizations to locate to and remain in the Geneva area, the Swiss confederation and the canton of Geneva, through FIPOI, have established a mechanism whereby organizations may apply for favourable terms to finance property acquisition in the region. The usual approach is an interest-free loan (over 50 years) to the organization concerned, with or without possible free land allocation by the canton of Geneva.

6. Following discussions with FIPOI and the Swiss authorities, they have recommended that the Secretariat lodge a request for an interest-free loan of \$ 50 million to fund the purchase of a building. Typically such loans are repayable over 50 years. The \$ 1 million per year amortization would compare to \$ 1.6 million annual rent in the BIBC building.

7. However the Swiss authorities have advised that a) the allocation of funds to FIPOI – the usual vehicle for such loans – is committed for several years to come, and the future levels of replenishment are uncertain, and b) the process for submission and approval of such loans is lengthy and it would be worthwhile considering alternative sources of bridge financing if the Secretariat wishes to move forward with a property purchase.

Part 2: Status of interactions with Governance to date

1. The March 6-8, 2005 meeting of the Monitoring, Evaluation, Finance and Audit Committee of the Board (MEFA) considered a paper which presented the business case and the associated pros and cons of a potential property purchase (annex 3 to Board paper GF/B10/8). A summary of the business case, pros and cons is attached as Annex 1.

2. In view of the long lead times for approval of Swiss government interest free loans and the tight FIPOI budget situation, the Secretariat proposed an alternative option to MEFA: to use Global Fund assets to purchase the property, pending granting of a loan by the Swiss authorities. It was emphasized, however, that if the Swiss loan were eventually not to materialize, then the same allocation would be made annually within the Secretariat budget to reimburse Global Fund cash holdings.

3. MEFA reviewed and explored what the Secretariat presented as significant financial advantages supporting the purchase of a building and discussed the pros and cons at some length. However the discussion indicated that MEFA members shared considerable concern that:

- a. MEFA had not received sufficiently detailed information to recommend to the Board that it move forward to approve an allocation of \$50 million for the purchase of a building;
- b. The potential for significant negative public relations and/or media attention was considerable;
- c. There had not yet been enough opportunity for wider discussion and consultation within constituencies on the issue.

4. In conclusion, MEFA asked the Secretariat to work with a small sub-group of the Committee in the immediate future. The MEFA Chair requested that this group review the project in more detail and, in consultation with the MEFA Chair and the Chair and Vice Chair of the Board, reach a consensus as to whether it was appropriate to bring the purchase recommendation to the attention of the Tenth or Eleventh Board meeting, through the appropriate Committee.

5. During these sub-group discussions, new information emerged – that it might be possible to secure a rent with option-to-purchase solution, allowing premises (such as the attractive option in Versoix) to be secured, while removing the time pressure on negotiating optimum financing.

6. Following a report by the MEFA Chair, the Tenth Board meeting noted the outcome of the initial exploratory work on the acquisition of permanent accommodation and anticipated that the Secretariat might bring forward detailed proposals to the Eleventh Board, through the FAC.

7. Since the Tenth Board meeting, further contacts with commercial Swiss banks suggest that particularly low cost borrowing options may be available which may further improve as the Swiss interest rate environment stays low or moves lower.

Part 3: Options going forward

1. Drop the idea of building purchase and focus on the move into BIBC (rented) premises. This approach will minimize management distraction and eliminate any risk of PR negatives associated with a humanitarian organization purchasing real estate in Geneva ("AIDs on the lake"). The BIBC is an attractive building, with first class facilities. The full period of the lease is for 8 years, with escape windows at 3 and 5 years. There is likely to be sufficient expansion space available within the building if required. The downside is that by continuing to rent rather than own, the Global Fund will pay a substantial longer-term financial premium as compared to building ownership with zero or low cost financing. The Fund also will not acquire an appreciating asset (see Annex 1 for financial comparisons).

2. Commit now (subject to September Board agreement) to rent space in the attractive Versoix building on completion with an option to purchase, using the 3 year escape window in the BIBC lease. In parallel, we would pursue the Swiss loan option and/or commercial low cost financing alternatives. On the positive side, this would allow us to secure the Versoix property without a purchase commitment and would also reduce the upfront PR risk of an outright purchase. Subsequent conversion from rental to ownership of the same building would be manageable discreetly. On the down side, the one-time costs of an additional move and installation (\$1 -2 million) would be incurred - relatively soon after the current move from Centre Casai to the BIBC. This option may only be feasible if the Board gives the go ahead at its June meeting, otherwise the developers will move on to other prospects (as may already be the case).

3. Continue to pursue the Swiss loan option and to explore low cost commercial financing alternatives, with no immediate commitment to rent elsewhere or to purchase. This would remove any short-term pressure to commit to rent in an as yet unbuilt project yet would allow us to position the Secretariat in due course to exploit any further appropriate real estate opportunities which may come on the market. In due course, and depending on our "comfort level" in the new BIBC premises, we would be able to reconsider the purchase option. However we would not get on the property "ladder" early so would lose some prospect of securing capital gain on a property asset.

Part 4: Recommendation

On balance, the Secretariat view is that option 3 represents the most pragmatic approach. The advice and guidance of the Finance and Audit Committee is requested.

BSU/jb
10/11/2005

26 September 2005

Clarification of statements of the Legal Counsel on consultations with WHO regarding establishment of the Office of the Inspector General

With regard to the Report of the Finance and Audit Committee (GF/B11/9) (Part 7, paragraph 6, reproduced below) we wish to provide additional information on one of the statements of our Legal Counsel during the FAC meeting of 6-7 July 2005, which was not completely reflected in the report. At that time, Legal Counsel had stated that a preliminary contact with WHO's legal office on delegation of authorities – both to the Inspector General under the WHO staff rules and with respect to the overlapping investigatory powers of WHO's own internal audit function – had not revealed objections in principle to the establishment of the OIG, and that he had not seen anything suggesting a different result. He added, however, that he had received no final advice on this from WHO, which had indicated that additional follow up would be required after the terms of reference of the OIG had been approved by the Board in July.

As additional background information, Legal Counsel's statement was based on an earlier contact with a WHO Senior Legal Officer, Joanne McKeough. During that conversation nothing emerged suggesting that the establishment of the OIG might present a problem of consistency with WHO requirements, although some delegation of powers arrangements would need to be made. However, Ms McKeough had clearly stated that the matter required further consideration, and that WHO would only be able to follow up once a formal request for delegation of authorities had been made by the Global Fund. It was agreed that this would need to occur later as the OIG's terms of reference had not yet been approved by the Global Fund's Board.

Shortly after the FAC meeting of 6-7 July, the FAC sub-group determined that, to safeguard the independence of the OIG, the Secretariat should not be involved in further work on the matter and that all preparations for the establishment of the OIG would be carried out by the sub-group itself or by the FAC. Accordingly, the FAC sub-group has itself, with the assistance of *external* legal counsel (DLA Piper Rudnick Gray Cary, who were fully apprised of the matter), taken the matter forward with WHO through a letter to the Director General and other contacts.

We provide this clarification to supplement the text of the FAC report, reproduced below.

Extract from Report of the Finance and Audit Committee (GF/B11/9)

Part 7: Establishment of Office of the Inspector General

6. "When asked, the Secretariat's legal counsel advised that:

- No modification of the Global Fund by-laws was required as a consequence of establishing the OIG, but the by-laws could be modified to acknowledge the Office if such was desired for symbolic purposes (which the Policy and Strategy Committee may wish to consider).
- The WHO Rules did not preclude the Global Fund from establishing the OIG. The existing delegation of authority from WHO to the Executive Director of the Fund would require a sub-delegation to the Inspector General in the interest of independence."