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Dear Dr. Loevinsohn,

We are writing to you regarding the Stop TB Coordinating Board's recommendation (October 2001) to explore avenues for a potential link between the Green Light Committee (GLC) and the Global Drug Facility (GDF). As respective chairs of the Working Group on DOTS-Plus for MDR-TB and the GLC, we have been discussing the options for harmonising the two operations for some time as DOTS is the foundation for DOTS-Plus and implementation of DOTS-Plus is part of the DOTS expansion movement. The basis for the harmonisation process lies in the fact that both operations are complimentary and that DOTS expansion benefits from a well functioning GLC and GDF. The Secretariats of the GLC and GDF have met on several occasions to examine the details of each potential option in order to determine the best possible route to harmonisation. Discussions within the GLC have also occurred and options for harmonisation were presented by the Secretariats of the GLC and GDF at the annual meeting of the Working Group in Tallinn, Estonia (10-12 April 2002). Accordingly, we would like to outline a specific plan of action regarding harmonisation of the GLC and GDF for your consideration based upon these discussions and our opinion as respective chairs.

Clearly, a harmonisation of the two operations can lead to greater efficiency, better advocacy, increased financing, and increased technical knowledge for the GLC and GDF. At the same time, the objective of the GLC is to focus on increasing access to and rational use of second-line drugs within the context of policy development for DOTS-Plus, while the GDF's objective is primarily the provision of first-line drugs within the standard DOTS strategy. Given these relatively different objectives, the two operations cannot be completely integrated into one operation. In view of this, we would like to propose that the harmonisation process is analysed in terms of six operational categories: scope, governance, procurement, administration, application and review process, and financing.

Scope

The GDF's focus is to provide access to low-cost, high quality first-line anti-TB drugs in DOTS-based TB control programmes. In contrast, the GLC's focus is as follows: to increase access to, and rational use of second-line anti-TB drugs (in either the DOTS or DOTS-Plus context), and to contribute to the evidence-based approach to developing policy regarding MDR-TB management. Nonetheless, both operations include the provision of technical assistance to potential projects and continual monitoring of approved projects. The harmonisation process should not interfere with the relatively different objectives of each, but should include collaboration between the two as much as possible to ensure that each operation achieves its objective in the most efficient manner possible. Accordingly, we recommend that the GDF includes the provision of second-line drugs within its focus, but to do so using the GLC process as its access mechanism.

Governance

Governance can be examined in terms of three concepts: accountability, reporting, and location within the Stop TB partnership structure. Regarding accountability, the GLC was established as a formal WHO committee and is accountable to WHO. On the other hand, a Memorandum of Understanding exists between the Stop TB Coordinating Board and WHO giving legal basis for the GDF. Thus, given the legal implications associated with accountability, we recommend to maintain the separate accountability structures. In reference to reporting, slight differences exist in reporting but these differences can be resolved by having the GLC and GDF provide their respective annual reports to the Stop TB Coordinating Board, WHO, and the Working Group on DOTS-Plus for MDR-TB. Thus, complete transparency of both processes is ensured. In terms of the Stop TB partnership structure, the GDF is located outside of the six Working Groups while the GLC is located within the Working Group on DOTS-Plus for MDR-TB. Given the integrated nature of the GLC and its legal basis as a special committee of the Working Group on DOTS-Plus for MDR-TB, we propose to keep the GLC within the Working Group but to formally establish a link to the GDF in order to indicate the harmonisation of both processes.

Procurement

The GLC (via WHO) and GDF (via WHO) are carrying separate procurement contracts with different procurement agencies. Certain issues regarding second-line drugs (such as obstacles in registration of drugs and technology transfer) can benefit from technical expertise of the GDF and should become integrated into the GDF as soon as possible. Upon expiration of the WHO procurement contracts with the International Dispensary Association (IDA) and MSF-Transfer for second-line drugs, we recommend the transition of all procurement issues related to second-line drugs to the GDF. However, mechanisms fostering increasing the number of suppliers of second-line drugs (such as provision of technical assistance to companies failing quality-assurance/quality control tests, and tiered tendering) while ensuring high standards of quality should be maintained.

Administrative

In principle, we recommend that all activities related to advocacy, training, and resource mobilization for the GLC and GDF should now be consolidated under the GDF. Thus, the GDF should be viewed as one comprehensive operation providing access to high-quality first- and second-line anti-TB drugs, which includes the GLC as a subcomponent. Nonetheless, the GLC secretariat should remain the focal point for all applications related to second-line anti-TB drugs. Online facilities of the GDF should incorporate parameters to address GLC applications as well. Applications related to access to second-line drugs should be sent to the GDF secretariat in WHO, who will request the GLC to start the review process. In reference to recipient projects, the GLC and GDF have separate contracts with the projects which will need to remain separate given the varying mandates, procurement situations, and legal accountability for the GLC and GDF.

Applications and Review

Given the relative complexities of implementation of DOTS-Plus and the application, and the monitoring processes for the GLC, it is our recommendation that the application and review process for the GLC and GDF should be coordinated but adapted to the needs and requirement of each operation. However, The GLC and GDF secretariats should create one document with an application form for each operation, and determine how to best streamline the GLC application form as well. In addition, monitoring missions to countries receiving GLC and GDF support should be coordinated so that one combined visit occurs in order to make best use of resources and minimize the burden on recipient countries. This process should include coordination with the regular Global DOTS expansion monitoring visits as well. However, in such visits at least on expert on MDR-TB issues should be present.

Financing

Although concessional prices have been achieved for second-line drugs, some programmes still find the cost of second-line drugs an obstacle for the implementation of DOTS-Plus. Accordingly, a parallel financing mechanism to that used by the GDF for first-line drugs should be implemented for second-line drugs. Specifically, we recommend that applicants should be provided with the same options for financing of first- and second-line drugs: grants for the purchase of drugs or the ability to purchase drugs at concessional prices. Such financing options would be integrated into the current review process established by the GLC, and simply provide projects with either option.

In addition, the GLC currently operates by having each member provide funding for its member's participation (i.e. for site visits, travel to meetings, etc.) with WHO attempting to cover, as much as possible, the expenses of the GLC. In order to operate effectively, all operational aspects of the GLC (meeting, pre-approval site-visits, post-approval monitoring visits, training courses, and consultant visits) should be covered by an independent funding source. Consequently, we also recommend that the GDF allocates funding for such activities. Because of the recent decision by the Global Fund to Fight AIDS, TB and Malaria that all requests for second-line TB drugs must go through the GLC, we believe that that task of finding funds for the operation of the GLC and for second-line drugs will be much easier than before.

Overall, the harmonisation of the GLC and the GDF should be done by maintaining the GLC process, and including the GLC and second-line drugs in the GDF's advocacy work and administrative functions. The secretariats of the GLC and the GDF should remain as separate entities located in their separate teams within WHO, although they should work closely to improve the application review and project monitoring process. Second-line drugs should be provided under the same provisions as first-line drugs (either free of cost or at concessional prices). Because of the technical complexities associated with the procurement of second-line drugs, the secretariat of the GLC will devote significant time to the transition of the procurement process to the GDF. Given the close link to the technical aspect of MDR-TB control and legal parameters, the GLC should remain an independent mechanism accountable to WHO but report its activities to the Working Group and WHO. Finances from the GDF should be allocated for activities of the GLC to ensure the GLC achieves its objectives in an efficient manner. However, we feel that both operations should be viewed as complementary and funds should not be diverted from one in order to fund the activities of the other.

We hope that the Stop TB Coordinating Board will agree to this plan for harmonisation of the GLC and GDF. If necessary, we would be happy to present this plan Board during the next meeting of the Stop TB Coordinating Board.

Sincerely,

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Chair, Working Group on
DOTS-Plus for MDR-TB
Harvard Medical School

C.S.B. Lambregts van Weezenbeek
Chair, Green Light Committee
Royal Netherlands Tuberculosis
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Cc: Jong-Wook Lee
Mario Raviglione
Jacob Kumaresan

Bcc: GLC Members