

**Rational Pharmaceutical Management Plus
Technical Assistance to GDF and GLC: Trip Report
Geneva, Switzerland September 26 – October 3, 2006**

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About RPM Plus

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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Abstract

The Global TB Drug Facility and the Green Light Committee of the Stop TB Partnership among other things are unique suppliers of tuberculosis medicines in that they purchase and supply medicines to over 65 countries worldwide. In order to function appropriately they depend on partners to carry out some of their activities. This report describes the adjudication of potential GDF procurement agents who participated in a tender and the analysis of data for a joint global study of medicines for multi-drug resistant tuberculosis.

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Key Words

Tuberculosis, TB, FDC, DOTS, GDF, GLC, MDR-TB, pre-qualified, suppliers

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Acronyms

DOTS	WHO scheme for controlling TB in national programs
FDC	Fixed dose combination products
GDF	Global TB Drug Facility
GLC	Green Light Committee
GFATM	Global Fund to Fight AIDS, Tuberculosis, and Malaria
NTP	National TB Program
Stop TB	Department of WHO responsible for promoting DOTS and good TB control worldwide
TB	Tuberculosis
USAID/BGH	U.S. Agency for International Development, Bureau of Global Health
WHO	World Health Organization

Background

Tuberculosis (TB) continues to be a major international killer disease that annually takes over two million lives worldwide, and a major threat to populations especially in countries where it is fueled by high prevalence of HIV. Significant progress in expansion of DOTS strategy – the most cost-effective package for tuberculosis control currently known – has been made in recent years supported by increased funding for national TB programs (NTPs) through the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM), and dramatically improved supply of quality assured first- and second-line TB medicines through the Global Drug Facility (GDF) and the Green Light Committee (GLC). In the last several years RPM Plus has worked with these international TB initiatives and donors to bring the issues of pharmaceutical management to the international agenda.

One significant achievement for RPM Plus with USAID/BGH funding to date has been to provide technical assistance to the GDF and GLC. During 2003-5, RPM Plus seconded a Procurement Officer who has assisted in issuing tenders for TB drug supply, pre-qualifying suppliers, quality control agents and laboratories, supporting GDF officers in day to day management activities, proposing and advising on management decisions specifically in procurement and supply, and representing GDF in discussions with manufacturers, QC agents, Ministers of Health, other departments of WHO and the GFATM. RPM Plus has also provided technical assistance in conducting monitoring missions to evaluate readiness of countries to receive GDF/GLC medicines and conducted various workshops and how to manage pharmaceuticals used in TB.

RPM Plus also provided technical assistance to GLC technical officers in understanding ramifications of poor TB pharmaceutical management, how to set up a tender for selecting a new procurement agent, developed a database which GLC uses to monitor medicines provided to GLC countries, and making presentations at MDR-TB partners workshops.

In 2006 GLC and GDF announced they would merge for purposes of procuring and distributing medicines for first- and second-line TB treatment. In July 2006 GDF/GLC issued a tender to select a new procurement agent for second-line drugs, as they as they had also done for first-line medicines in March 2006. The procurement agent manages the purchase, distribution and quality assurance activities of medicines procured for GLC.

In December 2005 at the request of GLC, RPM Plus organized and commenced a study on the size of the global market of second-line medicines for treating multi-drug resistant TB (MDR-TB) and the sources and prices of those medicines. This information is needed to encourage increased production of second-line medicines by suppliers thereby increasing availability and hopefully competition to help lower prices for the now expensive medicines used to treat MDR-TB.

Purpose of the trip

Realizing the contribution RPM Plus has made, the GDF/GLC called on RPM Plus to sit on the adjudication committee to select the most appropriate procurement agent among those who submitted proposals. Thomas Moore represented RPM Plus for this activity.

Simultaneously, Thomas Moore worked with GLC technical officer Dr. Matteo Zignol to clean and analyze data from the global study of medicines for treating MDR-TB.

Cost of the trip was covered through SO5 TB USAID funding.

Scope of Work

The Scope of Work was as follows:

1. Chair the GDF/GLC adjudication committee
2. Represent the committee in recommending the most cost-effective procurement agent for GDF/GLC
3. Clean and analyze data from the GLC global study of MDR-TB medicines

Activities

1. Chair the GDF adjudication committee

The adjudication panel consisted of the following members:

Thomas Moore - Management Sciences Health, (Chairman)
Stephanie Arzac - Chief Pharmacist ICRC
Fuad Mirzayev - GLC Secretariat
Anton Norder - EDM WHO
Giorgio Roscigno - FIND Diagnostics
Sarah Schmitt – Procurement Officer, Global Drug Facility

The GDF/GLC Procurement Officer distributed the adjudication rules and the proposed agenda. The committee nominated and accepted Thomas Moore to be the Chairman of the adjudication meeting. Thomas Moore received consensus for the agenda and collected the forms declaring any conflicts of interest and the need for confidentiality.

2. Represent the committee in recommending the most cost-effective procurement agent for GDF

There were two parts to the committee's review: a technical assessment and a financial assessment. In the same room and following the rules of the meeting, each committee member individually reviewed the information sent by all suppliers interested in bidding.

Technical assessment

Committee members reviewed each bidder's information and rated each criterion of the tender announcement. There were 13 *mandatory* criteria and 18 *other* criteria. Examples of criteria were: *Evidence of at least 3 years experience in purchasing pharmaceuticals from foreign-based suppliers on behalf of government and/or non-governmental organizations operating internationally*, and *Was the proposal submitted on time?*

The committee then came together to discuss the individual ratings and reached a consensus on the scores including both the mandatory and additional criteria.

Financial assessment

Following the consensus reached by the group on the technical review, the financial envelopes of the submitters' proposals were opened. Committee members individually reviewed each proposal comparing unit price of each GLC product and related costs. Examples of costs compared were: staff costs to manage supplier timelines including storage of buffer stock, quality assurance testing by an individual agent, and distribution to recipient country, and ability to offer a web-based ordering and tracking system among others.

The committee then came together to discuss their individual financial comparisons and reached a consensus on the rankings.

Overall assessment

Based on the consensus reached during the technical and financial discussions and combined ratings of individual committee members, the organizations submitting proposals were ranked best, second, third, etc. Included with the rankings were several questions that the GDF/GLC would need to know before making an offer.

Minutes of the meeting and results were documented and duly corrected by the committee and submitted to the GDF/GLC by its chairman, Thomas Moore.

The results are confidential and cannot be divulged in this report.

3. Clean and analyze data from the GLC global study of MDR-TB medicines

Thomas Moore met with Dr. Matteo Zignol on various occasions throughout this visit, reviewing the Access database used by RPM Plus to enter data from the study where 52 National TB Programs (NTPs) had responded to the study questionnaires.

Thomas Moore ran a quality assurance check on data entry by reviewing drug names, strengths, quantities procured and prices provided on each of the 52 questionnaire. Then Matteo Zignol and Thomas Moore marked unclear data for exclusion. Data were analyzed through several queries and various tables were created from the queries. The activity was completed by agreement on who would prepare which part of the draft report of findings. The indicator calculations and discuss sections will be done by Thomas Moore. The background, methodology and comparison of treatment regimens will be done by Matteo Zignol. The draft report of findings should be ready for technical review by December 2006.

Collaborators and Partners

Robert Matiru, GDF/GLC
Sarah Schmitt, GDF/GLC
Matteo Zignol, GLC

Next Steps

- No further action is needed by the chairman or committee members of the adjudication committee; however, GDF/GLC will send the committee's decision to the WHO contracts committee for review and approval before an award can be made to the winning proposal for 2nd line medicines.
- Global 2nd line medicine study, draft report of findings will be finalized by both RPM Plus and the GLC, submitted for technical review and then be ready for dissemination by end of the year 2006.

Outcomes

1. The GDF/GLC will be able to make an offer for procurement agent to the best qualified organization promoting the ideals of the GDF/GLC and Stop TB
2. TB prices will be the lowest possible for high quality TB pharmaceuticals
3. Both GDF and countries procuring from the GDF will be able to stretch their resources for procuring TB medicines even more
4. Manufacturers of 2nd line medicines will be encouraged to produce larger quantities making availability less of an issue as it is today
5. With the market full of 2nd line medicines hopefully the unit price will decrease making the treatment of MDR-TB more affordable for poor-resource countries

