Pre-read for the Stop TB Coordinating Board

1 INTRODUCTION

The Global Drug Facility (GDF) was formed in 2001 with a mandate to provide "uninterrupted access to quality TB drugs for DOTS expansion". This was intended to reduce the frequent shortages of drugs experienced in countries and prevent the emergence of drug-resistant strains of TB. GDF's original activities were to mobilize financing for drug procurement and supply, provide grants to countries, procure drugs for grantees and others organizations that were self financing and work with Stop TB partners on monitoring, evaluating and problem solving for effective drug delivery.[1]

The Global Drug Facility has had numerous successes. Between 2001 and 2009, it delivered over 16 million high-quality TB treatments through its grant service and direct procurement service and worked closely with over 90 countries world-wide. It did this while helping to foster the use of fixed dose combinations and blister packs as well as the new pediatric indication, per WHO guidance. Through its missions to countries and workshops, GDF has worked with countries to improve drug management systems. It works competitively and transparently with procurement agents and manufacturers to stimulate supply while negotiating low prices.

As GDF approaches its 10 year anniversary, it is clear that the TB landscape today has changed in important ways. New and existing organizations are engaging in activities that overlap with GDF's core mandate, making it critical to clarify roles and comparative advantages. GDF's business has become more complex. GDF now provides second line drugs (SLDs) and diagnostic kits in addition to the first line drugs (FLDs) it initially provided. GDF also has substantially expanded its DP business whereas GDF was originally primarily grants-based. Given this evolving landscape, it is time to review GDF's mission and role to ensure its relevance in the future.

2 METHODOLOGY

This work represents interim findings of an ongoing consultancy being conducted by the Boston Consulting Group (BCG). The objectives of the consultancy are to 1) conduct a strategic analysis of current TB landscape and GDF's current role and 2) propose several options for the future GDF business model. As part of the first phase of work on the strategic analysis, BCG has reviewed key background documents and analyzed internal GDF data and external market data to understand the potential market size and evolving market dynamics for different products. In addition, BCG has interviewed more than 50 GDF stakeholders, including suppliers, donors, procurement agents, country NTP managers, NGOs, GDF and WHO staff to understand how the international community views GDF and where the real need is for GDF. (See Appendix I) The next phase of work following the Board meeting will analyze the costs, financial sustainability, organizational implications and overall feasibility of different business models for GDF to arrive at the final recommendation in June.

[1] Global Drug Facility Prospectus, WHO 2001

3 Market Situation Today

Today, **the market for first line anti-TB drugs (FLDs)** is well developed, with a number of pre-qualified suppliers selling quality assured products at reasonable prices, due in part to GDF's activities. GDF's share of the market is sizeable. In 2008, 2.7M FLD patient treatments[2] were ordered from GDF. This covered 24% of the 11.2M estimated cases world wide or 40% of 6.8M cases detected[3]. In 2009, orders for 2.2M FLD treatments flowed through GDF. The non-GDF market is dominated by high burden countries that often procure drugs directly through a national procurement agent (e.g., China, South Africa, Russia). From 2008 to 2009, the value of GDF's DP business increased from $13M in 2008 to $21M in 2009. DP made up 28% of FLD deliveries in 2008 and 44% in 2009, although this is partially due to a decrease in the number of countries (from 35 in 2008 to 28 in 2009) receiving FLDs through GDF grants as well as the increase in DP business. The majority (>80%) of DP orders were for Global Fund (GF) grantees. At this time, GF does not provide a voluntary pooled procurement service for TB as it does for malaria and HIV/AIDs, since GDF occupies this role for the TB community.

The market for diagnostics in developing countries is currently dominated by diagnostics for active TB detection. Most countries rely on a combination of sputum smear microscopy and chest radiography to diagnose TB. Few countries currently have the capability to differentiate between susceptible TB and drug resistant TB because this requires a significant investment in laboratory equipment and skilled staff. GDF provides a small volume of diagnostics through grants and DP, mostly equipment starter kits, consumables kits and microscope kits. In 2009, GDF procured $1M of FLD diagnostics and $1M of MDR-TB diagnostics for Expand TB. Expand TB is a partnership between UNITAID, the Foundation for Innovative New Diagnostics (FIND), the Global Laboratory Initiative (GLI) and GDF that works to build infrastructure and capabilities to diagnosis MDR-TB at country level. In 2010, Expand TB plans to expand activities to 27 countries in 2010, thus setting the groundwork for a potential expansion in treatment of MDR-TB in coming years.

The market for second line anti-TB drugs (SLDs) is still relatively small in terms of patients treated, given the lack of diagnostic capabilities at country level. GDF is the designated procurement arm for the Green Light Committee (GLC), which reviews applications for SLDs from countries applying for grants. This gives GDF a monopoly in the supply of SLDs approved by the GLC, although the volume is very low. In 2008, GDF provided 6,000 treatments of SLDs (roughly 18% of the 33,000 patients reported diagnosed with MDR-TB in 2008). Over the past year, DP business has scaled up significantly for GDF, from $8M in 2008 to $22M in 2009, accounting for ~50% of GDF's DP business in 2009 because of the significantly higher cost per MDR-TB patient ($2000 - $7000/patient). To date, few suppliers are prequalified to supply SLDs, with most drugs only available from a single pre-qualified supplier.

4 Future Risks and Opportunities for GDF

This new landscape creates new risks, but also new opportunities for GDF. Probably the biggest challenge for GDF is the emergence of the Global Fund (GF) in providing grants for anti-TB drugs. This

[2] Number of treatments is estimated at the time when orders are placed and includes curative pediatric treatments. It includes buffer stock provided to countries, but the impact of this on GDF market share is difficult to estimate for a variety of reasons (e.g., countries may run through buffer stock)

[3] We use the prevalence as an estimate of the total number of treatments needed in a year, rather than incidence which would only give us the number of new cases.

has 1) siphoned donor funding away from GDF, especially in FLDs, thus making GDF more reliant on a few large donors (USAID, DFID, CIDA) and 2) made GF a critical influencer over 80% of GDF's DP customers. However, this is also an opportunity for GDF to maintain a close working relationship with GF to ensure that GF grantees continue to procure through GDF. Should the Global Fund decide to offer its own Voluntary Pooled Procurement service for anti-TB drugs, this would have major impact on GDF's DP operations. In SLD market, there are also some risks for GDF. The GLC is considering whether to let countries procure pre-qualified SLDs directly, provided the application is first reviewed by the GLC. This will not decrease GDF's current business but might decrease the number of countries procuring SLDs through GDF as scale up occurs. The other major risk is related to concerns about GDF's performance from key stakeholders, including the Global Fund and countries. Decisive action is needed by GDF to maintain stakeholder support, both to improve performance in line with partner expectations and to communicate the challenges GDF faces that are outside its control.

Several opportunities exist for GDF. Within the FLD market, potential may exist to expand GDF services to the highest burden countries (e.g., China, South Africa, Russia) that account for a major share of global burden. In many of these countries, local suppliers are not pre-qualified so greater GDF involvement could focus on ensuring high quality drugs are used. To be clear, this may require GDF to focus on convincing preferred local suppliers to become pre-qualified, rather than undertaking the procurement through GDF and may be an uphill battle. The market for SLDs and MDR-TB diagnostic represent opportunities for GDF to expand its current role in market shaping and scale up. The market for SLDs is poised to grow substantially with the scale up of diagnostic capacity via the Expand TB program. Much work is still needed to identify laboratory equipment and diagnostic tests for MDR-TB that meet the WHO standards under development and to ensure a steady supply of high quality, lower cost SLDs. Finally, given partners' expectations that GDF facilitate the smooth flow of drugs to countries, GDF may want to consider formalizing the use of novel mechanisms like a rotating stockpile and a revolving fund, such as GDF and UNITAID are currently working on.

5 OPTIONS FOR GDF'S ROLE

In view of the changing landscape as well as performance concerns, the role GDF plays in the future may need to evolve. Based on stakeholder input, we segmented activities for GDF into the following 5 categories for discussion.

1) **Basic procurement / logistics** - Includes routine order placement, bid preparation with service providers (suppliers, freight forwarders, etc), invoice review, processing/channeling of funds, confirmation of order receipt, etc.

2) **Market shaping** - Includes strategic aspects of supply chain management: estimating global market forecasts, negotiating prices with suppliers, encouraging suppliers to enter the market and get pre-qualified, working with manufacturers to cut costs from production process, etc.

3) **Focused Grants** – Includes grants aimed at a) scaling up use of new or underused products, b) preventing stock-outs in countries or c) providing drugs to countries not supported by GF.

4) Rapid response - Includes two main activities aimed at removing major bottlenecks to more rapid provision of drugs: 1) Management of a rotating stockpile for both FLDs and SLDs to ensure short lead-times on orders and 2) Oversight of a revolving fund to provide bridge loans to countries awaiting the release of funds.

5) Country support - Includes direct support for countries to improve their drug management systems for TB such as evaluation or assessment missions, regional or national workshops, real-time support on procurement orders through GDF or in-depth capacity building at the local level.

GDF currently participates in these activities: the question for the upcoming Board meeting is whether to expand, decrease or maintain GDF's level of engagement in these activities. The input from the Board will set the groundwork for a detailed recommendation on options for GDF's future role, including products offered, financial model, organizational structure, etc. .

APPENDIX I: STAKEHOLDERS INTERVIEWED

* indicated interviews that are scheduled but have not yet been conducted

Type of stakeholders	Name
Countries (NTP managers and WHO representatives)	Dr. D'Meza – NTP Haiti
	Erwin Cooreman – WHO Bengladesh
	Fraser Wares – WHO India
	Gabriel Marie Ranjalahy – NTP Madagascar
	Hashim Suleiman Elwagie - NTP Sudan
	Jeremiah Muhwa Chakaya – MoH Kenya
	L.S. Chauhan – MoH India
	Dr. Lyn Vianzon – NTP Philippines
	Dr. Rajendra – Prasad – NTP Papua New Guinea
	Valentin Rusovich – NTP Belarus
	Dr. Djibril Tamboura – NTP Burkina Faso*
	Dr. Hashim Dhafer – NTP Iraq*
	Dr. Lay Ofali – NTP D.R. of Congo
	Dr. Martine Toussaint – NTP Rwanda
	Nadia Wiweko – NTP Indonesia*
	Vianney Rusagura – NTP Somalia*
	Yutichai Kasetjaroen - NTP Thailand
GDF Donors	Christina Foley – CIDA
	Irene Koek – USAID
	Jorge Bermudez – UNITAID
	Susan Bacheller – USAID
Partners / others	Andrey Zagorskiy – MSH
	Bernard Fourie – Mend
	Giorgio Roscigno – FIND
	Grischka Schmitz-Ohl - GTZ
	Hastings Banda - REACH Trust in Malawi
	Mel Spigelman – Global Alliance for TB
	Michael Kimmerling – BMGF
	Mohammed Abdel Aziz – GF
	Myriam Henkens – MSF
	Nils Billo – The Union
	Owen Robinson – CHAI
	Patrizia Carlevaro – Eli Lilly
	Peter Evans –Independent consultant (formerly GDF)
	Peter Gondrie – KNCVTB
	Robert Gie – University of Stellenbosch
	Pedro Suarez – MSH (formerly NTP Peru)
	Poul Muller - UNDP/IAPSO
	Philippe Guinot - GAIN
	Stephen Patras – PFSCM
	Shrikant Kulkarni – Lupin
	Salmaan Keshavjee – Partners in Health

	Thuy Huong Ha – GF
	Kenneth Castro – CDC*
	Wendy Eggen – IDA*
	Vijay Agarwal – Mac Leods*
	Dr. Ridderhof – CDC
Stop TB / WHO / GDF	Anant Vijay – WHO, Stop TB Department
	Ian Smith – WHO, Director-General's Office
	Isis Pluut – WHO audit
	Jacob Kumaresan – WHO Center for Health development
	Karin Weyer – WHO / GLI Laboratory strengthening
	Léopold Blanc – WHO Stop TB department
	Marcos Espinal – Stop TB Partnership
	Mario Raviglione – WHO Stop TB department
	Paul Nunn – WHO / GLC / TB Team
	Robert Matiru – WHO, Director General's Office
	Tom Moore – GDF
	All Geneva-based GDF staff