

## **Future Direction for Global Drug Facility**

### ***Background***

The Global Drug Facility (GDF) was established by the Stop TB Coordinating Board in 2001 to improve access to high quality TB medicines by national TB control programmes for implementing the DOTS treatment strategy. The Board observed that countries with weak procurement practices were unable to procure and supply good quality medicines when TB patients needed them. Treatment regimens were not always standardized by TB programs, and quality of the medicines procured were suspect in many cases.

Since 2001, GDF managed to carry out its mandate by filling the procurement gap of these countries. In the beginning, GDF-supplied drugs were mainly free grants funded by donors such as CIDA, USAID, and the Netherlands. About the same time, the four-drug fixed dose combination (FDC) product was developed and approved by WHO and partners to simplify treatment of susceptible TB. Concurrent with the introduction of the four-drug FDC, GDF promoted the use of blisters versus loose tablets until today many countries are using the FDCs as 2,3 and 4-drug FDCs supplied in blisters to treat TB patients. This has contributed to standardization of TB treatment in many countries and promoted better adherence to treatment regimens by health workers and patients alike.

By 2003 countries began budgeting their own funds or obtained funds from donors but still needed procurement assistance to obtain lower priced drugs of good quality. As a result, GDF began to provide drugs via Direct Procurement (DP) through its procurement agents. To participate in DP, TB programs must apply to GDF and sign an agreement to meet certain conditions, such as TB drugs are free to patients and funds used for TB can not be diverted to treat other health problems because of the money saved through procurement from the GDF.

Later in 2003, GDF added other products to its supply list such as:

- patient kits which contain all the drugs needed to treat one patient
- diagnostic kits which contain supplies for conducting sputum smear tests

In 2007, GDF began procuring drugs for multi-drug resistant TB (MDR-TB) through the Green Light Committee (GLC) Mechanism. To procure good quality drugs at concession prices, a TB program first must be technically approved by the GLC.

Drugs for MDR-TB are mostly procured by DP from the GDF, and ever increasing DP activities are necessitating that donors increase support in the area of human resources to the GDF secretariat.

Along with the procurement activities GDF has always linked drug deliveries with an in-country monitoring mission and technical assistance as needed to promote good drug management practices in the country. This is sometimes supported by the GDF, other times by GDF partners.

To carry out its activities, GDF has had the help of its Technical Review Committee to review country applications for grants and DP orders, and the Business Advisory Committee to guide GDF through some of the internal and external factors that evolved over the years.

However, since 2001, the landscape for TB treatment activities has changed dramatically. For example, requests to GDF for free TB grants by countries are decreasing steadily; the Global Fund became a large donor of TB medicines and treatment support. PEPFAR was launched, the largest activity undertaken by the US government to date for treating HIV; TB patients are recipients of this activity since TB is a major co-morbidity in HIV patients around the world.

TB programs procuring drugs from the GDF do not pay a fee to support the GDF secretariat. These funds come from donors, some of which are becoming fatigued. For example, CIDA has announced its plans to stop funding GDF altogether in 2012. GDF donors have provided the support needed to pay for staff costs and overhead costs so that GDF could function in the capacities mentioned above.

Since 2007, UNITAID has become a large donor, but is primarily interested in funding drugs to change market dynamics rather than funding staff costs and technical assistance to TB programs.

Overall, GDF has had a global impact on reducing drug prices through its pooled procurement mechanism, and has been an international driver of TB drug standardization, unique packaging, good quality standards for drugs, and provider of in-country technical assistance. Technical assistance over the years has been a value-added component of procuring drugs through GDF, supported both by GDF and its drug management partners.

### ***Strategic analysis***

With the changing landscape, GDF needs a strategic analysis of its business model taking into consideration the donors, international stakeholders, TB control needs in country programs and current needs for international access to medicines. The following dynamics should be considered.

- Demand for drugs through the GDF to treat susceptible TB may still increase over the coming years
- Scale up of MDR-TB treatment is beginning in 2010 and could ramp up greatly in subsequent years causing drug procurement needs of TB programs to increase dramatically
- Donor fatigue may affect more organizations currently supporting the GDF, making it increasingly difficult for the GDF secretariat to sustain TB drug DP services for national TB programs
- Countries with larger MDR-TB populations such as China and India may require greater resources than the GDF can currently provide

- The need to strengthen countries' procurement and supply systems will continue (eg. capacity to accurately forecast drug needs and manage inventories)
- Although GDF has managed to promote more sources of quality assured drugs, will the number of sources diminish when suppliers do not win tenders to provide TB drugs (eg. certain financial costs must be born by suppliers to improve manufacturing sites and to register drugs in different countries)
- Ensuring availability of more suppliers of quality active pharmaceutical ingredients (APIs) for TB drugs to avoid disruption in drug supply (some APIs are only available from a single supplier)

During the analysis the following questions should be considered in order to provide the direction GDF will need for the future:

- Should GDF charge a fee for its procurement activities to cover staff costs
- Should GDF continue its technical assistance (TA) to countries through consultant monitoring missions or some other mechanism
- Should GDF continue to organize ad hoc drug management assistance to countries
- Should GDF continue to organize regional TB drug management workshops
- If GDF should continue its TA to countries, how should it be funded
- Should GDF modify its product line (eg. add more diagnostics, x-ray machines, N-95 respirators, other commodities)
- Should GDF continue to procure MDR-TB drugs or focus primarily on drugs and commodities for susceptible TB
- Should GDF continue with its current practices, such as free grants, direct procurement, drug quality assurance program, in-country monitoring missions and technical assistance or modify or discontinue some of the practices
- Will gaps in procurement of good quality TB drugs exist in the coming years requiring the services of an entity like GDF
- What is the role of GDF *vis a vis* the Global Fund, UNITAID, USAID and other major donors in the area of international TB drug supply
- Should GDF be charged with monitoring the use of MDR-TB drugs that are not purchased through GDF procurement agents; if so how would staff be financed, if not who should do that
- How will the Global Fund activities such as the voluntary pooled procurement (VPP) program affect the need for an entity like GDF
- Should GDF continue to promote more global sources of quality-assured TB drugs?

- What barriers (if any) are there for countries to use non-donor government funds to procure through GDF? How should GDF address them?
- Are other procurement mechanisms such as UNICEF, UNOPS, WHO, PEPFAR/SCMS a better model for GDF?

### **Methodology**

The situation analysis will be carried out by two or more consultants between February and March 2010 with draft report ready by 15 April 2010. At least one consultant must be familiar with GDF activities and national use of TB drugs. The other consultant will be familiar with the donor environment and other supply models.

In collaboration with the GDF, consultants will develop a guide and interview persons at GDF, GLC, donor agencies, stakeholder agencies, national TB control programs and other pooled procurement mechanisms and those TB programs which chose not to use the GDF. Country TB programs included in the analysis will be randomly grouped according to the different GDF services received and relative size of the TB populations. Persons to be interviewed will be selected in collaboration with the GDF. Interviews will be done using modern technology such as telephone, VOIP and emails, as much as possible.

Consultants will review existing documents either developed by/for the GDF or other international organizations involved in TB treatment and TB control (eg. *GDF Financing the Direct Procurement Service*, Timothy Ryan, 1-9-2009).

The deliverables for this Terms of Reference are a single document with a listing of findings and recommendations in the form of several options describing how the future GDF should function.