



## **Global Drug Facility: 6 months of implementing a new strategic framework for 2013-2016**

***Progress Update November 2012 – July 2013***

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The Global Drug Facility (GDF) is more than a procurement mechanism: it provides a unique package of services, including the procurement of high-quality tuberculosis (TB) drugs and diagnostics at affordable and sustainable cost, technical assistance to countries on drug management and monitoring of drug use. It actively shapes the market for TB drugs, linking drug demand with supply and monitoring activities, outsourcing services to partners on a competitive basis and using innovative product packaging to simplify drug management. GDF began supplying first-line drugs (FLDs) in 2001, and in 2008 added the supply of second-line drugs (SLDs), paediatric TB medicines and diagnostics. It is now a major source for GeneXpert.

Key milestones were achieved by the Stop TB Partnership's Global Drug Facility since the last Coordinating Board Meeting of November 2012. These achievements are presented here along with the strategic direction for 2013-2016, in the areas of services and products, the new operating model, product quality assurance, partners linking, new TB tools, Capacity building, market shaping, evidence from countries and market research and forecasting.

### **Services and Products:**

GDF continued its activities in the procurement and supply of first and second-line drugs and commodities (including traditional and new laboratory supply), with a total value of goods procured representing over US\$ 151 million in 2012 - and more than US\$ 89 million since the beginning of 2013.

After running competitive bidding processes, GDF signed new agreements early 2013:

- with IDA as the first- and second-line drugs procurement agent
- with GIZ as the procurement agent for diagnostics

Additional long-term agreements were then signed with suppliers, including with Cepheid for GeneXpert.

GDF continues to support projects including TB REACH, TB-Expert, ExpandTB as a procurement platform for all diagnostics items.

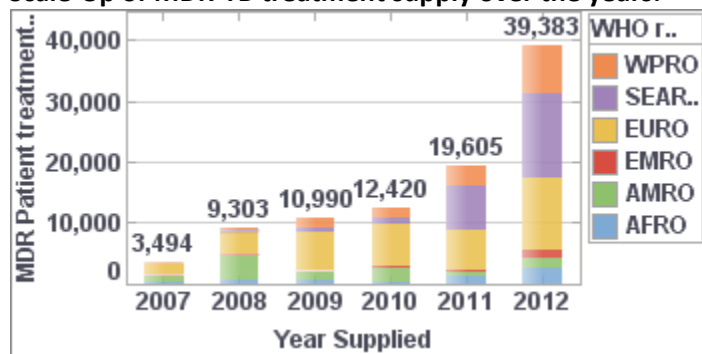
GDF's ISO 9001:2008 status was maintained after a new audit in February 2013. Decreasing overall treatment costs and improving delivery lead-times remain high on GDF's operations agenda: quality management reviews were conducted with all suppliers and procurement agents in July 2013 at a GDF stakeholders meeting.

GDF developed a concept note on the potential implementation of a strategic stockpile and a flexible procurement fund. GDF is currently engaging in further discussions with the Global Fund, UNITAID and partners on the benefits of these interventions, a dedicated expert consultancy is currently being selected to assist GDF and partners in conducting analysis and defining possible options and the most appropriate operational model.

Key performance measures include:

- ✓ In 2012, 39,383 treatments for MDR-TB and 1,067,087 treatments for susceptible TB were received by countries (including 162,000 first line paediatric treatments). Since 2001, a cumulative total of 21,880,991 patient treatments have been supplied. MDR-TB treatment supply doubled in 2012 compared to 2011, costs of MDR-TB treatments decreased by up to 27% in 2013 compared to 2012.

**Scale-Up of MDR-TB treatment supply over the years:**



- ✓ The GDF Technical Review Committee (TRC) convened in May 2013 to assess, in particular, emergency grant requests.
- ✓ GDF added four new suppliers for the supply of multidrug-resistant TB (MDR-TB) and extensively-resistant TB (XDR-TB) drugs: Reig Jofre (producer of Amoxiciline Clavunate), Pharmatex/Fisiopharma (producers of Amikacine), Dong-A (producer of Cycloserine) and Labatec (producer of Imipenem - Cilastatine). GDF will also continue procuring second-line drugs from Macleods, Vianex, Olainfarm, Jacobus and other supply partners.
- ✓ On the first-line front, progress was also achieved. Competitive outsourcing brought more suppliers on board, with longer shelf-lives for medicines and commitments for better delivery lead-times, and some price reduction for paediatric drugs.

- ✓ Lead times are monitored and are continuing to improve despite a reduced staff capacity and an increased number of orders.
- ✓ GDF clients' satisfaction surveys conducted on each order delivered are showing an increasing trend in grading GDF services as highly satisfactory. Moreover, GDF demonstrated a high level of responsiveness and commitment in several urgent situations: Bangladesh and Pakistan for SLDs access, or again Jordan for an urgent supply of FLDs to address its challenges with Syrian refugees camps

## **New operating model**

GDF's new operating model has been shaped based on market research data and countries feedback. The new model aims at zero tolerance for TB drugs stock-outs / overstock risks and is promoting a set of more pro-active actions to better support countries:

- ✓ GDF recruited and trained 2 additional Regional Support Officers (RSOs) – making a total of 4 for the African, South-East Asian, European and Eastern Mediterranean WHO regions - to serve as a catalyst and provide support at the country level on i) the dissemination of new tools for improved quantification and more accurate forecasting, ii) stringent and pro-active inventory tracking models for improved planning processes, and iii) supply chain systems capacity building. The RSOs are key in streamlining partner's efforts towards the establishment of an early warning system for stock-out risk situations.
- ✓ GDF started to merge FLDs/SLDs/Diagnostics procurement operations lines at Geneva headquarters. The Country Support Officers (CSOs) will therefore integrate the full scope of in-country supply chain issues for each of their assigned portfolio of countries.
- ✓ GDF is changing its templates for monitoring missions and switching to electronic templates for data submission. In addition, investments have been made into a new order management system with enhanced capacity and a more vertical integration with GDF procurement agents for improved data management
- ✓ The reshaping of GDF Operations is based on evidence and an assessment of the limitations of the current model and lessons learned. Terms of reference for all new organigram positions have been developed. GDF is expecting to get the green light for staffing its vacant positions within the best possible timeline.
- ✓ Looking at its sustainability, GDF has implemented a new fee for Direct Procurement (DP) services since 2013 and already collected around US\$ 155,000 from paid orders, with a total expected fee to be received for 2013's first semester reaching US\$ 533,000 (orders in process).

- ✓ A new communication strategy is being implemented:
  - open forums with partners : e.g. communication and interaction with civil society and NGOs was reinforced through meetings participation where GDF promoted a new guide on how to work with GDF for civil society, highlighting the current constraints and vulnerabilities of existing supply chain systems and identifying synergetic actions to overcome current challenges.
  - direct participation to regional Green Light Committees (GLCs) (in the Western Pacific and American WHO regions)
  - new website with refreshed lay-out and content – Go live pending some remaining content development and a final review.

## **Product Quality Assurance**

- ✓ To broaden its suppliers basis of quality-assured products, GDF a launched a joint Expression of Interest for quality-assured TB products in partnership with the Global Fund in January 2013, and a second one is being finalized for July 2013.
- ✓ GDF is contributing to the development of a new Quality Assurance policy for Diagnostics and Laboratory supplies with the Global Fund.
- ✓ In June 2013, GDF conducted a supplier meeting in Columbo, Sri Lanka, for FLD & SLD with the presence of all stakeholders, including all suppliers, donors and partners, with dedicated sessions on Quality Assurance policy. An update on TB landscape and GDF new operating model were presented and discussed with all suppliers who considered GDF and the Global Fund's potential initiative of implementing a strategic stockpile and a flexible procurement funds as of high impact for improved TB drugs access. GDF also announced its intention to add more points in its next tendering process to award FLD suppliers with extended product shelf-life (3 years) and compliance with climatic zone 4 requirements.
- ✓ As a result, GDF holds currently: 2 framework agreements with procurements agents (IDA and GIZ) with another one being in negotiation with UNOPS. About 23 long term agreements are signed for GDF with suppliers. Procurement service agreements were developed to allow for World Bank procurement with GDF and an additional MoU was created for the procurement of GeneXpert.

## **Partners Linking**

- ✓ GDF engaged with partners, including KNCV, MSH, IRD, PIH, Abt Associates, CHAI and the Lilly MDRTB Partnership, on collaborative activities to streamline best practices on e&mHealth in the public and private sectors to improve global medicines demand.

- ✓ GDF is also engaging with the Global TB Alliance as part of their UNITAID-funded project on preparing a strategic plan and activities to support the future uptake of new paediatric formulations by countries. GDF's expertise in drug management and innovative packaging is an asset to build on for assisting countries in the upcoming challenges.
- ✓ Together with the Union (IUATLD), plans are underway for the establishment of a dedicated stockpile to support the introduction of the 9 months MDR TB regimen approved by WHO in 9 Francophone African countries.
- ✓ GDF reactivated its relationships with the Kuwait Helping Fund and is discussing potential new projects to be developed globally and in Eastern Mediterranean region.
- ✓ GDF is working with other USAID-funded health programs like PQM (Promoting Quality Medicines) on identifying and addressing key supply chain vulnerabilities, and developing new pro-active models for ensuring broader access to quality assured Active Pharmaceutical Ingredients (APIs) for critical SLDs.

## **New TB drugs and Tools**

- ✓ GDF also engaged in discussions with Janssen & Janssen and the WHO Global TB Programme Department, the Gates Foundation and partners for developing strategies to ensure rational models for the introduction of new drugs such as Bedaquiline, recently approved by the US FDA.
- ✓ GDF started to discuss with Otsuka on potential synergies and strategies for a rational introduction framework for Delamanide.
- ✓ GDF engaged with several new suppliers for new Group 5 products inclusion (Linezolid, Clofazimine, Imipenem were made available through GDF products catalogue), GDF continues its efforts to identify additional producer for Clofazimine.
- ✓ New drug management tools like QuanTB and innovative approaches are being promoted to assist countries towards more accurate planning processes, improved forecasts and supply chain capacity building.

## **Capacity Building**

- ✓ 55 technical assistance missions were conducted to supported countries in 2012, and more than 20 in the first 2013 semester, which all received the usual high level

of appreciation from National TB Programmes. Most were organized in conjunction with other TB technical reviews.

- ✓ GDF facilitated sessions :
  - on benefitting from GDF services at the USAID/SIAPS “Applied health TB supply chain management” workshop organized in May 2013 in Swaziland and attended by National TB programme staff from selected African countries.
  - at the second Africa TB Regional Conference on Management of TB Medicines organized by MSH in Zanzibar, Tanzania in December 2012.
  - on SLDs drug management during a MDR-TB consultants capacity building workshop in the Americas, organized in partnership with PAHO and the Regional GLC AMRO.
  
- ✓ A training was organized in Headquarters in Geneva for Regional support officers and other technical partners on GDF new directions and new policies, with a focus on new tools dissemination and models to address main challenges in procurement and supply management at global and country level.

## **Market Shaping**

- ✓ Through a new invitation to bid, GDF achieved SLDs treatment price reductions of up to 27% between 2012 and 2013. The number of products and suppliers base also extended: the number of quality assured SLDs suppliers is now twice as big compared to 2009, and the number of SLDs products available for supply is three times higher than the 2009 portfolio.
  
- ✓ As a result of negotiations with bidders, GDF will now be able to provide Cycloserine for up to 37% less. This price decrease represents important progress, because Cycloserine is one of four medicines (along with Capreomycine, Kanamycine and PAS sodium and acid formulations known as PAS products) that together represent 80% of the product cost in second-line regimens.
  
- ✓ GDF continues to strengthen its relationships with current and potential suppliers on the market. The last GDF stakeholder’s meeting was convened in June 2013 with the presence of all suppliers, donors and key partners. A regular assessment of supplier’s capacity is conducted, TB global trends for drugs demand are communicated to suppliers, and the new GDF operational strategy was well received by suppliers and donors.

## **Evidence from Countries**

- ✓ GDF commissioned independent studies to gather evidences from countries. One in particular is focusing on the root causes analysis of the stock-outs observed in countries, providing insightful evidences on how financing models and planning issues are the main causes of shortages of TB drugs in countries, especially during the period countries transitioned from GDF grant support to direct procurement.
- ✓ The strategy for implementing a Stock-outs Early-warning System with partners has been developed. It aims to:
  - Provide assistance with innovative tools for improved forecast on future needs
  - identify potential risks of stock-outs at country level;
  - alert stakeholders at risk to take pro-active action and timely measures;
  - promote the use of information systems for drug management and disseminate best practices

## **Market Research & Forecasting**

- ✓ GDF is engaging with partners in new collaborative studies, such as:
  - Paediatric TB Market Analysis, with the Global TB Alliance and UNITAID;
  - SLDs Market Analysis with CHAI (funded by Bill and Melinda Gates Foundation);
  - Overview of paediatric forms uptake, with the Swiss Tropical and Public Health Institute (USAID funding).