

ACTIVITY REPORT 2012-2013



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ABBREVIATIONS

API Active Pharmaceutical Ingredient
CoA Certificate of Analysis
DFATD Department of Foreign Affairs, Trade and Development Canada
(formerly, Canadian International Development Agency, CIDA)
DFID United Kingdom Department for International Development
DIK Drugs in kind
DOTS Directly Observed Treatment Short Course
E ethambutol
EoIs Expressions of Interest
ERP Expert Review Panel
EWS Early Warning Stock-out System
FLD First-line drug
FTE Full-time equivalent
GDF Global Drug Facility
GIZ Deutsche Gesellschaft für Internationale Zusammenarbeit
GLI Global Laboratory Initiative
GLC Green Light Committee
H isoniazid
IDA International Dispensary Association
KNCV KNCV Tuberculosis Foundation
KPI Key performance indicator
PHFS Kuwait Patients Helping Fund Society
LED Light emitting diode
LOA Letter of Agreement
MDR-TB Multidrug-resistant TB
MSF Médecins Sans Frontières
MSH Management Sciences for Health
NFM New funding model
NOL No objection letter
NTP National tuberculosis control programme
PQP Prequalification programme
PQM Promoting the Quality of Medicines
QA Quality assurance
QC Quality control
QCA Quality Control Agent
R rifampicin
RSM Rapid Supply Mechanism
SIAPS Systems for Improved Access to Pharmaceuticals and Services
SLD Second-line drug
SRA Stringent Regulatory Authority
SRS Strategic Rotating Stockpile
TRC Technical Review Committee
USP United States Pharmacopeia
USAID United States Agency for International Development
WHO World Health Organization
Z pyrazinamide

The Stop TB Partnership Global Drug Facility (GDF), established in 2001 with support of United States Agency for International Development (USAID) and Department of Foreign Affairs, Trade and Development Canada (DFATD), is a one stop, bundled procurement mechanism for quality assured TB commodities through providing grants and direct procurement services to countries in need. Specific projects have been supported by UNITAID and Kuwait Patients Helping Fund Society (PHFS).

GDF strategic goals are to:

1. Save lives by ensuring an uninterrupted supply of quality-assured, affordable anti-TB drugs and diagnostics to population in need

2. Strengthen national drug supply management systems and sustainable procurement capacity by providing tailored technical assistance, innovative tools to countries/organizations in need and enhance partners' engagement for technical and financial support

3. Contribute to TB commodities market shaping by linking strategic interventions on the demand and supply sides with stakeholders/partners, focusing on market analysis, supply security, suppliers engagement, affordable and sustainable prices, innovation and new products introduction/uptake by countries

4. Maximize impact and value for money by enhancing efficiency/effectiveness of operations focusing on quality of services and clients/partners feedback

GDF key contributions since its inception include:

1. Country support GDF supported 133 countries since its inception thereby increasing access to quality-assured TB treatments. GDF also provided technical assistance and conducted trainings and monitoring missions in countries to ensure sustainability of national TB programmes.

2. Supplying life-saving treatments GDF provided total 23.7 million patient treatments including –

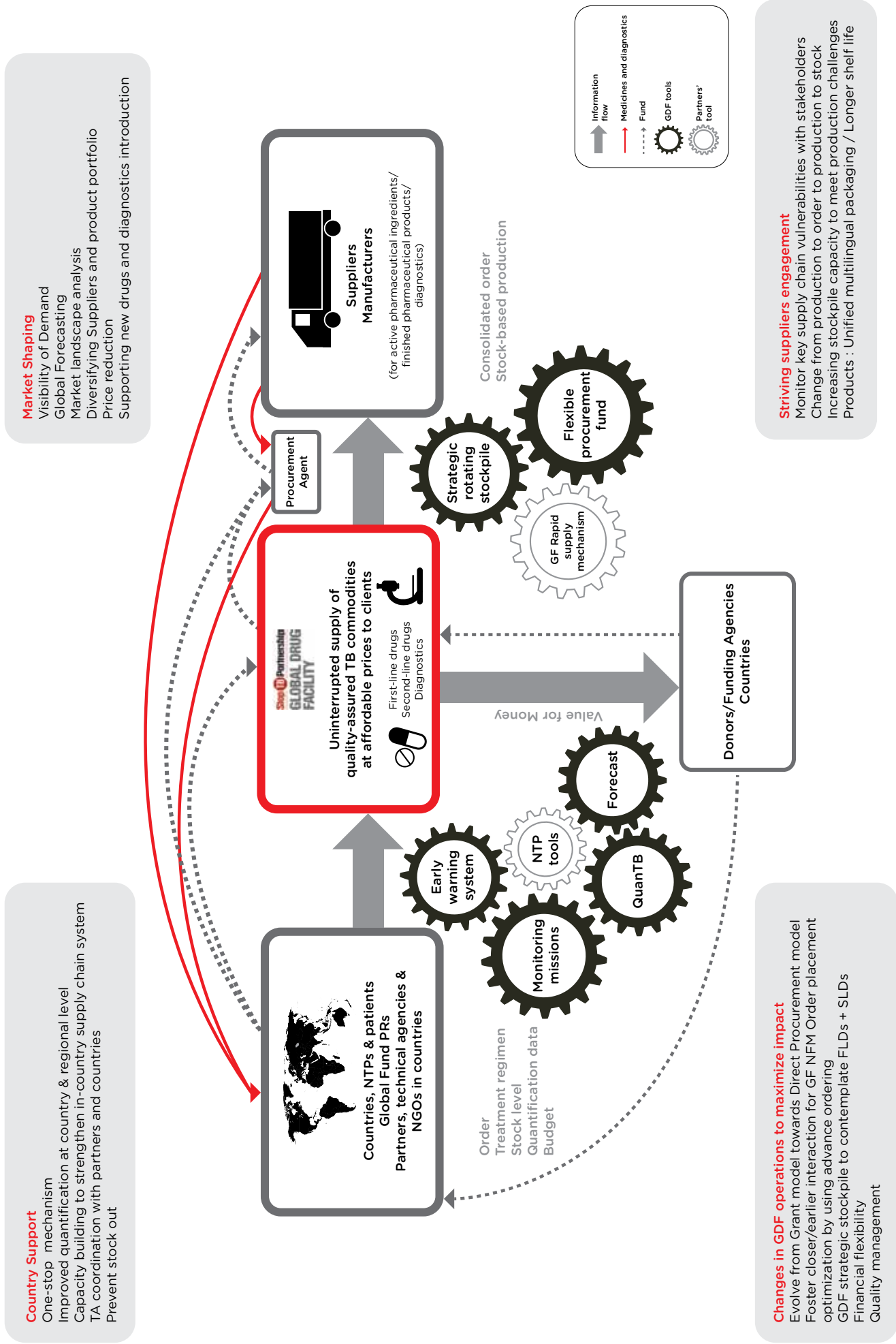
- First-line drugs (FLDs) for 22.5 million adult patients
- FLDs for 1.1 million paediatric patients
- Second-line drugs (SLDs) for 117,486 drug resistant TB patients

3. Active case-finding GDF delivered diagnostics worth of US \$ 68 million and served as a key platform for introduction of GeneXpert and new diagnostics through TB REACH, EXPANDx-TB and TB Xpert Project.

4. Market shaping GDF reduced the price of some major SLDs up to 30%, consolidated orders by using Strategic Rotating Stockpile, and increased number of eligible suppliers for TB products, contributing to a healthier market with improved security supply of TB commodities.



Figure 1 GDF model



MESSAGE FROM THE GDF MANAGER



2012 & 2013 has been a truly exciting biennium for the Stop TB Partnership Global Drug Facility with some key milestones reached and also an important process of organizational changes within an evolving TB landscape.

Therefore my first words are to express my gratitude to all GDF staff and former GDF managers who have been able to bring GDF to where it stands today and to fulfill the GDF mandate as a critical life-saving mechanism for anti-TB medicines and diagnostics delivery to populations in need, sometimes in very challenging conditions. This biennium is characterized by several global crises, natural disasters, emergencies and disease outbreaks, political instability and conflicts in several parts of the world which turned GDF activities more complex, requiring permanent adjustments or additional efforts to deliver our mandate.

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With the indefectible support of our donors and partners, we have been able to reach the critical cap of more than a billion USD of strategic commodities procured since GDF's inception in 2001 and to contribute to saving more than 24 million lives by the end of 2013. The Stop TB Partnership Board and GDF Strategic Advisory Committee have been strongly supporting GDF's new strategic roadmap and operational model developed in 2012 which served as a catalyst and framework to implement crucial managerial and operational changes.

GDF's mandate has evolved from that of a grant model towards a direct procurement platform over the years and critical new components have been introduced in its new strategic roadmap to maximize its impact and turn GDF's mechanism easier to access from a client / country perspective:

More financial flexibility Our clients benefit today from a flexible procurement fund that dispenses countries willing to use GDF mechanisms from a mandatory pre-payment, turning the GDF framework into a more accessible model for the use of domestic funding, positioning GDF as a transitioning mechanism to support countries "graduating" from donors' support and willingness to continue to procure medicines and diagnostics in line with GDF international quality assurance standards.

New tools With our partners and technical agencies, we harmonized our tools available to countries and technical assistance approaches to further address remaining in-country supply chain challenges like forecasting and adequate planning

New stockpile policies GDF's strategic rotating stockpile for SLDs have been doubled with the support of UNITAID to reflect the on-going needs and challenges of countries scaling-up their MDR-TB response

New systems GDF is investing in new IT platforms and further engaging in global forecasting and developing an early warning stock-out system to better link strategic interventions on demand and supply sides

New approaches to further prevent stock-outs in countries GDF has conducted independent analysis of root causes for recurrent situations of overstocking and stock-outs to adjust its operational model. GDF engaged with strategic partners like the Global Fund to build new appropriate responses needed such as strategic data sharing, the Rapid Supply Mechanism of TB commodities and aligning financial processes with supply chain operations for better impact and enhanced efficiency.

More market shaping with increased supply security of key products and a significant price decrease for SLDs Between 2011 and the end of 2013, GDF has more than doubled the number of eligible suppliers and finished products and reached up to 30% of price decrease, leveraging access to MDR-TB treatment for which medicines are not anymore today the main limiting factor but rather the treatment capacity needs to generate more volume on this still fragile market.

Supporting new drugs and diagnostics introduction GDF is now including new TB drugs and diagnostics in its catalogue to facilitate their early uptake by countries and is working on access strategies for the upcoming new pediatric formulations with partners.

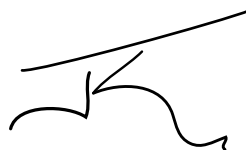
Although these are encouraging steps, there is still lots to do and we still have many challenges ahead: only more coordination and collaborative efforts with partners can help tackle critical supply chain vulnerabilities to align TB commodities supply with demand, drug management limitations in countries, including current regulatory issues, and country dependency on donors along with sustainable health systems strengthening strategies.

The journey will still be long towards TB elimination, but this battle can only be successful if we all join our efforts in a collaborative manner.

I thank you all for your partnership: donors and funding mechanisms, technical partners, NGOs, Technical Review Committee members, Health Authorities, National TB Programs, suppliers, patients, health professionals on the field and civil society representatives for all your collaboration and the trust you deposited in GDF. At the time of publishing this report, our Strategic Advisory Committee is working with us in light of the post-2015 TB strategy and on-going reforms within key GDF interfaces to reflect on these evolving

environments and to develop new strategies for maximizing our impact to ensure that our ultimate goal will be attained - that our patients will continue to have access to GDF quality-assured medicines, diagnostics and treatment support they need.

Kind regards,



Dr Joel Keravec
GDF Manager

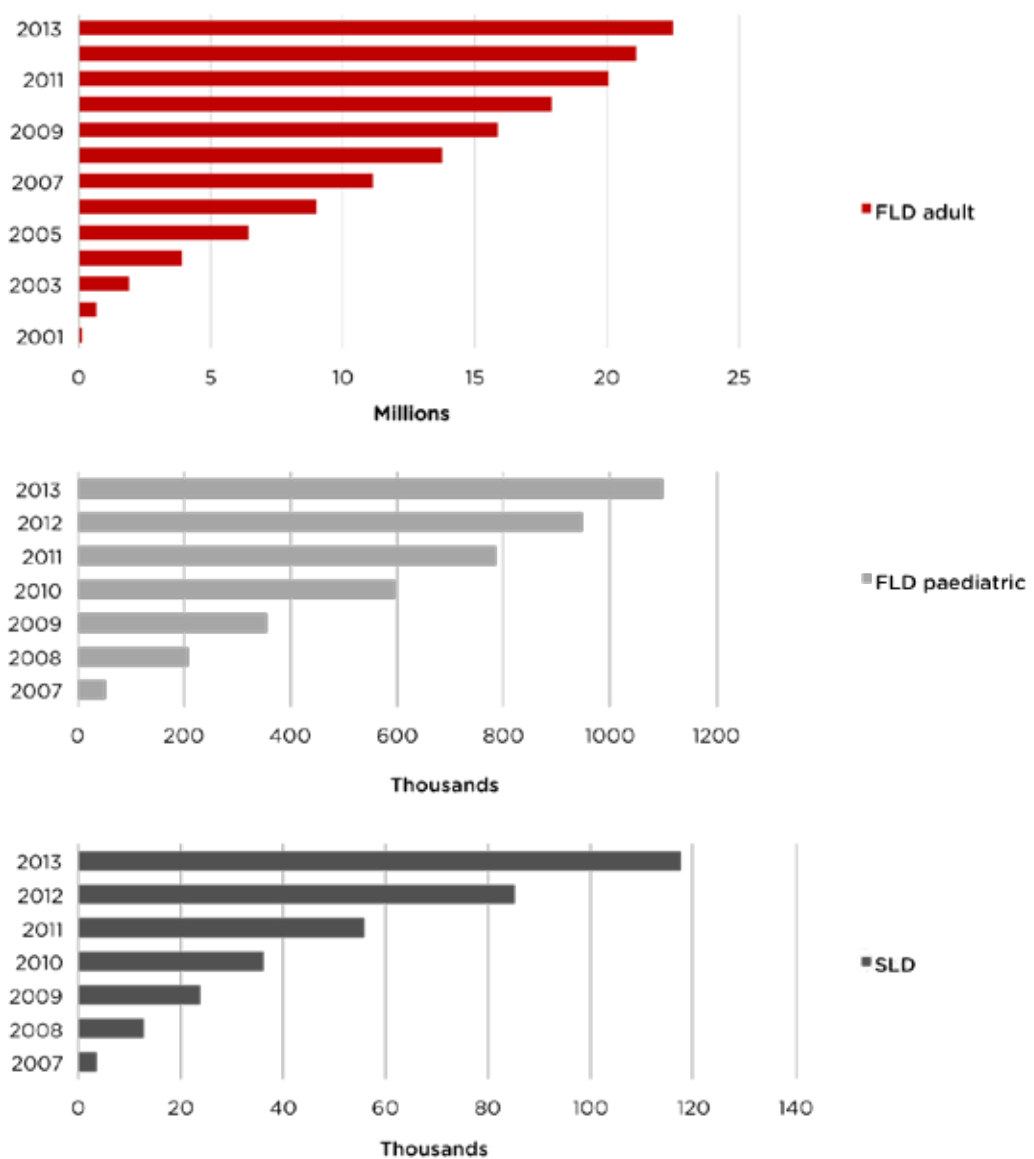


SAVING LIVES BY EXPANDING ACCESS TO QUALITY ASSURED DIAGNOSTICS AND TB TREATMENTS

Since GDF was established in 2001, 22.5 million adult FLD patient treatments, 1.1 million paediatric treatments and 117,485 SLD patient treatments have been delivered (figure 2), reaching the target of 25 million treatments supplied before 2015.

In 2012, 20% of notified patients with susceptible TB, a third of notified patients with drug resistant TB and more than half of TB notification for children (aged <15 years) were treated with quality-assured FLDs and SLDs provided by GDF (figure 3).¹

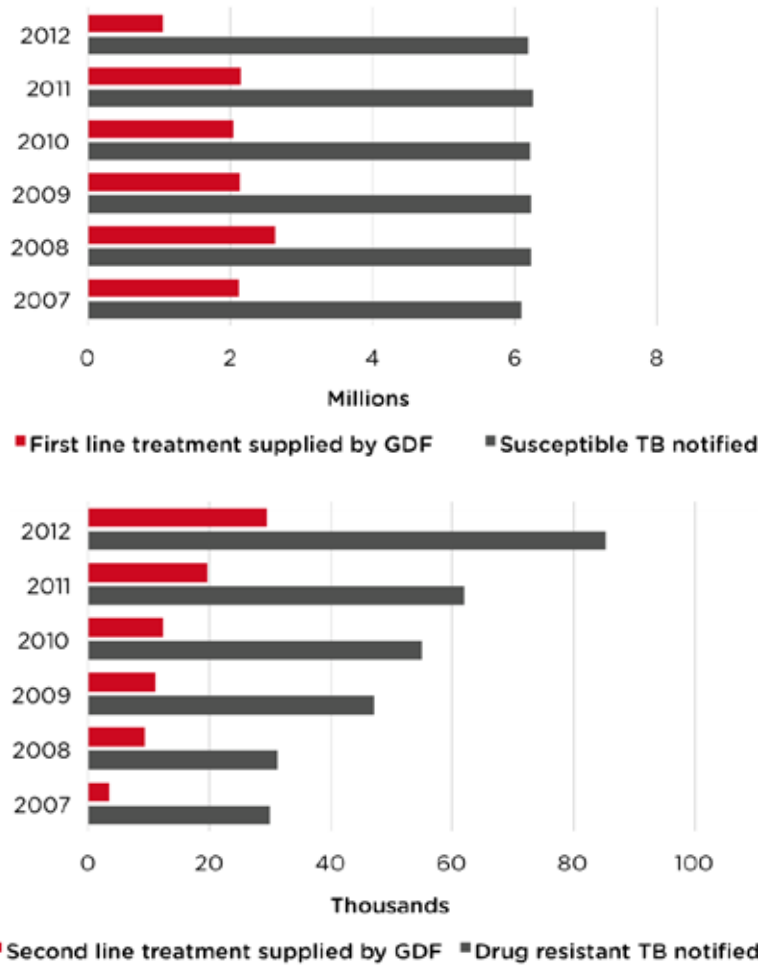
Figure 2 Patient treatments delivered



Note: The number of treatment delivered is based on the GDF's dynamic Order Monitoring System, which reflects the most recent changes in delivery date and cancellation of orders. This provides a snapshot of up-to-date situation.

¹ Global TB notifications for susceptible TB, MDR-TB and children (aged <15 years) is available at Global Tuberculosis Report 2013.

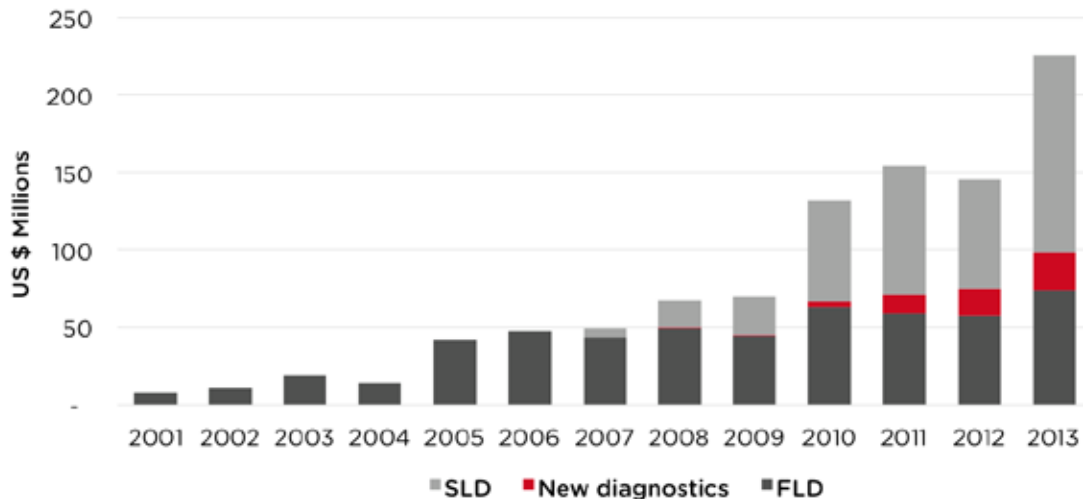
Figure 3 GDF market share



Note: TB notification for susceptible TB and drug resistant TB is from Global Tuberculosis Report 2013.

In total, GDF has processed orders for TB products with a value of approximately US \$1 billion. The total value of orders placed in 2013 increased by 56% compared with 2012 from US \$145.5 million to 226.4 million. The value of SLDs ordered in 2013 reached US \$128 million, with an increase of 83% from 2012 (figure 4).

Figure 4 Value of TB commodities procured



Note: The procurement value represents GDF order placed value in US \$ million all fee inclusive, such as commission, quality control, insurance, transportation as of December 2013.

Direct procurement service increased by 59% in 2013 (value of US \$185.2 million) compared to 2012, which accounts for 82% of total GDF procurement value of orders placed (figure 5).

Figure 5 GDF procurement services

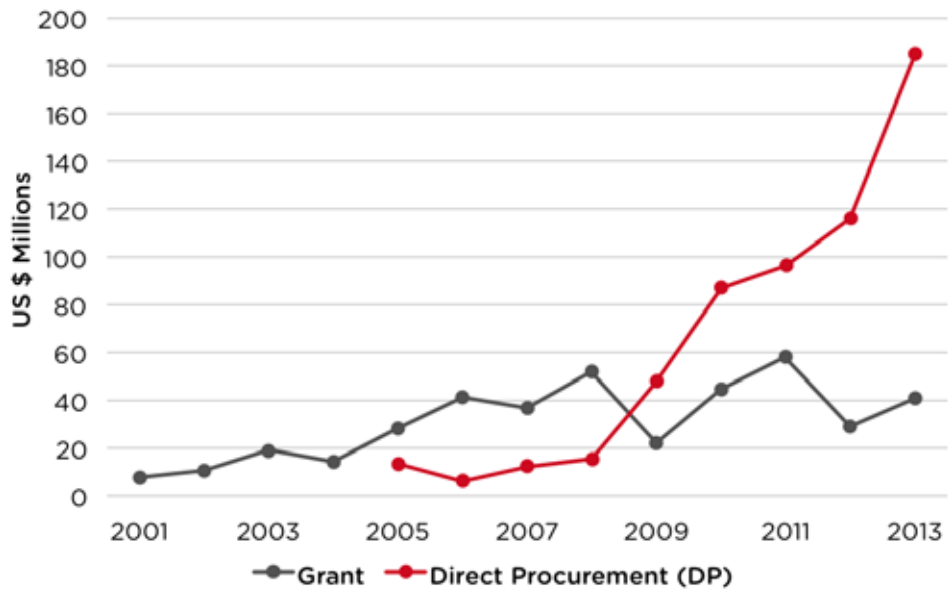
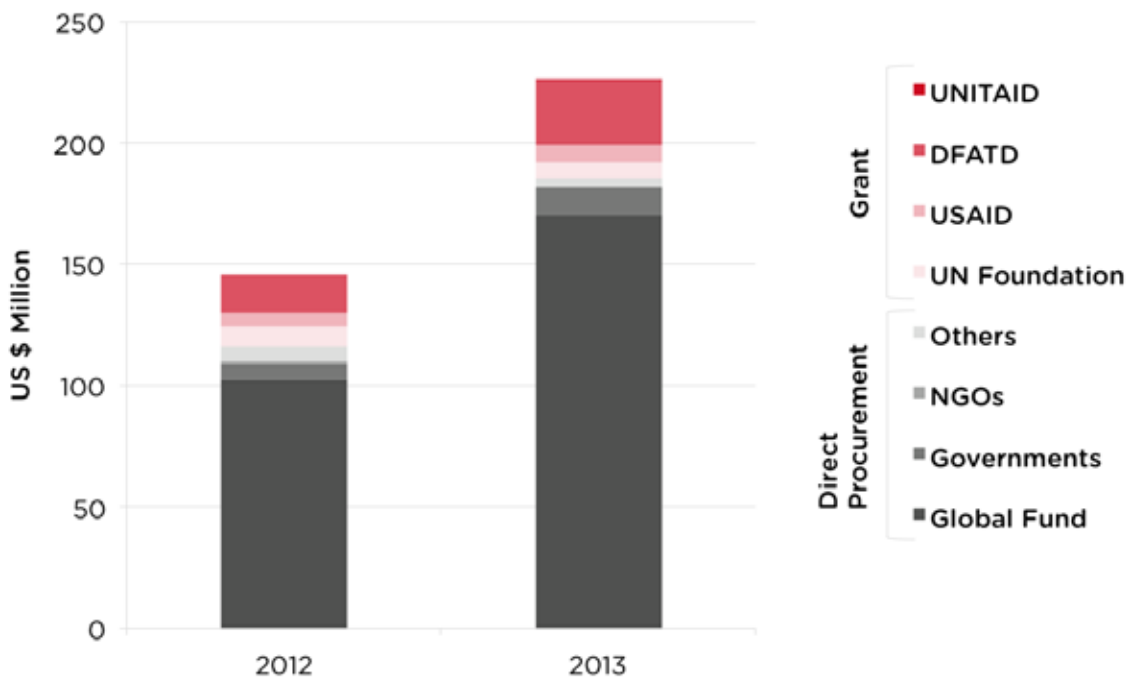


Figure 6 Value of TB commodities procured by funding sources



Note: Other sources for direct procurement include institutions for TB REACH

ACTIVE MARKET SHAPING FOR TB PRODUCTS

GDF ensures access to quality-assured TB commodities at affordable price by actively shaping the market (Box 1).

The mean cost of susceptible TB patient treatments supplied by GDF has been slightly increasing since 2010, when GDF's market share for FLD started to decrease (see Annex V for the price of GDF products). Meanwhile, the mean cost of MDR-TB patient treatments continued to decrease with an increase in GDF market share for SLD (figure 7).

Box 1 Strategies for GDF market shaping

- Competitive tendering process
- Consolidating orders by using Strategic Rotating Stockpile (SRS)
- Proactive supplier engagement

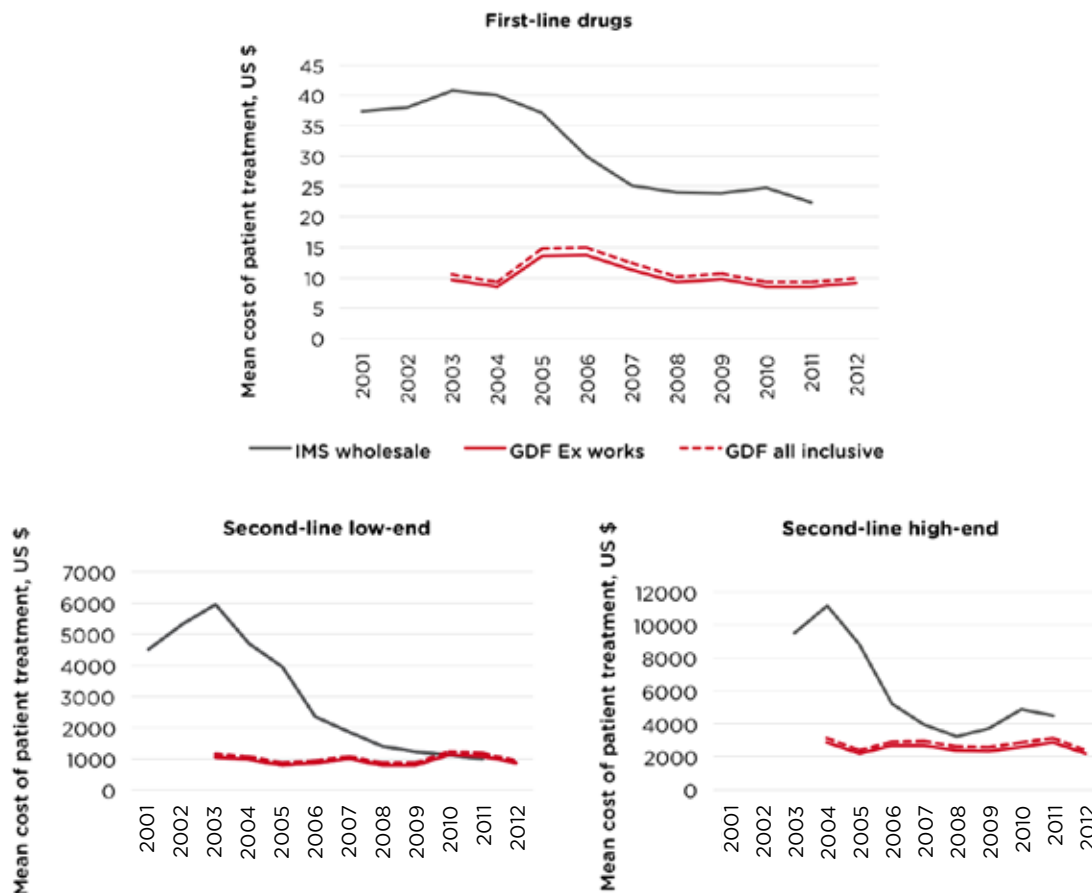
In 2013, GDF reduced the price of several key SLDs it supplies for the treatment of multidrug resistant TB (MDR-TB) by up to 27% compared to 2011 prices, resulting in a substantial decrease in the overall cost of treatment (figure 8).

The price reduction followed a competitive tendering process among prequalified anti-TB drug manufacturers and ongoing efforts to consolidate orders and diversify the supplier pool for quality-assured MDR-TB drugs. A capacity assessment performed by GDF in 2012 indicates that, with the increased number of manufacturers now able to supply quality-assured second-line

drugs, production capacity could be rapidly expanded to meet increased demand. All these efforts led to no supply disruption for SLDs in 2013: The most critical barrier to scale-up MDR-TB activities remains the treatment capacity at country level, NTPs having requested to GDF at several occasions postponement of placed orders for SLDs since targets of patients enrolment could not be achieved within planned timeframes.

In some settings, the roll-out of new diagnostics like GenExpert led to additional needs on SLDs with an unexpected number of MDR-TB being diagnosed: GDF has been working with donors like UNITAID to support countries and ensure access to SLDs for these additional cohorts of patients diagnosed (Box 2). Due to the savings achieved while successfully running the UNITAID-funded MDR-TB Scale Up project, in 2013 GDF was able to support the treatment of an additional 1081 MDR-TB patients and 17,054 patients in total. Myanmar was able to receive additional medicines delivery to treat 673 patients, while Kyrgyzstan received 218, Kenya 166 and Guinea an additional 24 patient treatments for MDR-TB patients.

Figure 7 GDF treatment cost²



Note: Cost of patient treatment in US \$ was corrected by inflation.

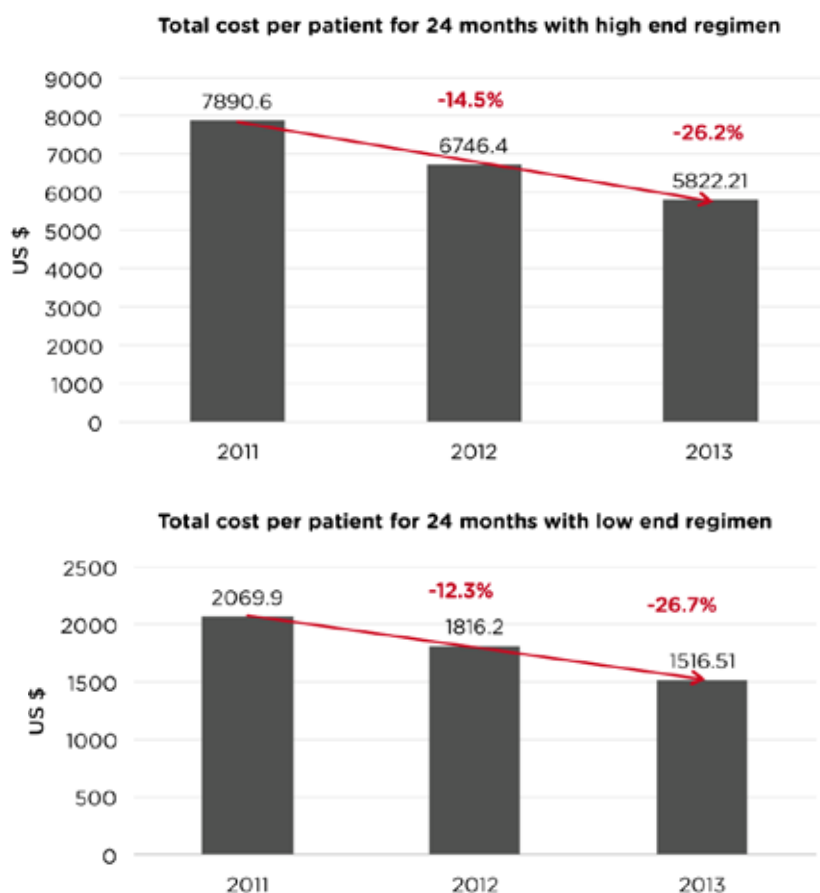
² N. Arinaminpathy, T. Cordier-Lassalle, K. Lunte, C. Dye & P. Stephens. The Global Drug Facility as an intervention in the market for tuberculosis drugs. 2014. Final draft.

Box 2 UNITAID-supported MDR-TB project highlight

Strategic Rotating Stockpile (SRS) In November 2008, UNITAID signed a Letter of Agreement (LOA) with the Stop TB Partnership/GDF. They committed US\$ 11,458,000 for SLD stockpile containing up to 5,800 patient treatments. In December 2013, UNITAID's Executive Board approved a Cost Extension to the SRS Project in order to a) allow for transition to other source(s) of funding and b) increase the stockpile size. The UNITAID Board approved the additional commitment of up to US\$ 14,890,675 for a maximum 18 months until June 2015. In 2014, increased SRS will be established containing medicines for up to 12500 DR-TB patient treatments, to meet the increased demand and continue to reduce the lead time. Additional medicines are included with USAID support. SRS is the key instrument to smooth the delivery and shape the SLD market. It is envisioned that SRS will be a key component to serve Rapid Supply Mechanism (RSM) development in partnership with the Global Fund to avoid stock-out in Global Fund-supported countries.

MDR-TB Scale-Up Initiative Recognizing MDR-TB as a priority funding niche, in 2007 UNITAID agreed to provide financial assistance to meet the cost of the MDR TB Scale-Up Initiative for selected 17 low- and low middle-income countries. The UNITAID funding was initially intended to cover an estimated 4,716 treatments for MDR TB Scale Up by the end of 2011. The implementation of the project was extended until the end of 2013, using the unspent funds due to the savings achieved by GDF under this project. In total, GDF delivered 17,054 patient treatments to 19 countries by the end of this Project.

Figure 8 SLD cost reduction³



Note: High and low end regimen used in this analysis are sample regimens. High end regimen: 12 Cm Pto Cs Mfx PAS/ 12 Pto Cs Mfx PAS, Low end regimen: 8 Am Eto Cs Lfx/ 16 Eto Cs Lfx.

³ Data is from GDF Invitation to bid 2012/2013.

Box 3 Quality Management

The Global Drug Facility was ISO 9001 certified in Dec. 2005. ISO 9001 international standards set the requirements of organizations' quality management system (QMS) as the expression of its commitment toward continuous improvement and as a structured approach for organizations to ensure that they manage their activities and processes in a systematic way in order to meet the objectives they have set.

Core to ISO 9001 Quality Management System are the instruments for maximizing customer satisfaction and feedback, for achieving continual improvement, as well as other objectives that are core to GDF activities, such as regulatory compliance, quality of products supplied, capacity building, etc.

ISO requirements address organizational aspects such as management responsibilities and commitment, resources availability and planning, operations for products and services realization, training and development activities, as well as monitoring and measuring of performance. It also establishes the premises for a risk management framework.

Systemic customer feedback to all clients that order through GDF enables to identify improvements areas in 20 key GDF Activities. An electronic survey is sent to all GDF clients each time an order is being delivered. Current GDF customer satisfaction ranks at 95% (median since 2008 is 92%). Systemic complaint Management: All GDF partners, staff, suppliers and clients can at any moment send a complaint to GDF Quality manager through GDF website.

Specific business intelligence instruments support business analytics and research. GDF develops further its quality management activities by implementing new systems to cover all GDF core activities and to provide transparent and fact based frameworks for processes and operations performance assessment as well as improvement analysis.

Annual suppliers meetings and other management reviews such as regular Stop TB Partnerships Board Meetings, GDF Strategic Advisory Committee, internal and external audits support continuous improvement activities and implementation of corrective and preventive action in GDF Quality Management system.

To address the limited number of quality-assured TB products in past years, GDF has made significant progress to increase the pool of eligible suppliers. By the end of 2013, the total number of eligible suppliers increased to 29 from 12 in 2011 (Annex V).



ADDRESSING STOCK-OUTS IN COUNTRIES

GDF has continued to provide assistance in preventing and managing stock-outs in countries through various mechanisms and tools.

According to an independent analysis of the root causes of stock outs of anti-TB drugs experienced from 2007 to 2013,⁴ countries transitioning to donor support often procured FLDs from different sources without having adequate national capacity in supply chain management (figure 9). Analysis shows that in-country management issues and funding constraint, sometimes associated with delays in grant disbursement to countries, caused most of stock-outs in those countries.

To prevent stock-outs and minimize the risk of transition, GDF has been collaborating with its partners to develop and implement key mechanisms including:

1. Early Warning System (EWS) GDF developed EWS to collect and analyse stock levels in countries to proactively identify the risk of stock out and collectively act on with partners. EWS collates information from existing data collection systems or quantification tools used in countries such as QuanTB, eTB manager, Open LMIS and others and has built-in data dictionary in partnership with KNCV Tuberculosis Foundation/ TB CARE. EWS has been piloted in several African and Asian countries and will be scaled-up in 2014 onwards.

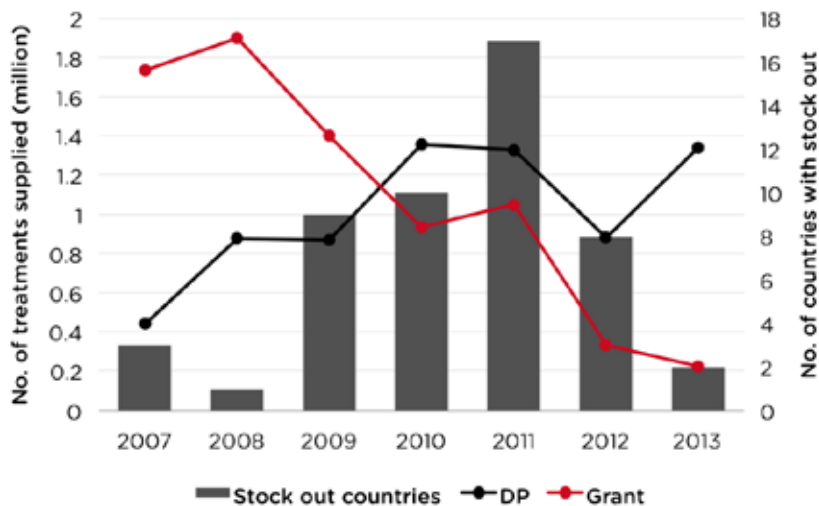
2. Rapid Supply Mechanism (RSM) GDF contributed to developing the new concept of RSM with the Global Fund which will give the Global Fund-supported countries access to GDF expanded stockpile of SLD and FLD through a fast mechanism in emergency since 2013. It is expected that the Global Fund will launch RSM in 2014 and GDF will support RSM operation for TB commodities.

3. MDR-TB Strategic Rotating Stockpile (SRS) In 2013, UNITAID committed US \$14.9 million to GDF to double its current stockpile for MDR-TB. The SRS helps to reduce the risk of stock-outs of MDR-TB drug by guaranteeing supply and improving delivery times of SLDs.

4. USAID Flexible Procurement Fund This mechanism enhances financial flexibilities by allowing countries or GDF clients to use the fund as a guarantee for all direct procurement. Through this life-saving mechanism, countries can place orders on time without having to issue an upfront payment and avoid treatment interruption. In 2013, Kenya and Pakistan placed an order through this mechanism (Table 1).

5. Improved forecasting In addition to monitoring missions, GDF has supported the roll-out of new monitoring tools for regular planning and enhanced programming such as QuanTB,⁵ in close collaboration with MSH/SIAPS. The data from such monitoring tools will be linked to EWS.

Figure 9 Stock-out trend



Note: No. of stock out countries is based on the reported case to the GDF through monitoring missions. No. of treatments supplied in millions by DP and Grant is only for FLD.

⁴ Carlos Chirinos-Rojas, An independent analysis of the root causes of stock-outs of anti-TB drugs in the period 2007-2013 based on the documented evidence available at the Global Drug Facility (GDF) 2013.

⁵ QuanTB is an electronic forecasting, quantification, and early warning tool designed to improve procurement processes, ordering, and planning for TB treatment, developed by the USAID-funded Systems for Improved Access to Pharmaceutical and Services (SIAPS) Program, Available at <http://siapsprogram.org/tools-and-guidance/quantb/>



Table 1 Flexible Procurement Fund

Country	Product line	Order placed	Amount
Pakistan	MDR	February 2013	US \$976,596
Pakistan	MDR	April 2013	US \$814,367
Pakistan	MDR	September 2013	US \$1,196,222
Kenya	Diagnostics	December 2013	US \$1,024,255

CAPACITY BUILDING

GDF provides expertise and technical assistance to countries with a holistic approach to address immediate gaps in drug supply and establish long-term drug management capacity and overcome systematic problems. TA includes monitoring missions, targeted technical assistance for specific challenges and workshops on supply chain management. GDF conducted 52 and 43 monitoring missions in 2012 and 2013, respectively. GDF in collaboration with USAID-funded SIAPS program has been supporting the countries to increase in-country capacity for forecasting and supply planning with new quantification tool, QuanTB.

COST-EFFECTIVE AND CUSTOMER ORIENTED OPERATION

In 2013, GDF merged all procurement activities for FLDs, SLDs and Diagnostics with one focal point per country (Country Support Officer) for all products lines, facilitating the communication process and oversight of country supply portfolios. Significant collaborative activities and enhanced processes optimization, including regular information sharing are on-going with Global Fund PSM Managers, preparing the transition to the New Funding Model.

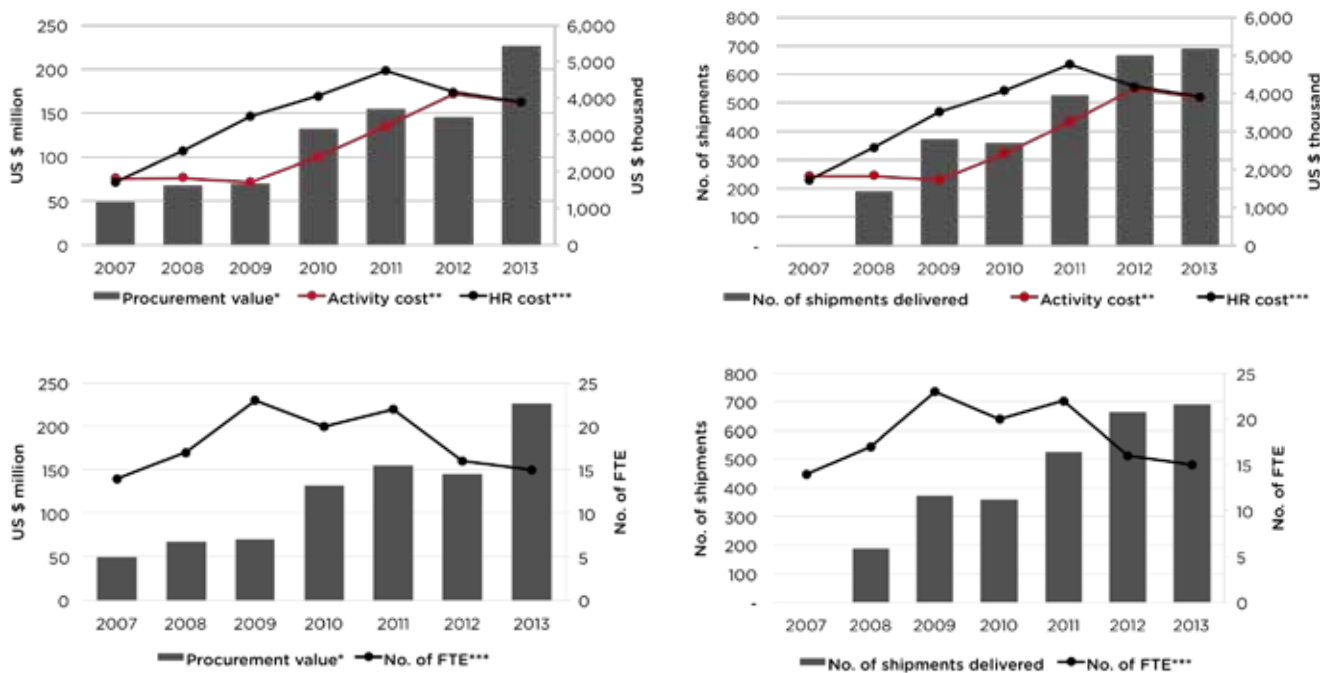


Figure 10 shows the evolution of procurement activities (total procurement value and number of orders handled/ shipments delivered) by GDF from 2007 till 2013 versus its activity and Human Resources costs highlighting significant gains regarding the cost efficiency trend of GDF operations.

In addition, GDF consolidated all TB drugs procurement activities (FLDS and SLDs) within one single procurement platform (IDA) since 2013, resulting in significant savings on transport/freight costs: the ratio Ratio Freight / EXW Cost for FLDs decreased from 13.43% in 2012 to 6.36% in 2013 by applying a proper transport management strategy aiming at :

- Facilitate negotiation with freight forwarders through improve accuracy of forecasts
- Rationalize delivery planning by increasing shipments from stock instead of ex-suppliers deliveries
- Consolidate FLD and SLD shipments to countries where applicable
- Decrease urgent requests & air shipments by global reduction of lead-times and steadiness of deliveries

Figure 10 Monitoring operational cost versus procurement activities



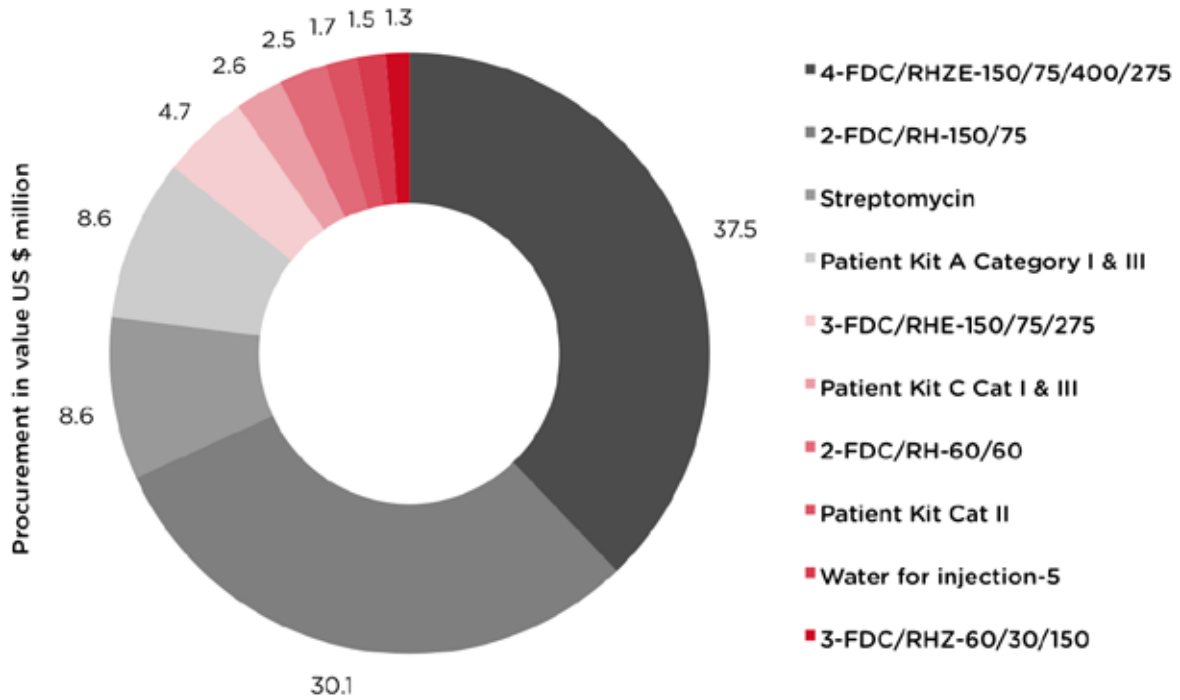
Note: *Procurement value represents the total value delivered all fee inclusive.
 **Activity cost includes cost associated with quality assurance and prequalification, technical assistance and monitoring missions, advocacy, communications & management, fund transferred to Stop TB Department and indirect costs (WHO Programme Support Costs). It doesn't include HR cost.
 ***HR cost and No. of FTE includes prorated cost and FTE for GDF staff, Stop TB Partnership staff and administration supported by GDF.

OVERVIEW BY PRODUCT LINE

FIRST-LINE DRUGS

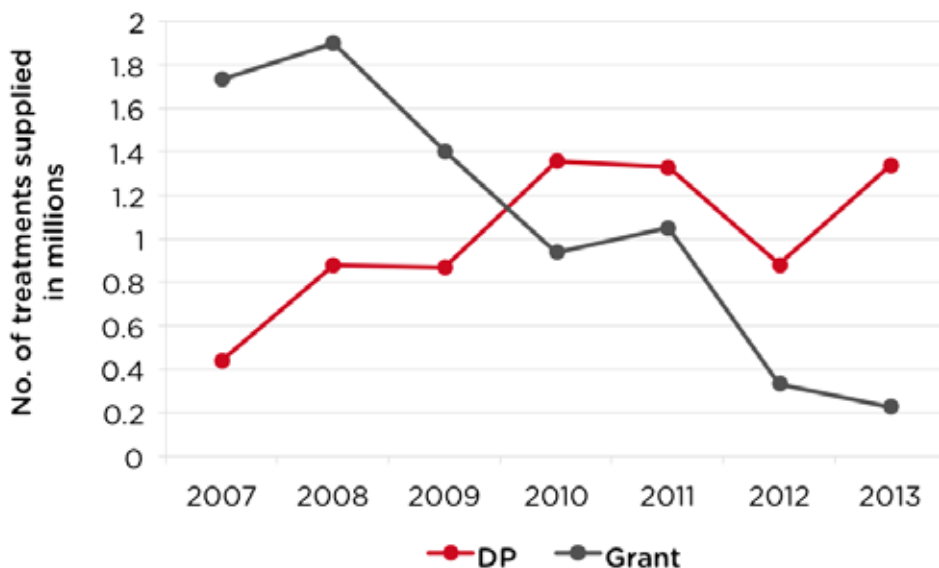
An analysis of expenditure trends in 2012 and 2013 indicates that top 10 products account for 93% of GDF's total expenditure on FLDs (figure 11). In 2013, almost 85% of FLD treatments are supplied through direct procurement, compared to 56% in 2011 (figure 12).

Figure 11 Top 10 FLDs, 2012-2013



Note: The figures presented here are only the value of goods procured for both adults and paediatrics and do not include the cost of freight, insurance, procurement, agent handling fees, quality control and pre-shipment inspection charges. The procurement value is based on the GDF's dynamic Order Monitoring System, which reflects the most recent changes in delivery date and cancellation of orders. This provides a snapshot of up-to-date situation.

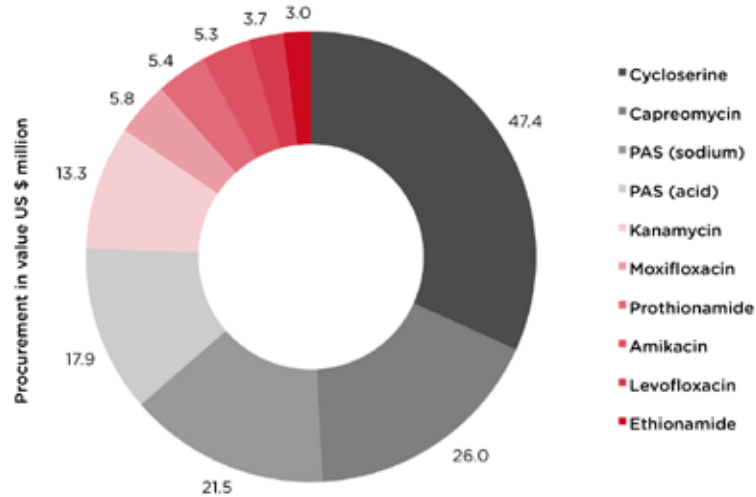
Figure 12 FLD patient treatment supplied by service



SECOND-LINE DRUGS

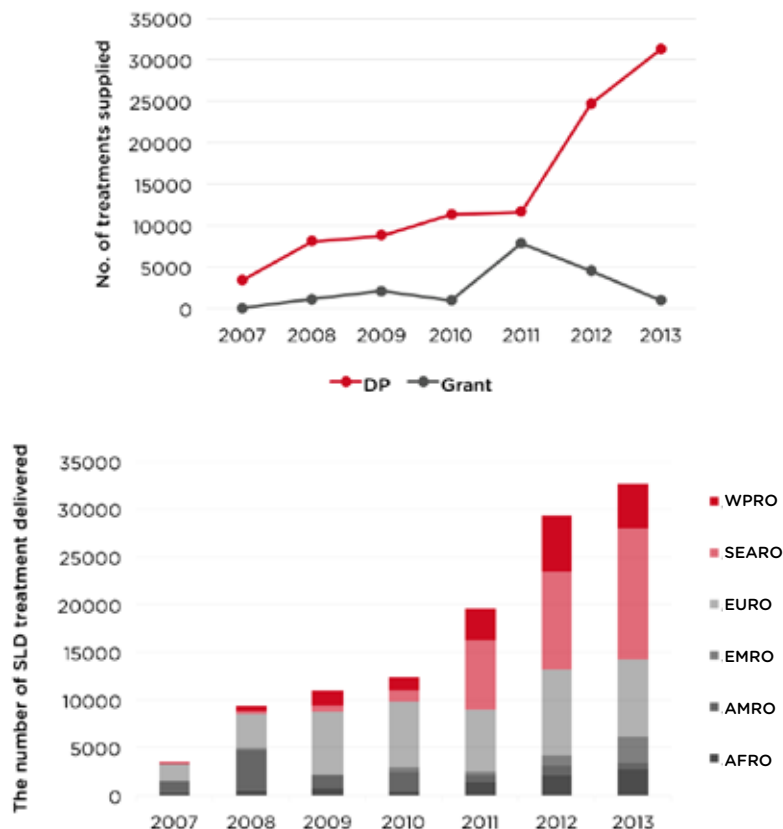
An analysis of expenditure in 2012 and 2013 indicated that top 10 products account for 92% of the GDF's total SLD costs (figure 13). In 2013, almost 94% of SLD treatments are supplied through direct procurement, compared to 56% in 2011 (figure 14).

Figure 13 Top 10 SLDs, 2012-2013



Note: The figures presented here are only the value of goods procured and do not include the cost of freight, insurance, procurement, agent handling fees, quality control and pre-shipment inspection charges. The procurement value is based on the GDF's dynamic Order Monitoring System, which reflects the most recent changes in delivery date and cancellation of orders. This provides a snapshot of up-to-date situation.

Figure 14 SLD patient treatment supplied by service and region

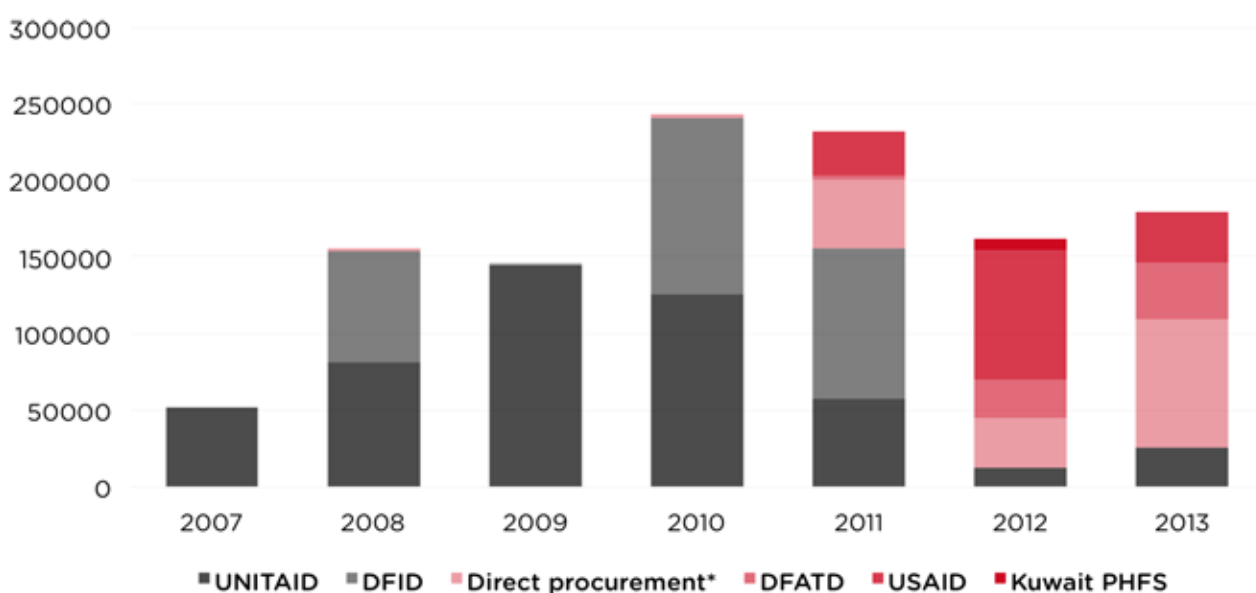




PAEDIATRIC DRUGS

In 2012 and 2013, the funding source for paediatric TB drugs was diversified to DFATD, USAID, Kuwait Patients Helping Fund Society (PHFS) and direct procurement through the Global Fund in addition to UNITAID (figure 15). The number of paediatric treatment supplied by GDF accounts for more than half of global paediatric notification in 2011 and 2012.

Figure 15 Paediatric patient treatments delivered



Note: DFID provided funding for the procurement of India-specific paediatric formulations in 2008, 2010 and 2011. This funding was limited to this specific market and timeframe. This is based on the GDF's dynamic Order Monitoring System, which reflects the most recent changes in delivery date and cancellation of orders. This provides a snapshot of up-to-date situation. *Direct procurement includes unspecified proxy Global Fund and government domestic funds.

Box 4 Paediatric TB project highlight

Recognizing the need for child-friendly TB treatment and diagnostics, UNITAID provided financial support to GDF in 2007 to implement Paediatrics TB Project. The objectives of the project were to foster the development of child-friendly formulations, provide appropriate-strength paediatric drugs for children under 15 years of age, increase the number of pre-qualified paediatric products, and secure lower prices for new paediatric products. The project was extended till December 2013 with total commitment of US \$12.8 million. By the end of 2013, GDF provided more than 1.3 million paediatric treatments.

Key milestones

- 1. Improved access to paediatric treatment** The project has delivered 526,508 paediatric curative treatments and 776,980 prophylactic treatment, representing 96% of treatment targets achieved. This represents that GDF provided treatment to 40% of notified cases^a with UNITAID support through this project and up to three-quarters of notified cases with all funding sources from 2007 to 2012.^b From 2007 to 2012, GDF provided paediatric treatments at least once to 14 of the 22 High-burden countries (HBCs). This project made this niche market for paediatric more visible and allowed countries to further structure and improve their national TB programs for children by having access to an uninterrupted supply of paediatric forms (dispersible tablets / FDCs).
- 2. Increase in security supply for quality-assured medicines** As of 2013, 8 of the 12 of the qualified suppliers are WHO prequalified, with the remaining 4 products SRA authorized, compared to only 7 quality-assured products in 2007.
- 3. Affordable access to medicines** Treatment prices still remain within an acceptable range given the particularities of this nascent market and high quality standards.
- 4. Promoting the rational use of paediatric medicines** Though there is no formulation available in market that aligns with the WHO guideline 2010, GDF facilitated the uptake of new WHO guidelines at country-level. GDF encouraged countries to follow the instructions on the use of the new dosages with the existing FDC of TB medicines through monitoring missions and on-going technical assistance. To date, 23 countries among 61 UNITAID-supported countries adopted the new guideline. This leads to improving the rational use of paediatric medicines by preventing inappropriate dosing, treatment failure, spread of disease and the emergence of drug resistance. Recently, WHO published a updated guideline in 2014, which provides an opportunity to make the treatment regimens easier to quantify and administer with currently available formulations. GDF plans to collaborate with WHO Essential Medicines and Health Products (EMP) and TB Alliance to accelerate the uptake of this new guideline until the new child-friendly formulations are available by 2016 through UNITAID-supported STEP-TB project.
- 5. Sustaining the impact** As the UNITAID project was winding down in 2013, GDF has engaged other donors such as USAID and DFATD to bridge the gaps in grant offering and sustain the market for TB paediatric products. Also, the proportion of countries placing orders for their paediatric drugs through direct procurement is increasing up to 50% (2013). However, still 21 of the 62 countries supported by UNITAID funds have no clear transition plan to secure the sources of funding.

Source: a. Scott C GE, de Lucia A, Keravec J. Distribution of First-line Pediatric Drugs in 22 HBCs: Analysis of Global Drug Facility Procurement (unpublished analysis). 2013.

b. GDF. Final Report on GDF/UNITAID Paediatric TB 2007-2013 (submitted to UNITAID). 2014.

DIAGNOSTICS

GDF has started to distribute TB diagnostic commodities for microscopy in 2008. With the launch of the EXPANDx-TB project funded by UNITAID in 2009, the diagnostics portfolio increased with the inclusion of new TB diagnostic tools such as liquid culture and line probe assay. In 2011, GDF together with the TB REACH initiative has set up the procurement system for Xpert MTB/RIF cartridges and services. In 2013, new diagnostic kits have been made available for light emitting diode (LED) microscopy, in collaboration with the Global Laboratory Initiative (GLI).

GDF is guided by the principles to offer diagnostics to its clients:

- To perform most of the diagnostics methods recommended for use by WHO's Strategic and Technical Advisory Group for Tuberculosis (STAG-TB).
- To be implemented at all levels of the diagnostics algorithm, from community to central reference level.

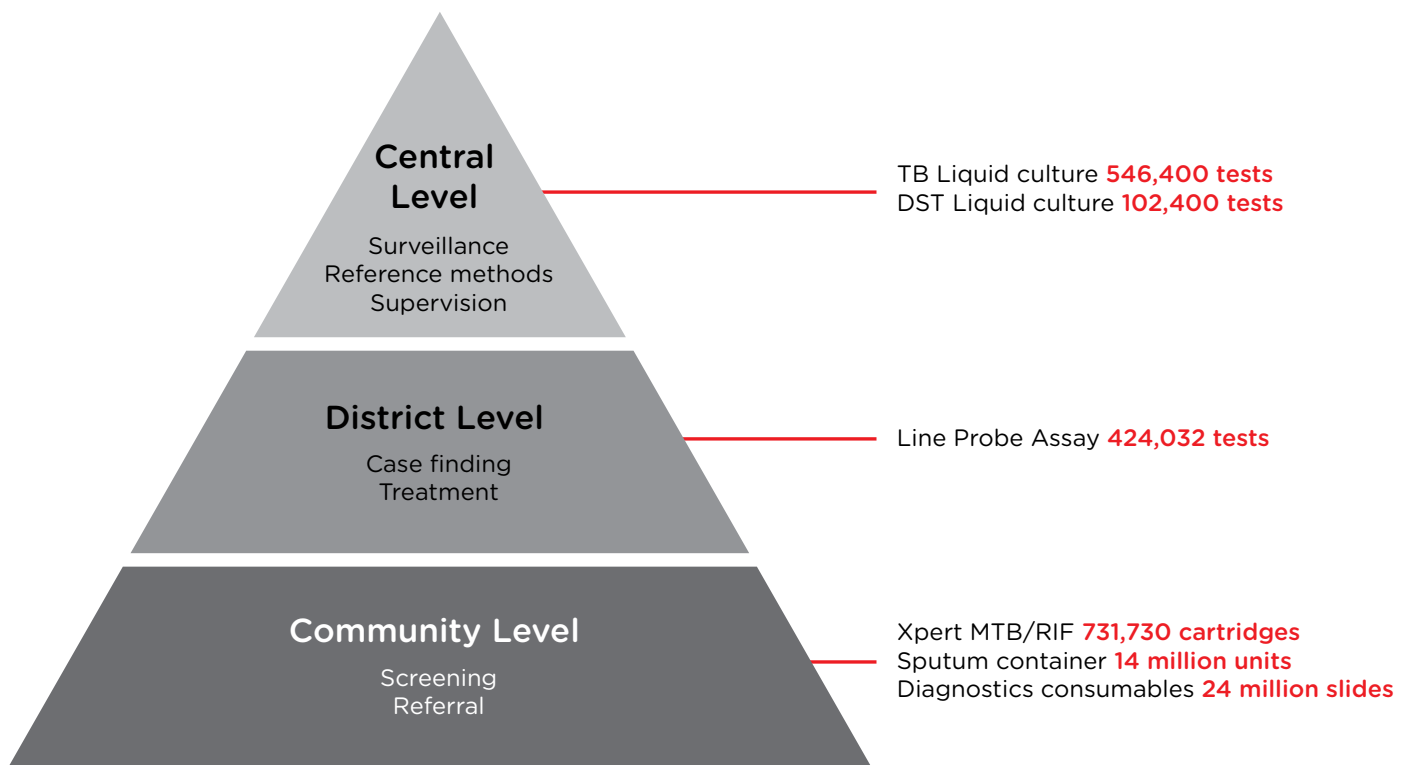
Since 2008, GDF procured diagnostics worth of US \$59 million. Total expenditure on diagnostics in 2012 and 2013 is US \$18.1 million and 24.4 million, respectively. The value of orders placed almost doubled in 2013 compared with 2011.

GDF ensures the quality of all diagnostic products procured:

- In Vitro diagnostics must be registered by Stringent Regulatory Authority (SRA) or bear the CE marking or equivalent and be manufactured under ISO 13:485 standards.
- For laboratory instruments, consumables, chemicals technical assessment, acceptability of products during selection process and specifications for products, GDF collaborates with the Global Laboratory Initiative (GLI) and experts.



Figure 16 Increased access to diagnostics



Note: The number of diagnostics supplied represents cumulative figures from 2007 to 2013.

Box 5 TB diagnostics project highlight

Through its procurement platform for TB diagnostics, GDF supports:

EXPANDx-TB, funded by UNITAID, started in 2009, targets to detect 140,000 MDR-TB patients by the end of 2015. Since 2009, GDF has provided new diagnostics to 27 low and middle income and high-burden TB countries where they now have 92 fully functioning TB reference laboratories. In India, 90% of the MDR-TB cases were detected through EXPANDx-TB with GDF support on the supply of new diagnostics in 2012.

Source: http://www.who.int/tb/publications/factsheet_expand_tb.pdf

The TB Xpert Project, funded by UNITAID, is providing approximately 1.4 million Xpert MTB/RIF test cartridges and over 225 GeneXpert machines in 21 recipient countries in 2013-2015. In 2013, GDF supplied 222 GeneXpert machines and 234,760 test cartridges. This resulted in the detection of 7,647 cases including 1,791 rifampicin-resistant TB cases.

TB REACH, launched in 2010 with support from DFATD, has procured over 165 GeneXpert machines and more than 290,000 Xpert MTB/RIF cartridges to support TB case detection through GDF. With the diagnostics supplied by GDF, 41,000 cases were detected including 5,117 rifampicin-resistant TB cases by the end of 2013.

Source: Creswell J et al. Results from early programmatic implementation of Xpert MTB/RIF testing in nine countries. BMC Infect Dis. 2014 Jan 2;14:2. doi: 10.1186/1471-2334-14-2. <http://www.biomedcentral.com/1471-2334/14/2>



ENSURING ACCESS TO QUALITY ASSURED PRODUCTS



GDF has been continuously addressing the constraints arising from the low number of quality-assured products through proactive engagement with manufacturers and close collaboration with various partners such as the WHO Prequalification Programme, U.S. Pharmacopoeia (USP) Promoting the Quality of Medicines (PQM) program (USAID funded) and the industry. By the end of 2013, the GDF FLD portfolio consisted of 26 quality assured products supplied by 11 manufacturers, while the SLD portfolio reached 32 quality assured products supplied by 25 manufacturers representing all 5 groups of medicines that are currently recommended by the WHO treatment guidelines for MDR and extensively drug-resistant TB (Annex V).

Bi-annual and joint GDF and the Global Fund Expressions of Interest (EoIs) were conducted within 2012 -2013 with the aim to increase access to the quality assured products and to motivate and support manufacturers towards prequalification of their products. There are manufacturers expressing their interest in supplying good quality TB products through GDF, but many of them still require technical support and marketing incentives to move forward and reach quality standard.

Within the period of 2012 -2013, the GDF drug quality monitoring programme continued all the specified activities through the Quality Control Agent (QCA), such as pre-shipment inspections (PSI), randomised sampling and quality testing, review of all products Certificate of Analysis (CoA).

Sampling are carried out at (i) the manufacturer's site, (ii) the procurement agent storage facility, (iii) the country of use on consignment on arrival or (iv) different location on a need/case by case basis according to the principles and methods established in the Request for proposal (RFP). Testing is conducted on 10% of the WHO prequalified products and 20% of the ERP-

Box 6 QA & QC findings

- There were no recalls and out of specifications (OOS) reported for products in 2012 and 2013.
- In 2013, the Global Fund with WHO and GDF requested Lao to conduct additional independent re-testing of RHZE-150/75/400/275 batches to confirm product quality. Given that the manufacturer was in process of submitting variation for dissolution test method, it was agreed that the registered method should be used in the meantime. The variation submitted was approved in November 2013 by Medical Product Agency, Sweden and will be applied to stability test of new batches.
- Quality test deviations reported for 7 batches in 2012 and 5 batches in 2013 from five suppliers; 80% of these were the ERP approved products. Most of variations were for rifampicin containing products and related to the dissolution test. Most of these batches were re-tested and reconfirmed to be fully compliant with the reported results.
- Major reported PSI deviations were addressed immediately.
 - 97 outer cartons for RH-150/75 were found missing during PSI; and found under different shipping reference and returned to the related order;
 - 5 batches of water for injection were rejected and replaced due to shelf life limitations;
 - Patient information leaflets for RHE 150/75/275 and RHZE-150/75/400/275 were missing and supplier repacked the goods accordingly.



Box 7 Response to global shortage of Isoniazid

In 2013, there was a severe disruption in the global pharmaceutical market for the Isoniazid. This led an expeditious and coordinated response from all stakeholders including GDF. As a result, a new API supplier got its product prequalified by WHO within very short period of time and supplied its products through GDF.

- Limited number of suppliers with qualified drugs for a few FLD and SLD products leading to delays in deliveries and creating dependence/ risks of monopolies
- Long importation and cumbersome registration of medicines in countries which leads to delays in delivery of goods and prolonged custom clearance procedures
- Some of manufacturing, packaging and testing variations are not informed to GDF in timely manner. This could lead to change in supplier, delays with delivery of goods and eventually customer dissatisfaction. Requirements for and variations in quality testing methodologies of suppliers and NDRA

reviewed products following the mandatory testing of the first five batches. Key findings from QA&QC activities are summarized in Box 6.

Key challenges in 2012 and 2013 were:

- Short shelf life (24 months only) for some products, which hampers programmes ability to adequately plan their procurement and leads to waste of medicines in countries

To overcome some of these challenges, GDF has continued its close collaboration with its partners to facilitate inspections and product assessments for alternative manufacturers to become eligible for supplying through GDF procurement mechanism. In 2012 and 2013, 8 API and 73 anti-TB finished pharmaceutical products (FPP) obtained the WHO prequalification status. Box 7 shows the concerted effort to address the shortage of quality assured product.

GDF PROCUREMENT MODEL

GDF provides procurement services for quality assured drugs for susceptible TB and drug-resistant TB and diagnostics through use of contracted procurement agents. GDF applies a holistic approach to TB drug procurement, by linking demand for medicines to supply and monitoring, outsourcing all services to contractors on a competitive basis, adopting a web-based order tracking system to allow customer satisfaction, using product packaging to simplify drug management, and providing technical assistance to countries for better planning.

GDF serves national TB programs and governments in need of additional resources for procurement of quality-assured TB products through grants and the Global Fund-supported national TB programs through Direct Procurement (DP). Other GDF clients include countries procuring quality assured medicines with domestic funds, implementing agencies, donors or financing mechanisms in countries, NGOs, TB programs in the field, and international technical partners working both globally and with national TB programs. GDF also offers opportunities for countries to procure partial regimens for SLD based on their specific needs.

- GDF grants procurement. GDF provides opportunities for countries to apply for grants, using GDF donor funding from USAID, DFATD, and UNITAID among others. According to criteria

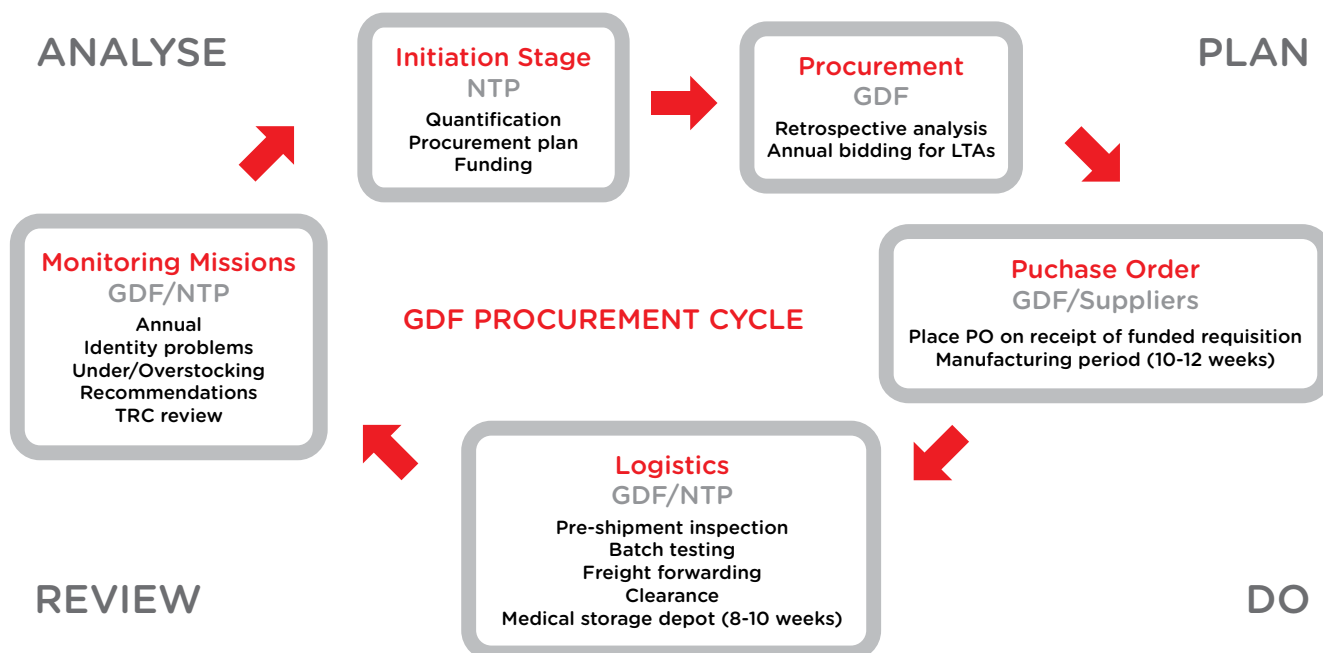
established and approved by donors, grants have provided access to FLDs and diagnostics. SLDs and paediatrics were provided for selected UNITAID supported countries. GDF also offers emergency grants for FLD of one year to prevent stock outs due to factors such as insufficient funding, procurement delays, national disasters and humanitarian crisis. Grant applications are reviewed by independent Technical Review Committee (TRC) meeting usually twice per year.

- Direct procurement (DP). Countries approach GDF to place orders using external donor funding, generally from the Global Fund and sometimes from national government domestic budgets. DP accounts for 85% of total GDF procurement value of orders placed in 2013.

Planning is critical to success in ensuring that quality goods can be delivered to the right people at the affordable price and at the right time. Many of the steps in the supply chain are beyond the control of GDF, yet GDF is often the first entity to receive a complaint that there are stock outs of anti-TB drugs and concern as to the resulting interruption of treatment. GDF models aim at further assisting countries in preventing stock outs and avoiding disruption in supply by strengthening in-country supply chain systems and implementing an Early Warning Stock-out System.

Figure 17 illustrates the supply chain management cycle, actors responsible and the estimated time frame.

Figure 17 GDF procurement cycle





PRODUCT CATALOGUE

25 The Product Catalogue (available at <http://www.stoptb.org/assets/documents/gdf/drugsupply/katalog2014web.pdf>) displays the highest and lowest product prices offered by GDF's principal suppliers. For the majority of products, GDF maintains long-term agreements with multiple suppliers, with target market share allocations based on the outcomes of tender. Allocations may vary depending on performance, product status and other criteria monitored by GDF and its Procurement Agents selected in 2012, International Dispensary Association (IDA) Foundation for FLDs and SLDs and Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) for diagnostics. Volume discounts are also available for some products.

MANUFACTURERS MEETING

As part of its quality management policy and management review process, GDF convenes regular meetings with manufacturers for TB medicines. The 2013 meeting held in Sri Lanka with manufacturers and stakeholders built on previous manufacturers meetings, provided an opportunity to discuss issues around access, market dynamics, quality assurance and procurement for TB products, reviewed with all stakeholders the past performance of the GDF model against defined key performance indicators (KPIs), and discussed related strategic issues for continuous improvements and moving forward in a coordinated approach between GDF donors, partners and stakeholders.

Box 8 Recent achievements in the Gambia TB Program

The National Leprosy and Tuberculosis Control Programme of the Ministry of Health and Social Welfare in Gambia recently highlighted its stride in maintaining a good performance in Phase 2 of the Global Fund TB grant. Key achievements include:

- Increased new smear-positive cases diagnosed from 1306 in 2008 to 1431 in 2012;
- Treatment success rate reaching 88%, exceeding WHO's global target of at least 85%;
- No stock-outs of anti-TB drugs

GDF has provided FLDs to Gambia since 2011, through direct procurement service, contributing to an uninterrupted supply of TB drugs.

CAPACITY BUILDING & TECHNICAL ASSISTANCE

In addition to procuring FLDs, SLDs and diagnostics, GDF provides support to countries in strengthening national capacity for procurement and supply chain management in the form of monitoring missions, hands-on technical assistance, and workshops and trainings. GDF expands the outreach for capacity building through strong collaboration with key partners. GDF has moved towards a holistic approach to address immediate gaps and bottlenecks in drug supply, while assisting countries in overcoming systematic problems and establishing the long-term capacity of national TB control programmes and ministries of health in drug management. Long term partnering relationships established between GDF Country Support Officers based at GDF Headquarters in Geneva and NTPs, annual monitoring missions, technical assistance and country support through a network of consultants and Regional Support Officers (RSOs) form the cornerstone of this approach to support countries on key supply chain challenges.

Through this model, GDF further provides technical assistance to GDF clients requiring support in quantification, forecasting and overall drug management needs. In 2013, GDF has further extended their support to clients by collecting quarterly stock level information from countries, allowing for determining stock out risk or over stocking of medicines. This information is currently collected by RSOs and consultants, and linked to the Early Warning System that helps countries plan their procurement in an effective manner and avoid stock out situations. GDF also maximized the impact of technical assistance by collaboration

with its technical partners such as KNCV and MSH for example, through other USAID funded programs like TB CARE and SIAPS to harmonize data collection tools such as the roll-out of QuanTB and other drug management support strategies. GDF trained three MSH regional staff to serve as GDF focal points in their respective regions and carry out monitoring missions as necessary. GDF has also developed strategic agreements with other partners such as the Union for conducting joint monitoring missions and leverage improved coordination on supply management activities at country level.

In 2012 and 2013, 52 and 43 monitoring missions were conducted, respectively in countries where GDF supplies TB products (Annex 4). Through the monitoring missions, GDF was able to validate stock on hand levels, assess risk for stock-outs, follow up on the implementation of recommendations made by TRC and GDF terms and conditions, assist with quantification and planning for future requirements, and identify challenges in supply chain management.

A revamped monitoring mission report will be launched in 2014, which is strategically focused on procurement and supply chain management indicators and quantification. This monitoring report will allow electronic submission of key supply chain data into the data management system to enable the efficient analysis and information dissemination. GDF also helps countries to plan for the transition to more sustainable funding sources, either through domestic funding or donor support (Box 8).





Box 9 Sustainable financing for procurement of TB drugs

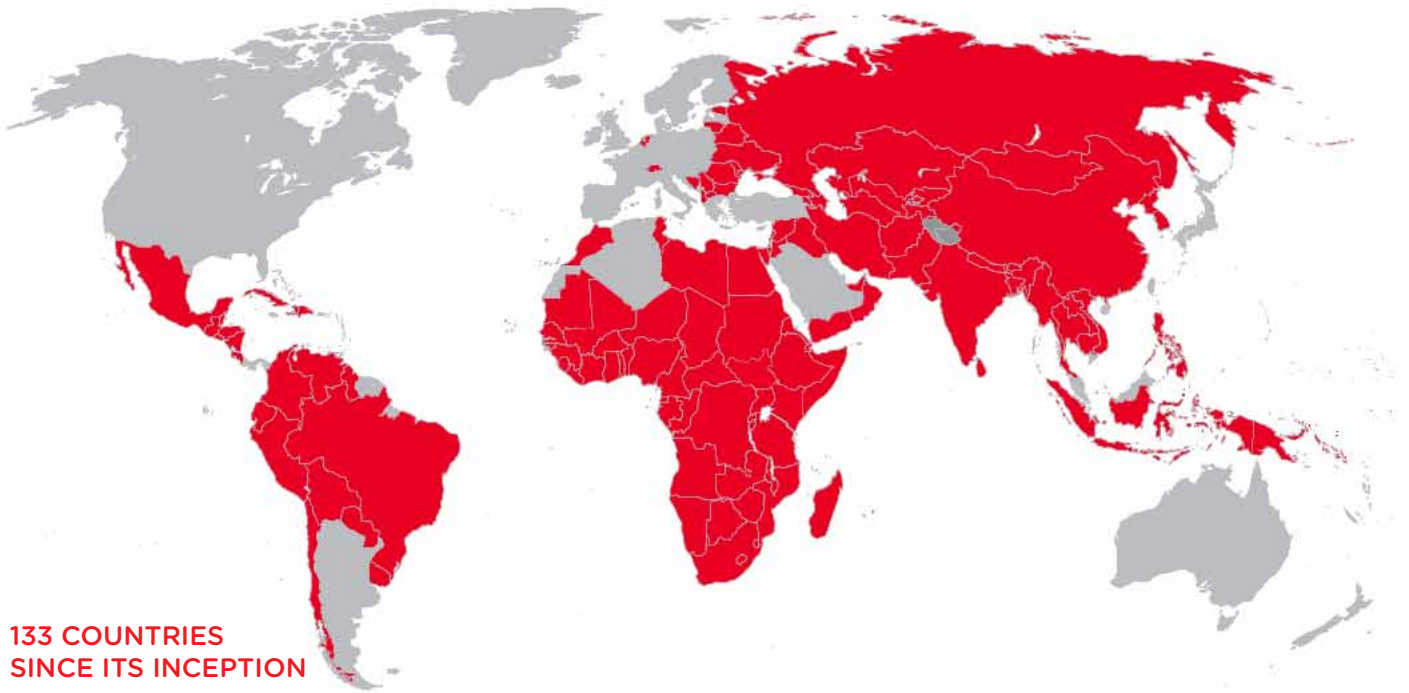
Lesotho Lesotho has become one of the first Low Middle Income Countries from the African region to be able to transition to self-financing of the procurement of adult first line drugs for tuberculosis without further dependence on a grant from GDF.

In 2007, Lesotho received a 3-year grant from GDF for first line drugs for adults. Following GDF monitoring mission in 2007, it was recommended that Lesotho should plan for direct procurement for FLDs. A year later, the Ministry of Health (MoH) committed to an increase of the governmental contribution to TB drugs corresponding to 20% every year. In April 2009, Lesotho used funds from national budget through Direct Procurement with GDF to procure 20% of its annual adult FLD needs and buffer stocks. The government's contribution has continued to increase till 2013 according to its plan and demonstrated support for the initiative by committing 100% resources for the procurement of drugs from its national budget starting 2014.

Not only funding for drugs, the MoH also demonstrated commitment to securing quality assured TB products through continued engagement of GDF and negotiations to obtain a waiver on open tendering, single source procurement and pre-payment. This allows the MoH to use direct procurement service and avoid open market thus minimising vulnerability to procuring non quality assured drugs, which may compensate the treatment outcome.

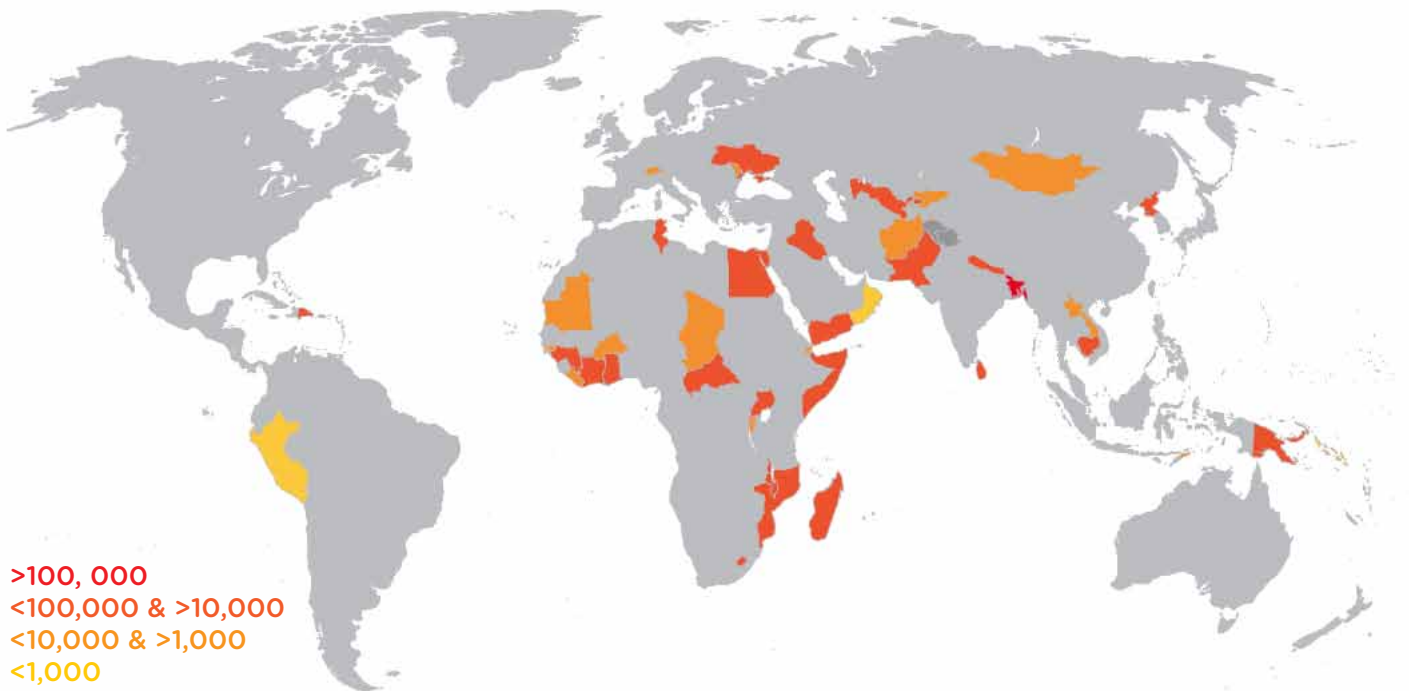
Vietnam In 2013, the government allocation for the first line drugs was significantly reduced from previous year's budget. With this budget cut, National TB Program (NTP) could only procure 30% of annual treatment need for 2014. To fill this gap, NTP requested GDF, in August 2013, to provide one year need for FLDs and 50% buffer stock. Recognizing the GDF grant as an intermediary intervention, the government re-allocated additional budget for 2015 to cover one year need for FLDs. It was committed that from 2015 onwards, FLD will be fully funded from national resources, contributions from government funding with health insurance and increased provincial contributions.

ANNEX I COUNTRIES SERVED BY GDF

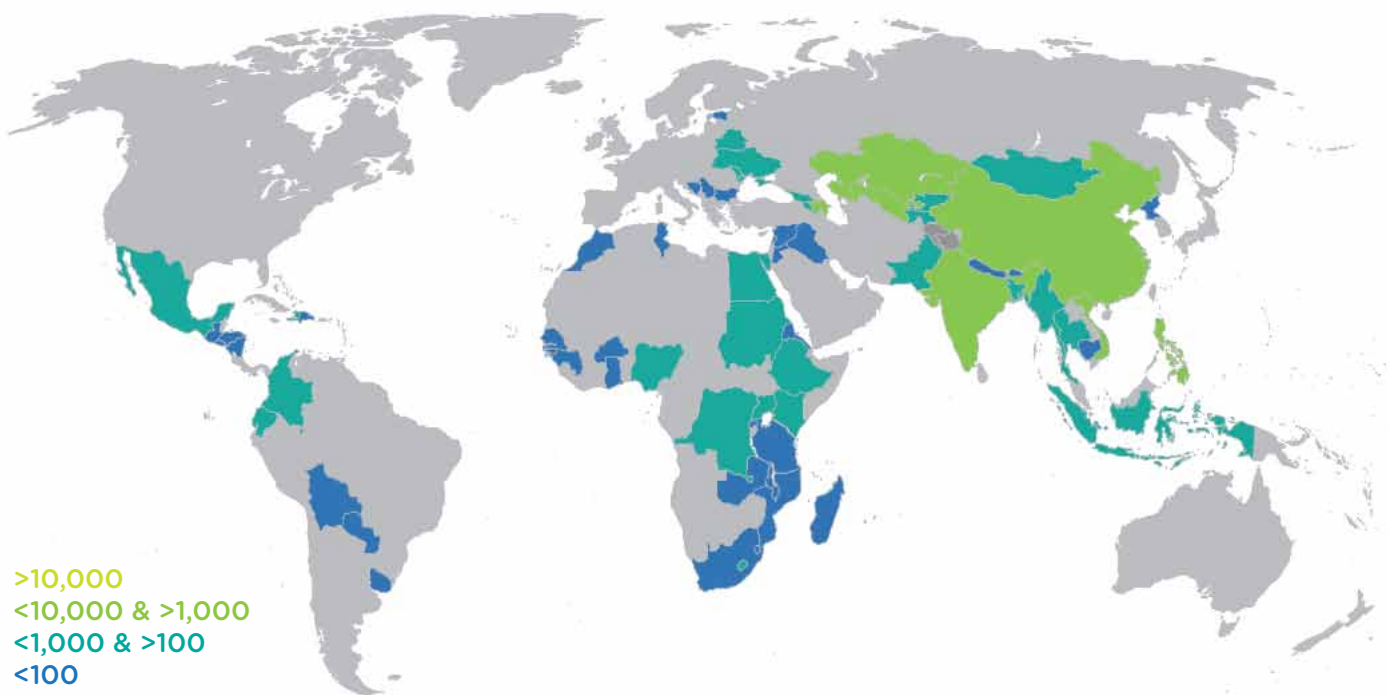


ANNEX II PATIENT TREATMENTS BY COUNTRY

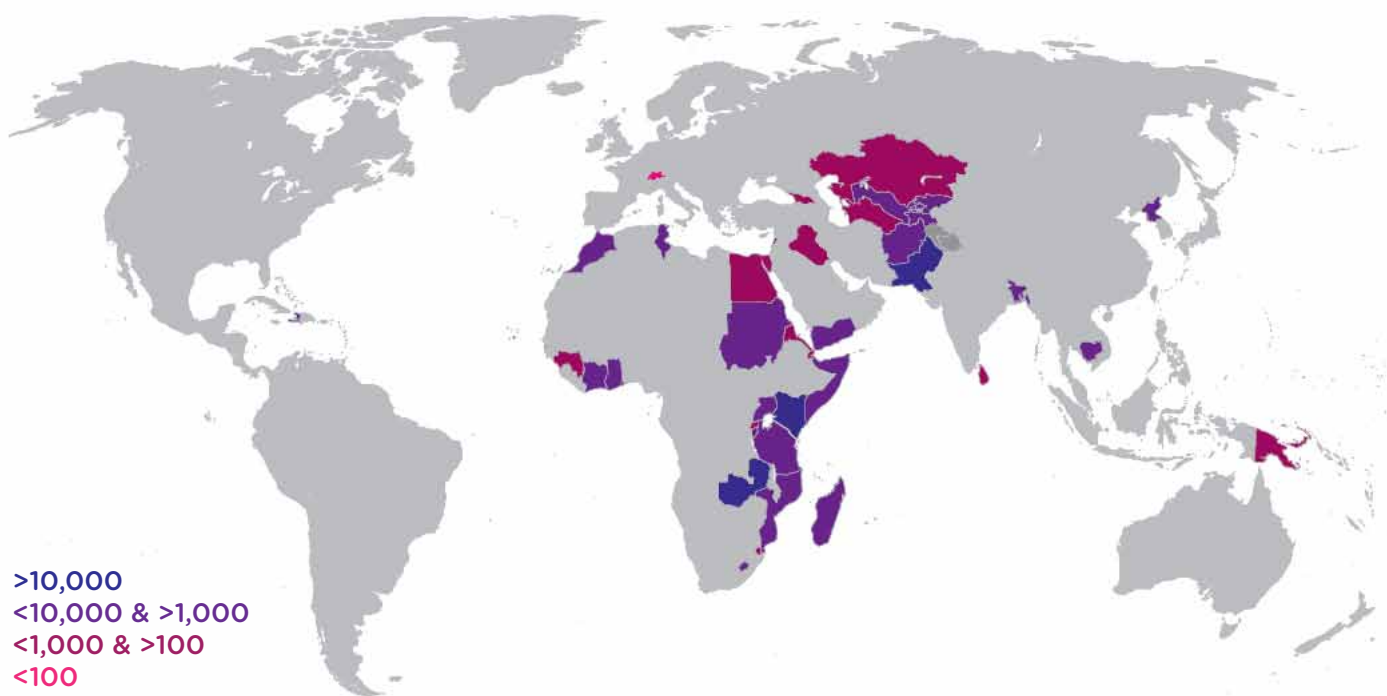
FLD 2012



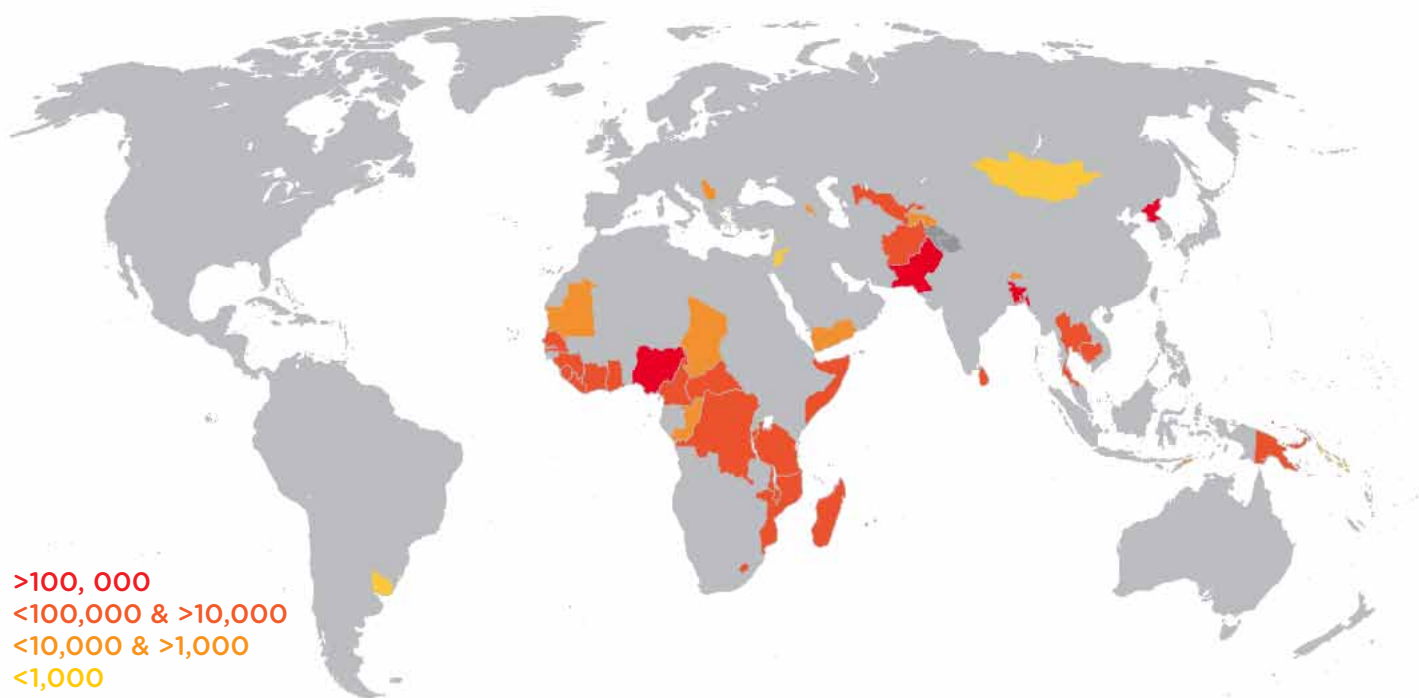
SLD 2012



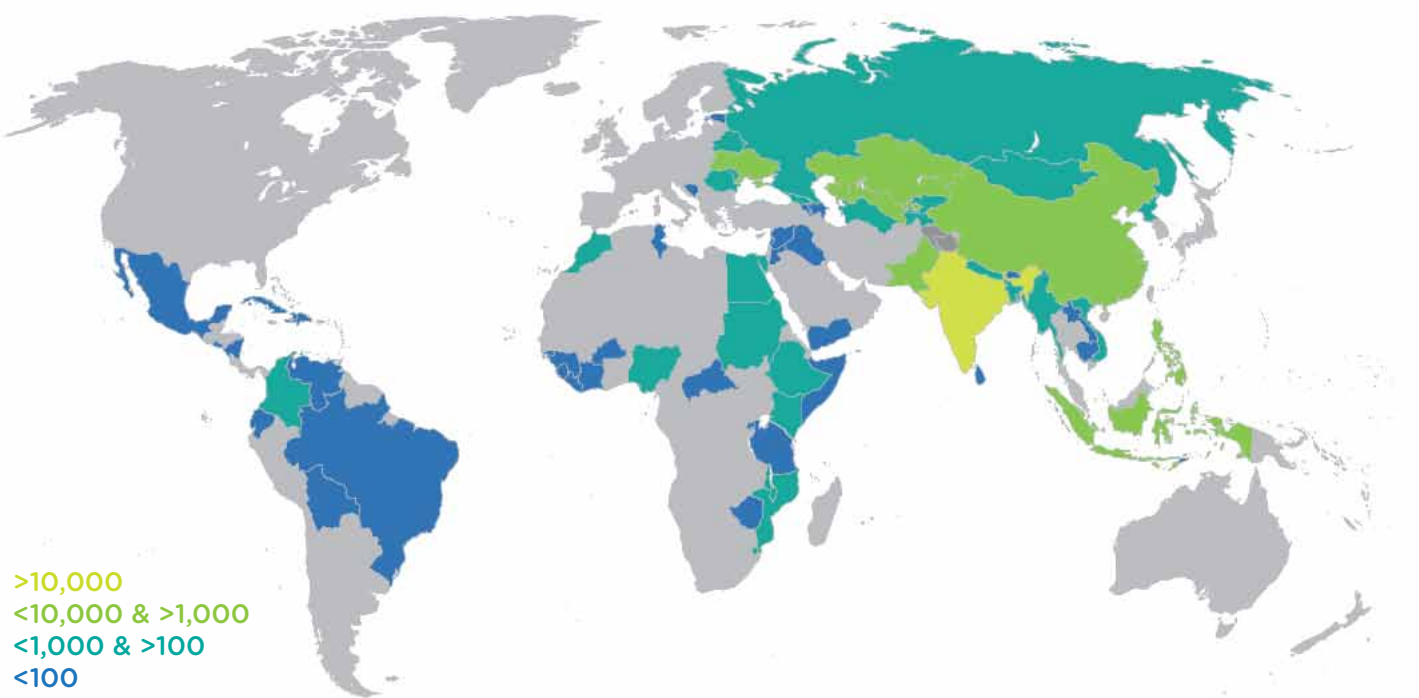
PAEDIATRICS 2012



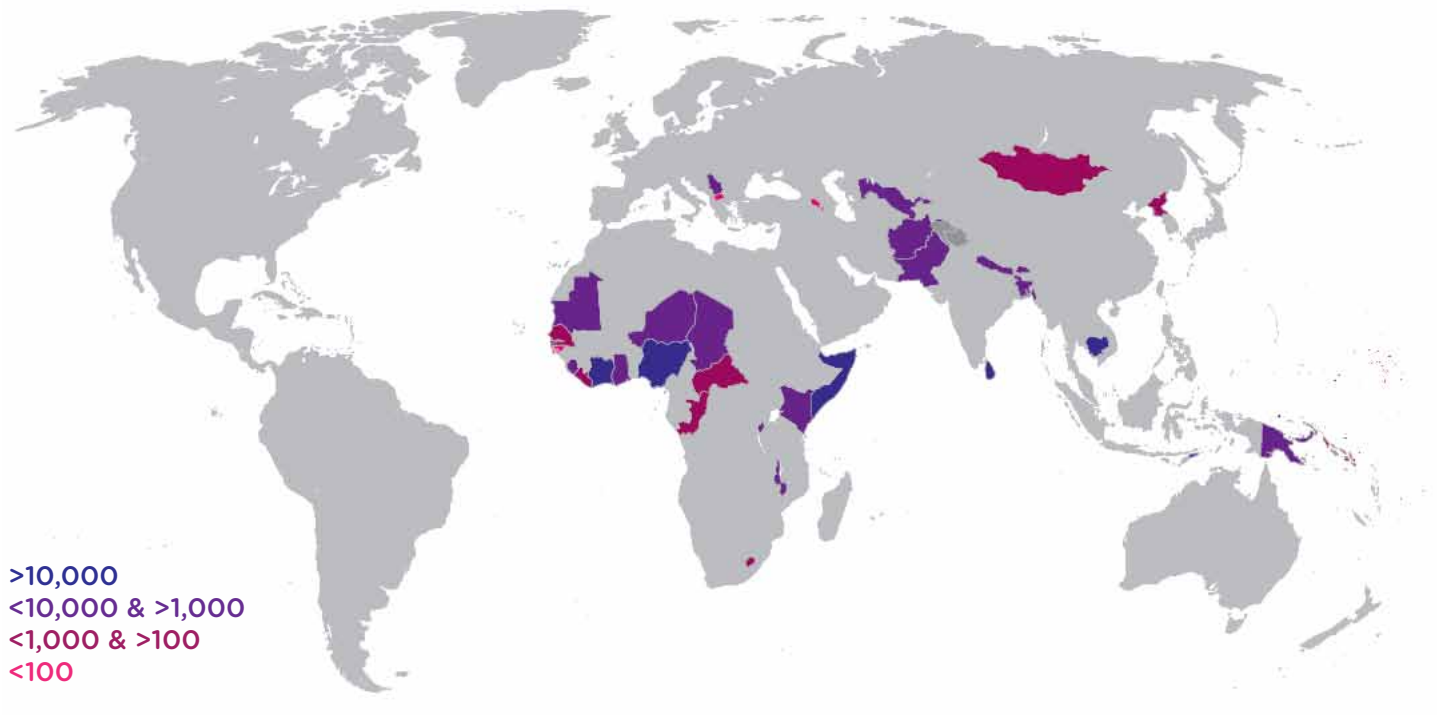
FLD 2013



SLD 2013



PAEDIATRICS 2013

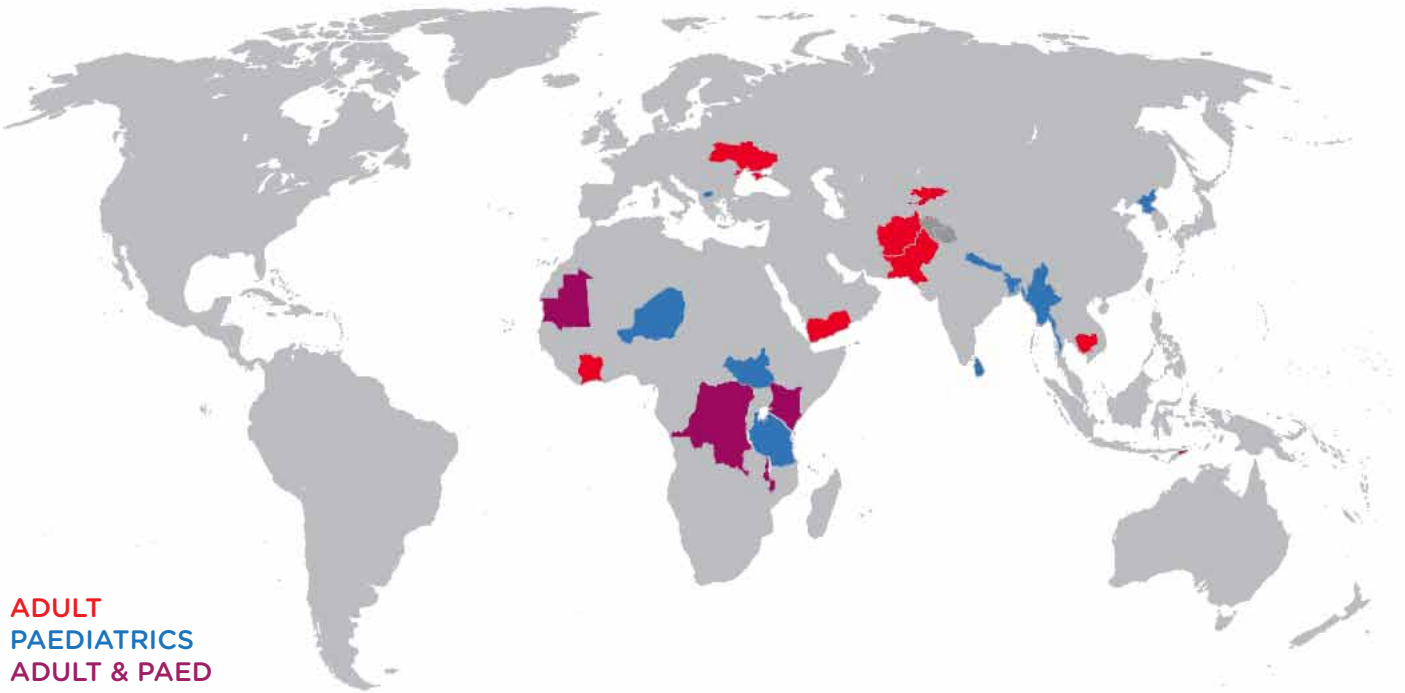


ANNEX III COUNTRIES SUPPLIED WITH DIAGNOSTICS IN 2012 & 2013

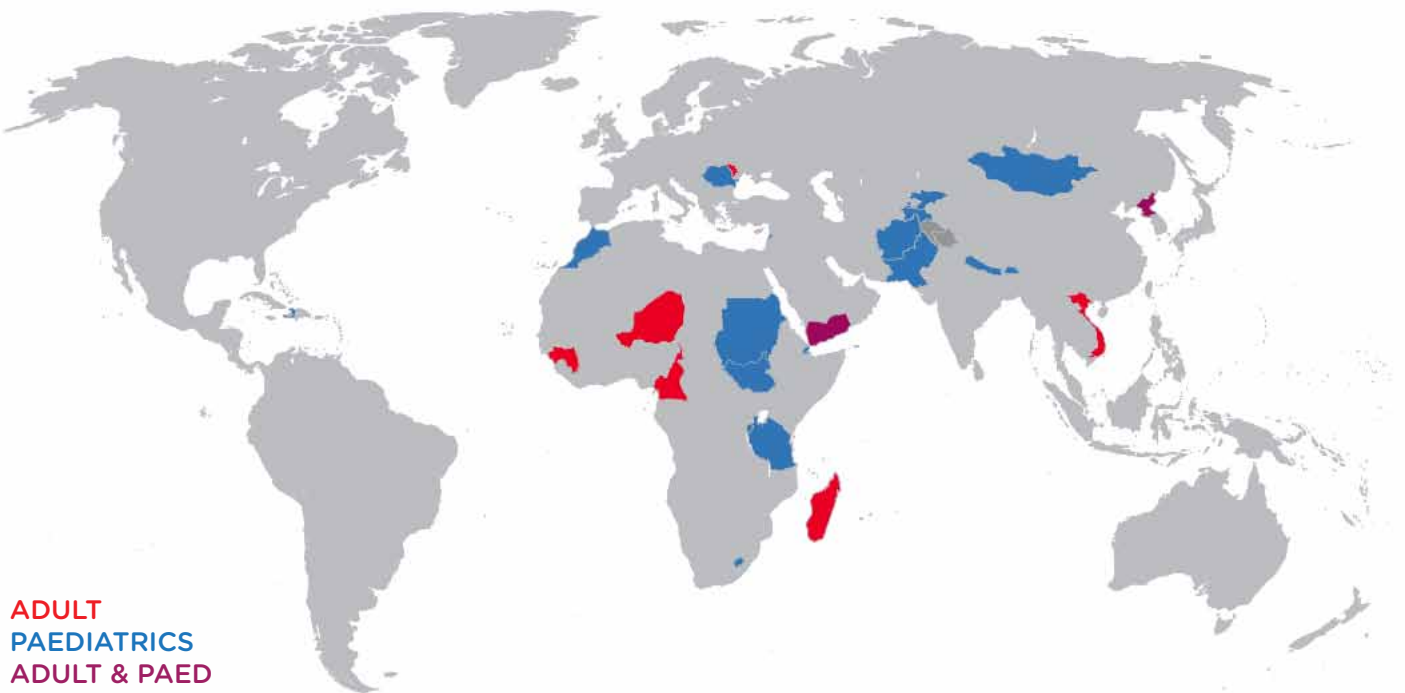


ANNEX IV COUNTRIES RECEIVING GDF GRANTS APPROVED BY THE TECHNICAL REVIEW COMMITTEE FOR FLDs IN 2012 & 2013

2012



2013



ANNEX V GDF PRODUCT CATALOGUE

As per its Quality Assurance policy, GDF provides quality-assured products to countries and programmes which enable health care providers to treat patient according to the latest WHO treatment guidelines. The use of Fixed Dose Combination (FDC) tablets greatly contributes to rational use and assists in effective implementation and expansion of the STOP TB Strategy. Intake of FDC tablets reduces the number of pills a patient needs to consume, while avoiding mono-therapy and thereby reduce the risks of developing Multidrug-Resistant TB (MDR-TB). Innovative packaging like the GDF patient kits further contributes to patient adherence and facilitates in-country drug management practices.

FIRST LINE ANTI-TUBERCULOSIS MEDICINES

Oral solid dosage forms: Fixed dose combinations for adults

Product	Description	Packaging	Price EXW (USD)*
4FDC/RHZE 150/75/400/275 (blister)	Rifampicin 150 mg/Isoniazid 75 mg/Pyrazinamide 400 mg/Ethambutol 275 mg film-coated tablets	28 tablets * 24 blisters	41.35-43.90
4FDC/RHZE 150/75/400/275 (loose)	Rifampicin 150 mg/Isoniazid 75 mg/Pyrazinamide 400 mg/Ethambutol 275 mg film-coated tablets	HDPE container of 1000 loose tablets	57.50
3FDC/RHE 150/75/275 (blister)	Rifampicin 150 mg/Isoniazid 75 mg/Ethambutol 275 mg film-coated tablets	28 tablets * 24 blisters	31.50
3FDC/RHE 150/75/275 (loose)	Rifampicin 150 mg/Isoniazid 75 mg/Ethambutol 275 mg film-coated tablets	HDPE container of 1000 loose tablets	44.90
2 FDC/RH 150/75 (blister)	Rifampicin 150 mg/Isoniazid 75 mg film-coated tablets	28 tablets * 24 blisters	19.71-21.20
2 FDC/RH 150/150 (blister)	Rifampicin 150 mg/Isoniazid 150 mg film-coated tablets	28 tablets * 24 blisters	23.05
2 FDC/EH 400/150 (blister)	Ethambutol 400 mg/Isoniazid 150 mg film-coated tablets	28 tablets * 24 blisters	22.27

Oral solid dosage forms: Single dose formulations for adults

Product	Description	Packaging	Price EXW (USD)*
Ethambutol 400 mg	Ethambutol 400 mg film-coated tablets	28 tablets * 24 blisters	22.50
Isoniazid 300 mg	Isoniazid 300 mg film-uncoated tablets	28 tablets * 24 blisters	13.52
Pyrazinamide 400 mg	Pyrazinamide 400 mg film-uncoated tablets	28 tablets * 24 blisters	13.75-15.00
Pyrazinamide 500 mg	Pyrazinamide 500 mg film-uncoated tablets	28 tablets * 24 blisters	21.00
Pyrazinamide 750 mg**	Pyrazinamide 750 mg film-uncoated tablets	28 tablets * 24 blisters	31.00
Rifabutin 150 mg	Rifabutin 150 mg hard capsules	30 capsules * 1 blister	12.60-30.00

(**India-specific product)

Oral solid dosage forms: Fixed dose combination for children

Product	Description	Packaging	Price EXW (USD)*
2 FDC/RH 60/30	Rifampicin 60 mg/Isoniazid 30 mg dispersible, film-uncoated tablets	28 tablets * 3 blisters	1.47
2 FDC/RH 60/60	Rifampicin 60 mg/Isoniazid 60 mg dispersible, film-uncoated tablets	28 tablets * 3 blisters	3.00
3 FDC/RHZ 60/30/150	Rifampicin 60 mg/Isoniazid 30 mg/Pyrazinamide 150 mg dispersible, film-uncoated tablets	28 tablets * 3 blisters	2.14

Oral solid dosage forms: Single dose combination for children

Product	Description	Packaging	Price EXW (USD)*
Ethambutol 100 mg	Ethambutol 100 mg film-coated tablets	10 tablets * 10 blisters	3.60
Isoniazid 100 mg	Isoniazid 100 mg, dispersible tablets	10 tablets * 10 blisters	0.93

Parenteral injectables

Product	Description	Packaging	Price EXW (USD)*
Streptomycin 1 g inj	Streptomycin 1 g powder for injection	100 vials	64.00

SECOND LINE ANTI-TUBERCULOSIS MEDICINES

Group 2: Parenteral injectables

Product	Description	Packaging	Price EXW (USD)*
Amikacin 500 mg inj	Amikacin 500 mg solution for injection (2ml)	1 ampoule in a carton box	1.00
Amikacin 500 mg inj	Amikacin 500 mg solution for injection (2ml)	10 ampoules in a carton box	6.90-8-56
Amikacin 500 mg inj	Amikacin 500 mg solution for injection (2ml)	5 vials in a carton box	8.25
Capreomycin 0.5g inj**	Capreomycin 0.5g powder for injection	1 vial in a carton box	2.99
Capreomycin 0.75g inj	Capreomycin 0.75g powder for injection	1 vial in a carton box	3.99
Capreomycin 1 g inj	Capreomycin 1 g powder for injection	1 vial in a carton box	4.95-6.25
Kanamycin 1 g inj	Kanamycin 1 g solution for injection (4ml)	10 ampoules in a carton box	25.80
Kanamycin 1 g inj	Kanamycin 1 g powder for injection	50 vials in a carton box	45.00

Group 3: Fluroquinolones

Product	Description	Packaging	Price EXW (USD)*
Levofloxacin 250 mg	Levofloxacin 250 mg film-coated tablets	Blister pack of 100 tablets	4.01-8.41
Levofloxacin 500 mg	Levofloxacin 500 mg film-coated tablets	Blister pack of 100 tablets	12.00-16.21
Levofloxacin 500 mg	Levofloxacin 500 mg film-coated tablets	Blister pack of 80 tablets	5.62-5.82
Moxifloxacin 400 mg	Moxifloxacin 400 mg film-coated tablets	5 tablets * 20 blisters	64.51
Moxifloxacin 400 mg**	Moxifloxacin 400 mg film-coated tablets	10 tablets * 10 blisters	64.51
Moxifloxacin 400 mg***	Moxifloxacin 400 mg film-coated tablets	Blister pack of 5 tablets	3.30
Ofloxacin 200 mg	Ofloxacin 200 mg film-coated tablets	Blister pack of 100 tablets	4.92-5.80
Ofloxacin 400 mg	Ofloxacin 400 mg film-coated tablets	Blister pack of 100 tablets	9.00-10-90

(***This product is also available from the originator.)

Group 4: Bacteriostatics

Product	Description	Packaging	Price EXW (USD)*
Cycloserine 250 mg	Cycloserine 250 mg hard capsules	Blister pack of 100 capsules	42.00-43.00
Cycloserine 250mg	Cycloserine 250 mg hard capsules	HDPE container of 100 capsules	33.00
Ethionamide 125 mg**	Ethionamide 125 mg film-coated tablets	Blister pack of 90 tablets	10.06
Ethionamide 250 mg	Ethionamide 250 mg film-coated tablets	Blister pack of 100 tablets	6.57-11.10
Ethionamide 250 mg**	Ethionamide 250 mg film-coated tablets	Blister pack of 90 tablets	5.94
PAS acid	P-aminosalicylic acid (PAS) sachet 4 g enteric coated delayed-release granules in sachets	30 sachets in a carton box	40.00
PAS sodium	100 g of PAS sodium granules 60% w/w	100g in HDPE container	12.49
PAS sodium	PAS sodium salt powder for oral solution 5.52 g sachet	25 sachets in a carton box	34.25
PAS sodium	9.2 g of PAS sodium granules 60% w/w	30 sachets in a carton box	34.50
Prothionamide 250 mg	Prothionamide 250 mg film coated tablets	Blister pack of 100 tablets	14.90-15.53
Prothionamide 250 mg	Prothionamide 250 mg film coated tablets	Blister pack of 140 tablets	18.10
Terizidone 250 mg	Terizidone 250 mg capsules	Blister pack of 50 capsules	79.40-83.30

Group 5

Product	Description	Packaging	Price EXW (USD)*
Amoxicillin Clavunate 250 mg	Amoxicillin clavunate 250/62.5 mg powder for oral suspension	1 bottle	2.03-2.23
Amoxicillin Clavunate 250+125 mg	Amoxicillin 250 mg and clavulanic acid 125 mg film-coated tablet	Blister pack of 14 tablets	2.38-2.92
Amoxicillin Clavunate 250+125 mg	Amoxicillin 250 mg and clavulanic acid 125 mg film-coated tablet	Blister pack of 20 tablets	2.40-2.70
Amoxicillin Clavunate 500+125 mg	Amoxicillin 500 mg and clavulanic acid 125 mg film-coated tablet	Blister pack of 100 tablets	15.92-19.21
Amoxicillin Clavunate 500+125 mg	Amoxicillin 500 mg and clavulanic acid 125 mg film-coated tablet	Blister pack of 15 tablets	2.21
Amoxicillin Clavunate 500+125 mg	Amoxicillin 500 mg and clavulanic acid 125 mg film-coated tablet	Blister pack of 20 tablets	2.70-3.00
Amoxicillin Clavunate 875+125 mg	Amoxicillin 875 mg and clavulanic acid 125 mg film-coated tablet	Blister pack of 100 tablets	22.90
Amoxicillin Clavunate 875+125 mg	Amoxicillin 875 mg and clavulanic acid 125 mg film-coated tablet	Blister pack of 12 tablets	1.89
Amoxicillin Clavunate 875+125 mg	Amoxicillin 875 mg and clavulanic acid 125 mg film-coated tablet	Blister pack of 14 tablets	4.41-4.62
Clofazimine 100 mg	Clofazimine 100 mg capsules	HDPE container(s) of 100	126.72
Clofazimine 50 mg	Clofazimine 50 mg capsules	HDPE container(s) of 100	CHF 59.35
Clarithromycin 250 mg	Clarithromycin 250 mg film-coated tablets	Blister pack of 14 tablets	1.90-4.01
Clarithromycin 500 mg	Clarithromycin 500 mg film-coated tablets	Blister pack of 14 tablets	3.00-6.22
Imipenem/Cilastatin 500 mg + 500 mg	Imipenem 500 mg /Cilastatin 500 mg powder for solution for IV infusion	1 vial	7.32-10.64
Linezolid 600 mg	linezolid 600 mg film-coated tablets	10 tablets * 2 blisters	138.00

New anti-TB medicine

Product	Description	Packaging	Price EXW (USD)*
Bedaquiline 100mg	Bedaquiline 100 mg film-uncoated tablets	Blister pack of 188 tablets	Available on request

PATIENT KITS

Product	Description	Price EXW (USD)*
Cat I & III-A	Stop TB Cat. I+III Patient Kit A: 6 blisters (168) 4-FDC tablets (R150/H75/Z400/E275); 12 blisters (336) 2-FDC tablets (R150/H75)	20.23-22.25
Cat I & III-B	Stop TB Cat. I+III Patient Kit B: 6 blisters (168) 4-FDCs (R150/H75/Z400/E275); 18 blisters (504) 2-FDC tablets (E400/H150)	30.25
Cat I & III-C	Stop TB Cat. I+III Patient Kit C: 6 blisters (168) 4-FDCs (R150/H75/Z400/E275); 6 blisters (168) 2-FDC tablets (R150/H150)	16.17
Cat II-A	Stop TB Cat. II Patient Kit A: 9 blisters (252) 4-FDC tablets (R150/H75/Z400/E275); 60 vials of Streptomycin 1g; 60 vials of water for injection 5ml; 60 2-stroke auto-disabling syringes & needles; 15 blisters (420) 3-FDC tablets (R150/H75/E275)	97.40
Cat II-B	Stop TB Cat. II Patient Kit B: 9 blisters (252) 4-FDC tablets (R150/H75/Z400/E275); 60 vials of Streptomycin 1g; 60 vials of water for injection 5ml; 60 2-stroke auto-disabling syringes & needles; 15 blisters (420) 2-FDC tablets (R150/H75); 10 blisters (280) tablets E400	98.90
Cat II-C	Stop TB Cat. II Patient Kit C: 9 blisters (252) 4-FDC tablets (R150/H75/Z400/E275); 7 blisters (196) 2-FDC (RH 150/150); 7 blisters (196) E400; 60 vials of Streptomycin 1g; 60 vials of water for injection 5ml; 60 2-stroke auto-disabling syringes & needles; 1 Hub cutter	90.40

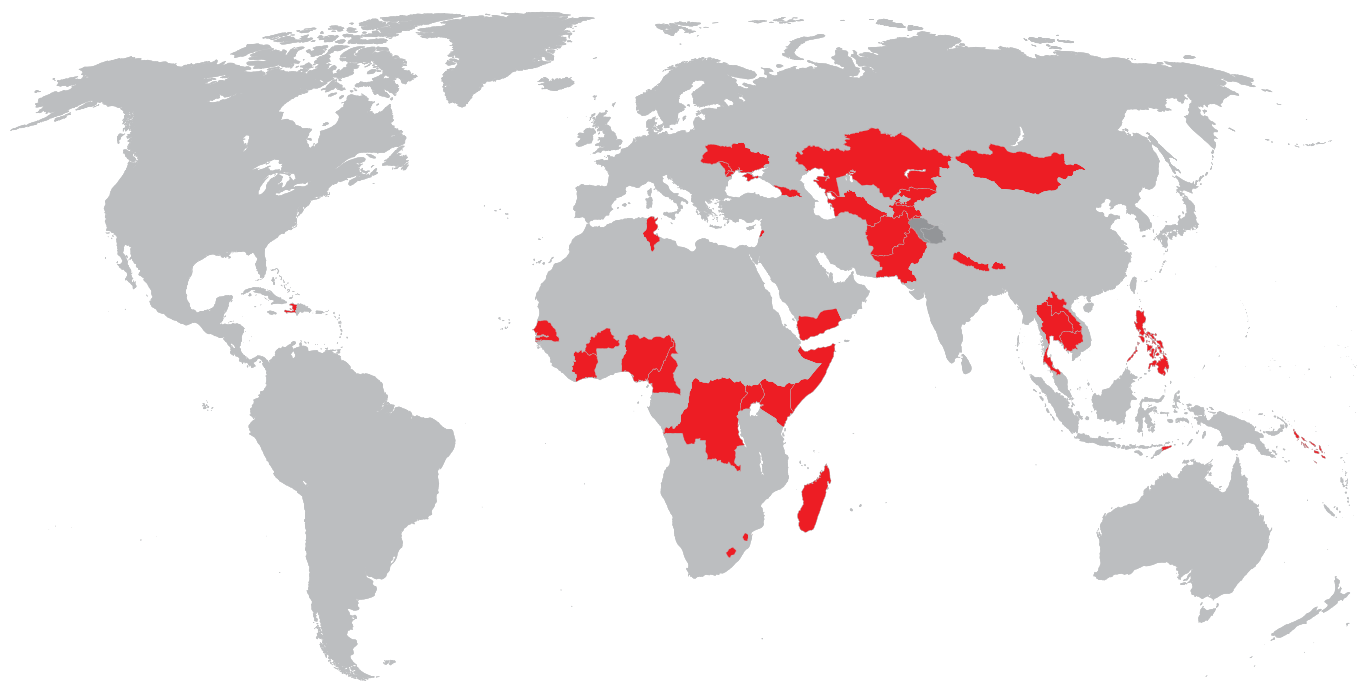
Water for injection and single use sterile medical devices

Product	Description	Packaging	Price EXW (USD)*
Water for injection 5 ml	Water for injection, sterile, 5 ml plastic ampoules	100 ampoules in a box	10.40
Hypodermic AD syringes and safety box for used syringes & needles, 5ml (21Gx1.5, 22Gx1.5, 23Gx1)	Auto-disabling (AD) feature, capacity of 5 ml, sterile, needle dimension 21Gx1.5", 22Gx1.5" or 23Gx1"	100 pieces in a sterile blister pack, 1 safety box per 100 syringes (25 boxes in one carton)	5.18-5.75

* The Product Catalogue displays the highest and lowest product prices offered by GDF's principal suppliers. Prices are valid until 31 December 2014 for first-line medicines and medical devices and 31 March 2015 for second line medicines. For the majority of products, GDF maintains long-term agreements with multiple suppliers, with target market share allocations depending on supplier status. Allocations and supplier status may vary depending on performance, product status and other criteria monitored by GDF and its Procurement Agent. Volume discounts are available for some products. GDF and its Procurement Agent also hold contracts with back-up suppliers and occasionally, products from these suppliers are offered by GDF. Prices listed above indicate the base cost of the product and do not include costs for procurement agent fees, quality control, pre-shipment inspection, transport (air freight or sea freight) or insurance. For budget purposes, GDF clients are strongly advised to utilise the highest product prices displayed in the Catalogue. For more details, please contact GDF at gdf@who.int.

ANNEX IV MONITORING MISSIONS

2012



2013

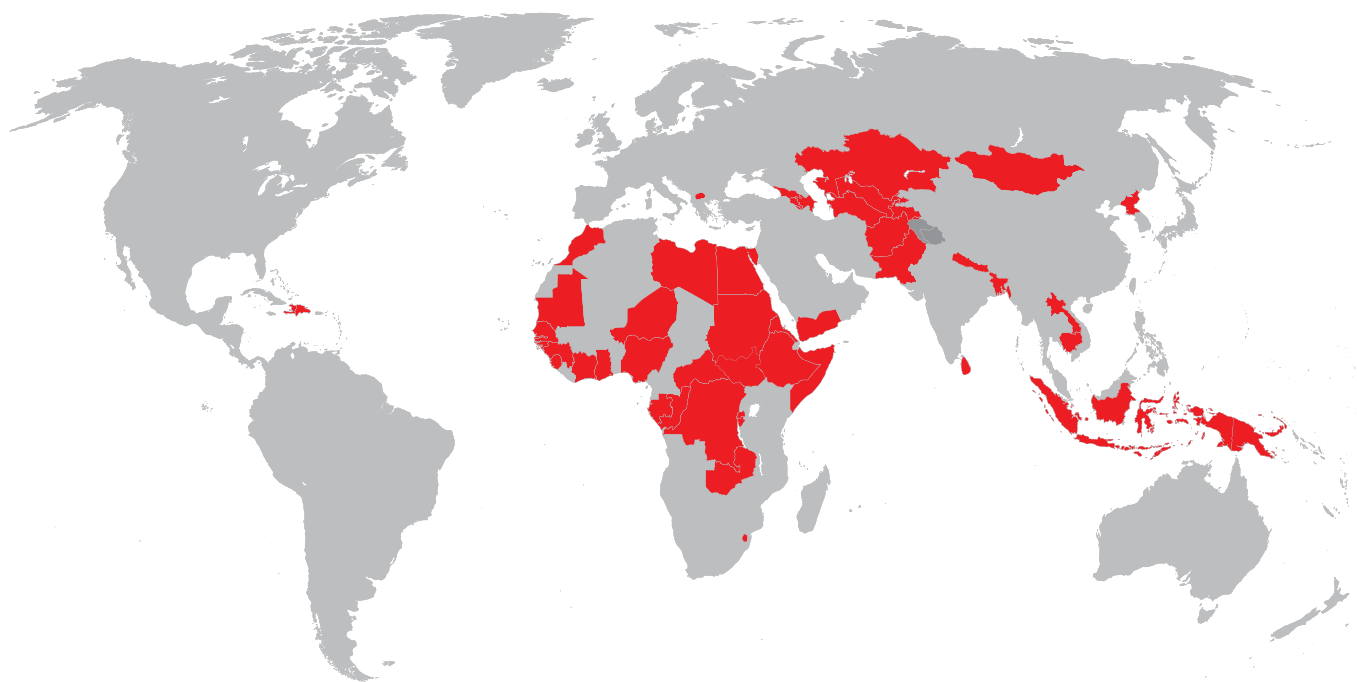


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Stop TB Partnership

www.stoptb.org

World Health Organization

Global TB Programme

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Printed by the
WHO Document Production Services
Geneva, Switzerland

Designed by Tashira Muqtada
The Bright Sun
www.thebrightsun.com

