

# **INDEPENDENT FINAL REVIEW**

## **OF THE PAEDIATRIC TB GRANT TO GDF**

UNITAID

PARTNERS: GDF

5 JANUARY 2015

## **Acknowledgements**

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All views represented in this evaluation are those of Dalberg and do not represent the views of UNITAID, the Project Management and Advisory Groups, or other entities quoted herein.

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## 1 Executive Summary

Between 2006 and 2013, UNITAID granted GDF USD 12,823,105 to procure affordable quality-assured paediatric anti-TB drug formulations. This is an independent final evaluation of the project initiated by the UNITAID Secretariat in November 2014. The purpose of this review is to 1) assess the performance and impact of the project over its lifetime and 2) identify opportunities to improve the design or implementation of future projects.

Findings: Relevance was rated as HIGH

- **The agreement between UNITAID and GDF targeted clear gaps in the paediatric TB market.** In 2006 (before the start of the project), the number of annual cases of TB in children was estimated at 500,000 to 900,000 and treatment coverage was very low in developing countries. There was little global funding available for the procurement of paediatric TB drugs and very few national programmes had dedicated programmes for paediatric TB. Driven by this lack of demand, there were no quality-assured and appropriate paediatric drug formulations on the market. Existing drugs for the treatment of paediatric TB were unsuitable for ensuring successful and safe treatment of children.
- **The project addressed two of UNITAID's strategic objectives.** The grant fulfilled two of UNITAID's six strategic objectives, namely to increase access to paediatric TB medicines and to increase access to products for the prevention of TB.

Findings: Efficiency and effectiveness were rated as MEDIUM

- **GDF achieved the most recent treatment volumes target and supplied the equivalent of 40% of global paediatric case notifications.** GDF effectively delivered 96% of the ~550,000 treatments they agreed to supply under the fourth and final amendment in 2013, but fell short of delivering the ~750,000 treatments agreed in 2008. They were also unable to achieve the 25% coverage of annual incidence, as defined in the original agreements, but did achieve in supplying ~40% of global paediatric TB notifications.
- **GDF procurement achieved progressively lower prices for the most common paediatric products.** GDF secured progressively lower prices for the two products that accounted for 70% of all procurement. The prices of the other three formulations increased, but a number of interviewees felt that products remained affordable throughout the project.
- **UNITAID funding contributed to attracting additional donor funding into the market.** Between 2007 and 2013, the number of global donors funding appropriate paediatric treatments increased from one, namely UNITAID, to four. In that time the number of treatments supplied more than tripled.
- **The number of quality-assured formulations available increased from zero (before the project) to five by 2009.** The number of quality-assured, child-friendly TB treatments increased from zero before the project, to three during the first year, and five by the third year. UNITAID grants undoubtedly contributed to this increase but it is difficult to isolate the impact on market entry of this project alone. However, some interviewees did suggest that the new formulations were developed with the UNITAID-GDF programme in mind.
- **The vast majority of treatments were procured from just two suppliers.** In total there were six manufacturers of child-friendly TB treatments. However, more than 85% of procurement went through two manufacturers. It is difficult to evaluate whether this represents an appropriate and

successful outcome because i) the paediatric TB treatment market operates with small volumes and ii) additional market entrants may have been discouraged by changes to WHO paediatric treatment guidelines or via procurement process issues (see next bullet).

- **GDF experienced a number of challenges relating to their procurement process and procurement agents.** The implementation of a competitive tender process for supplier contracts was repeatedly delayed and the majority of paediatric TB drugs procured under the programme were not supplied under competitive long-term agreements (LTAs). Anecdotal evidence from stakeholders suggests that between 2009 and 2012, a lack of certainty and clarity on these processes negatively affected supplier interest. Country-level stock-outs also increased during this period, although this can also be partially explained by the fact some countries struggled to transition to new funding sources.

Findings: Impact was rated as MEDIUM/HIGH<sup>1</sup>

- **UNITAID grants procured a large number of paediatric treatments, but the public health impact cannot be accurately measured.** UNITAID grants provided funding for the supply of 526,508 curative and 776,980 prophylactic treatments. However, GDF could not measure the number of treatments administered to patients or associated health outcomes due to a lack of monitoring infrastructure in grantee countries. Therefore, it is not possible to assess the full health impact.
- **Several countries have struggled to transition to alternative funding sources since the completion of UNITAID funding.** Transition to new funding sources was slower than expected but it appears that countries will continue to procure quality-assured appropriate drugs using alternative funding.

Recommendations for future projects

- **Develop measurable and consistent targets.** This can encourage easy and precise assessments of project progress and success.
- **Analyse the benefit of using one procurement agent across multiple products.** If appropriate, this can exploit synergies along the supply chain to reduce costs and improve efficiencies.
- **Recognize and prevent actions that needlessly reduce supplier confidence.** This can encourage market entry of new suppliers (where desired) and improve production and delivery efficiencies.
- **Inform targets through economic and epidemiological analysis of how many suppliers a healthy market can sustain.** This can ensure appropriate expectations on the optimal number of manufacturers and enables manufacturers to achieve minimum efficient production volumes.
- **Support national programs to streamline procurement processes.** This can reduce the time delays between provision and approval of quotations, thereby increasing coverage and improving supplier confidence.
- **Plan for and support grantee transition to sustainable funding models.** This can boost the long-term impact of the project by ensuring sustainability of market funding.
- **Assess the need to support the introduction of new formulations into grantee countries.** This can accelerate the uptake of new paediatric treatments in countries that might otherwise have to wait several years.

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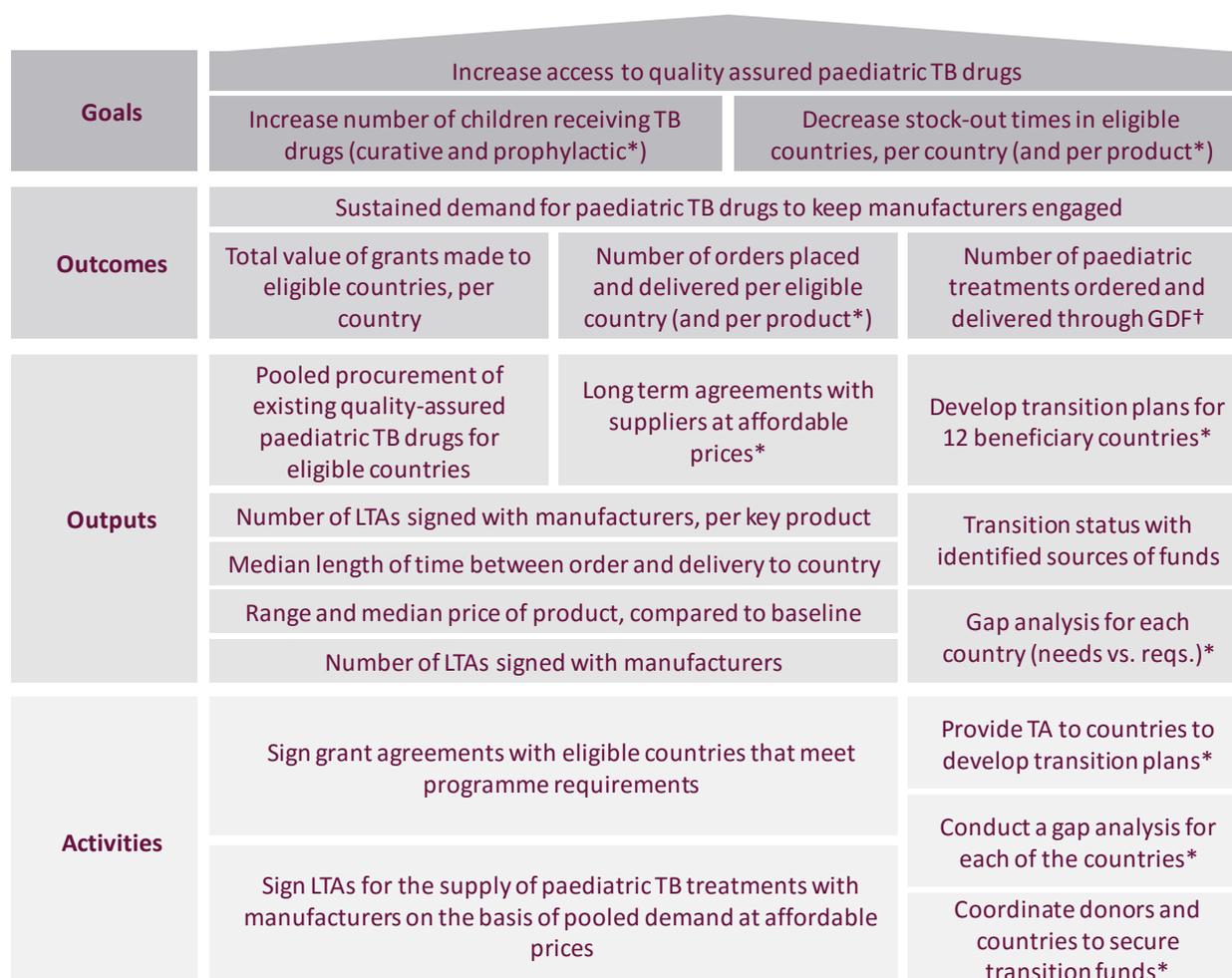
<sup>1</sup> Additionally, the evaluation revealed that reporting and feedback were inconsistent throughout the project, making it difficult to track and independently verify the full impact of the project.

## 2 Theory of Change

A Theory of Change illustrates the linkages between activities, outputs, outcomes, and impact as a means to test and learn from this initiative (see Figure 1). As a whole, the Theory of Change explains how each activity contributed to outcomes that would impact beneficiaries over the course of the project. When available from project outset, a Theory of Change can guide a project by ensuring that the activities undertaken ultimately contribute to desired outcomes and impact. It is also used to show the consistency of metrics used to assess the project over time.

Dalberg created the following Theory of Change based on a combination of a) the original project objectives as mentioned in the final project report b) the 2011 logframe and c) the 2013 logframe. There was no logframe at the beginning of the project, which creates a challenge to assess whether the project achieved its targeted outcomes in the first few years. This report refers to each of the activities, outputs, outcomes, and goals included in Figure 1 as a way of assessing the project's relevance, effectiveness, efficiency, and impact.

**Figure 1: Theory of change for paediatric TB GDF project**



\*Added in 2013 logframe †Excluded from 2013 logframe Please note: Position of indicators in logframe also changes between years in some cases

## **3 Introduction**

### **3.1 Context**

The grant by UNITAID to GDF for the procurement of paediatric TB drugs was one of the earliest UNITAID projects and only the second TB project undertaken by UNITAID. At the time GDF, who were a part of the Stop TB Partnership under the auspices of the World Health Organization (WHO), were already actively involved in the first line (adult) TB drug market and were working in many lower-income countries (LICs).

The state of paediatric TB care globally was widely considered to be very poor in the years before the start of the grant. Very little designated global funding existed for the procurement of paediatric TB drugs. Furthermore the drugs available were, for the most part, expensive and inappropriate for rational use in resource limited systems. National tuberculosis programmes (NTPs) were unlikely to have designated training, procurement or reporting procedures for childhood TB cases.

GDF and other partners were in discussions with existing TB drug manufacturers over the production of child-friendly fixed-dose formulations (FDCs) when they approached UNITAID over the possibility of a new grant for paediatric TB drug procurement. GDF proposed to introduce a pooled procurement mechanism, whereby countries could apply for grants to fund the procurement of paediatric TB drugs through GDF. UNITAID and GDF signed an original agreement in the first quarter of 2007 and after a series of extensions covered by four amendments, the project finally came to end in the final quarter of 2013. More details on the agreement and amendments can be found in the annex.

### **3.2 Objectives of the review**

In 2014, the UNITAID Secretariat initiated a final review to assess the progress of the project over the course of its lifetime. Dalberg Global Development Advisors, an international development consultancy, was selected to complete this review. The objectives of this independent evaluation are threefold:

- To assess the extent to which the project has achieved the agreed objectives
- To assess the effectiveness and efficiency of project implementation in achieving said objectives
- To recommend ways in which lessons from the project could be used to improve future UNITAID projects.

The sections that follow summarize the key findings from the evaluation and provide recommendations on how UNITAID can learn from the project.

## 4 Findings

This section presents the key findings of the final review of the GDF paediatric TB project. As with any market-shaping project, there are a number of challenges to assessing the efficacy of market interventions. For example, there are a host of external factors that could have influenced a market result and project activities can be difficult to disentangle from these external factors. The paediatric TB market is not a closed system, and other factors influenced the market besides GDF's intervention.

Findings are organized into three categories: relevance, effectiveness and efficiency, and impact. As per the TOR, we also include findings on learning and risk mitigation. Figure 2 below presents a high-level summary of key the findings and review ratings for each category.

**Figure 2: Summary of findings**

	Rating	Successes	Challenges
<b>Relevance</b>	<b>HIGH</b>	<ul style="list-style-type: none"> <li>+ Low paediatric coverage pre-project</li> <li>+ No paediatric formulations available pre-project</li> <li>+ Alignment with UNITAID strategic objectives</li> </ul>	<ul style="list-style-type: none"> <li>- Alignment with UNITAID grantee income-group targets</li> </ul>
<b>Efficiency &amp; Effectiveness</b>	<b>MEDIUM</b>	<ul style="list-style-type: none"> <li>+ Delivery of 96% of treatments</li> <li>+ Development of quality assured (QA) child-friendly formulations</li> <li>+ Increase in QA manufacturers</li> <li>+ Overall affordability of drugs</li> </ul>	<ul style="list-style-type: none"> <li>- Coverage of paediatric TB incidence</li> <li>- Initial procurement processes</li> <li>- Increased stock-outs &amp; lead times</li> <li>- Reliance on two suppliers</li> <li>- Country funding transitions</li> </ul>
<b>Impact</b>	<b>MED/HIGH</b>	<ul style="list-style-type: none"> <li>+ Supply of targeted curative and preventative treatments</li> </ul>	<ul style="list-style-type: none"> <li>- Reporting on health outcomes</li> </ul>

## 4.1 Relevance

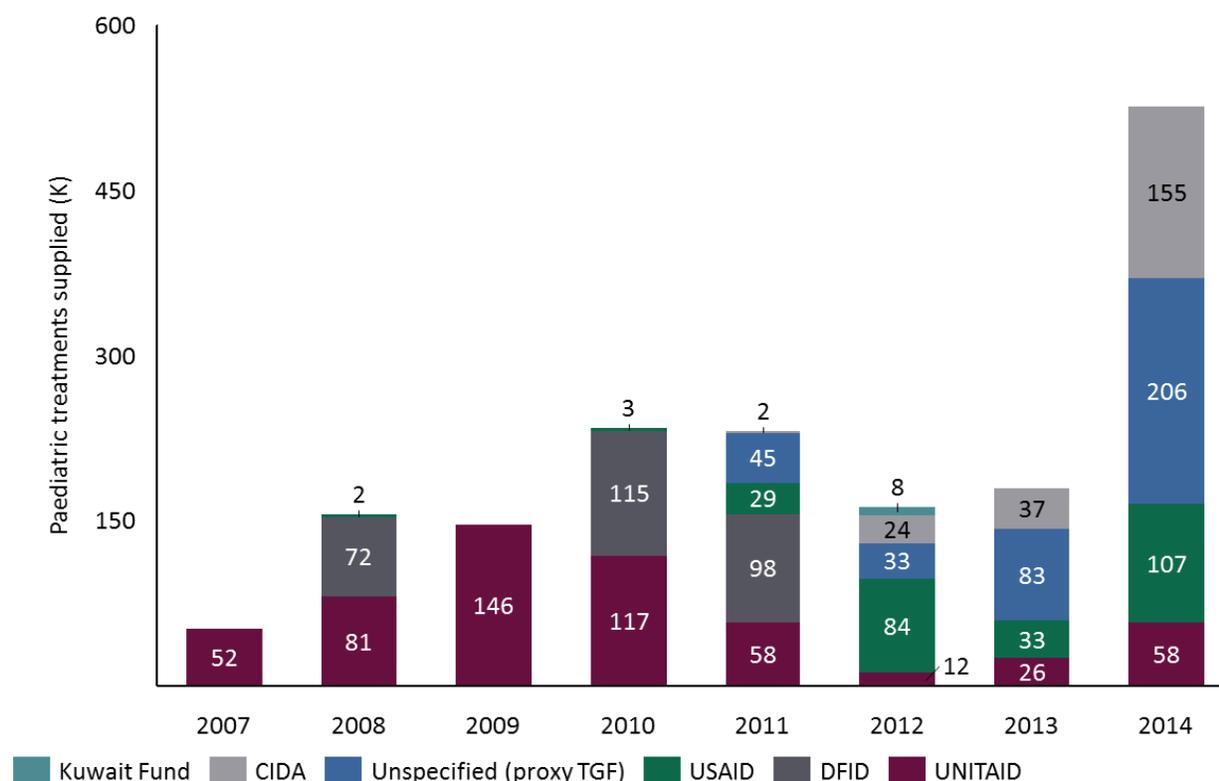
Final review rating: **HIGH**<sup>2</sup>

### 4.1.1 Paediatric TB coverage was very low before the grant

The World Health Organization (WHO) estimates there are up to 500,000 new cases of TB in children annually and that up to 74,000 children die from TB each year<sup>3</sup>. Yet, in 2006, few countries had a national paediatric TB programme and the number of children treated for TB was very low<sup>4</sup>. Reasons for this included a lack of Fixed Dose Combinations suitable for children (see below); a lack of available funding; and a lack of awareness and data to define the need. Diagnosing TB in children is notoriously difficult and national reporting to WHO was not differentiated by age.

The paediatric TB market needed a clear funding source for national paediatric TB programmes in order to increase global coverage of paediatric TB. UNITAID's grant to GDF directly addressed this problem and, in 2007, meant that UNITAID was the sole global funder of paediatric TB drugs (see Figure 3).

**Figure 3: Total paediatric treatments supplied by donor 2007-2014**<sup>5</sup>



<sup>2</sup> Findings constitute a combined qualitative and quantitative assessment of the different areas under review. They represent a summary of evaluator's views. A "high" rating indicates that all or most goals in an area have been achieved; a "medium" rating indicates that a significant portion of goals has been achieved, but that some important gaps exist. A "low" rating indicates that the majority of goals in an area has not been achieved.

<sup>3</sup> WHO 2012, note that these figures would likely be much higher if they included incidence and mortality in co-infected HIV-positive children. GDF assume 900,000 cases in 2007 with a 10% annual increase.

<sup>4</sup> Given a lack of designated treatments and reporting for paediatric TB, it is not possible to estimate the global funding in 2006. However, UNITAID was the only significant funder in 2007 and GDF reports that very few countries under the grant had pre-existing paediatric TB programmes.

<sup>5</sup> Final Report on GDF/UNITAID Paediatric TB Grant 2006-2013, Stop TB Partnership Global Drug Facility (2014)

#### 4.1.2 There was a need for child-friendly TB formulations

In 2006, before the start of the project, child-friendly TB treatments were not available (and no paediatric TB products were WHO pre-qualified (PQ)). NTPs often provided paediatric TB patients with adult formulations. Health workers had to cut up or crush tablets (and potentially mix with water) to provide the dosages specified by contemporary WHO guidelines. This was a cumbersome process and leaves significant room for sub-optimal treatment administration, either increasing the risk of MDR-TB or over-exposing children to drug toxicity (as well as wasting adult formulations). It is clear that national TB programs required new child-friendly TB treatment formulations in order to simplify the administration process; reduce wastage; and increase accuracy of paediatric treatment.

#### 4.1.3 Project objectives were in alignment with UNITAID Strategic Objectives (SO) 2 and 6

UNITAID's grant to GDF was aligned with the UNITAID mission to impact health outcomes and market dynamics in either HIV, TB or malaria. Specifically, the project aimed to "increase access to affordable, paediatric medicines to treat HIV/AIDS, tuberculosis, and malaria" (SO 2). The decision to include prophylactic treatments for children also fulfilled UNITAID's aim to "increase access to products for the prevention of HIV, TB, and malaria" (SO 6).

Further information on UNITAID's strategic objectives can be found in Annex E

#### 4.1.4 GDF did not achieve UNITAID criteria on grantee income classification

GDF reported on income classifications for the distribution of grant orders up until 2010, during which time they did not achieve the target UNITAID criteria. During the first year under the 2<sup>nd</sup> Amendment (2008), UNITAID came closest to achieving the target. However due to a number of factors, including countries changing World Bank income country designations, by 2010 GDF had still not achieved the target balance. UNITAID introduced a portfolio approach to this measurement in 2009 and GDF reporting suggested that, even in 2010, the "deviation for this Project in the TB niche (1 of 5) was not a cause for concern."<sup>6</sup>

**Table 1: Trends in % distribution of UNITAID funds among income groups between 2007 and 2010<sup>7</sup>**

Income classification	2007	2008	2009	2010	UNITAID criteria
LIC	84%	84%	85%	74%	> 85
LMIC	16%	12%	14%	23%	< 10
UMIC	0%	4%	2%	3%	< 5

<sup>6</sup> 2010 Report on GDF/UNITAID Paediatric TB Grant 2006-2013, Stop TB Partnership Global Drug Facility

<sup>7</sup> 2010 Report on GDF/UNITAID Paediatric TB Grant 2006-2013, Stop TB Partnership Global Drug Facility

## 4.2 Effectiveness and Efficiency

Final review rating: **MEDIUM**

### 4.2.1 GDF effectively delivered 96% of the agreed curative treatments and 99% of prophylactic treatments, but struggled to meet the original treatment volume targets

GDF and UNITAID determined the target number of curative treatments for the project based upon target treatment coverage. The original agreement between UNITAID and GDF aimed to cover “10% of global annual incidence” through the procurement of “approximately 100,000 to 150,000 treatments”. Following the first year of the project (Q4 2007), GDF were confident that they would significantly exceed these targets, leading to the first amendment of the contract which allowed for the supply of 600,000 treatments over 3 additional years. This first amendment targeted the “strategic objective of procuring treatment for at least 25% of the market from 2007-2010.” A concurrent second amendment increased the budget available to GDF to cover the procurement of 750,000 paediatric treatments until 2011. GDF intended for this to account for a re-evaluation of the required treatments to reach 24 to 26% of annual paediatric TB incidence (see Table 2 below). In 2012 a 3<sup>rd</sup> amendment was signed to extend the length of the contract by one year, with the same target of 750,000 treatments. In 2013, a fourth amendment provided funding to countries who had not managed to transition to alternative funding sources and set a target of ~790,000 prophylactic treatments. This final amendment also adjusted the target number of treatment down to ~550,000 treatments, citing an overestimation by countries of their needs; grants rejected by the TRC; and a lack of interest in the grant from some countries.

GDF effectively delivered 96% of the ~550,000 curative treatments agreed under the final amendment although this was clearly less than the 750,000 curative treatments envisaged in the second amendment. GDF achieved approximately 70% of this second amendment target. During the same reporting period, GDF supplied 776,980 prophylactic treatments, which was ~99% of the 786,574 target set under the 4<sup>th</sup> amendment.

The initial treatment targets outlined in the first amendment are based on a desire to cover 25% of annual incidence over a three year period. However, the absolute volume of treatments targeted did not change as the length of the grant increased. The first amendment extended the project to 4 years and the second amendment, despite referring to this coverage target, increased the project to 5 years. The 3<sup>rd</sup> and 4<sup>th</sup> amendments increased the project to 7 years and lowered the absolute number of treatments required. Therefore, effectively delivering the agreed number of treatments implies that coverage targets were not met.

Although GDF did not reach the target of covering 25% of paediatric TB annual incidence during the project, it did successfully supply more than 25% of *reported* paediatric TB cases (paediatric notifications). Following the methodology of the original agreement and first two amendments (with the same assumptions of market size), in supplying 526,508 curative treatments<sup>8</sup> (numerator) GDF covered ~18% of 3 years of paediatric incidence (denominator). If the denominator is adjusted to account for the duration of the numerator, namely 7 years, this coverage figure would be significantly less. However, if a more conservative estimate of the target market is used, based on the number of paediatric TB notifications between 2007 and 2012, then UNITAID-procured treatments account for ~40% of the market.

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<sup>8</sup> 96% of 4<sup>th</sup> amendment target

**Table 2: Project coverage of annual estimated incidence under the 2nd amendment<sup>9</sup>**

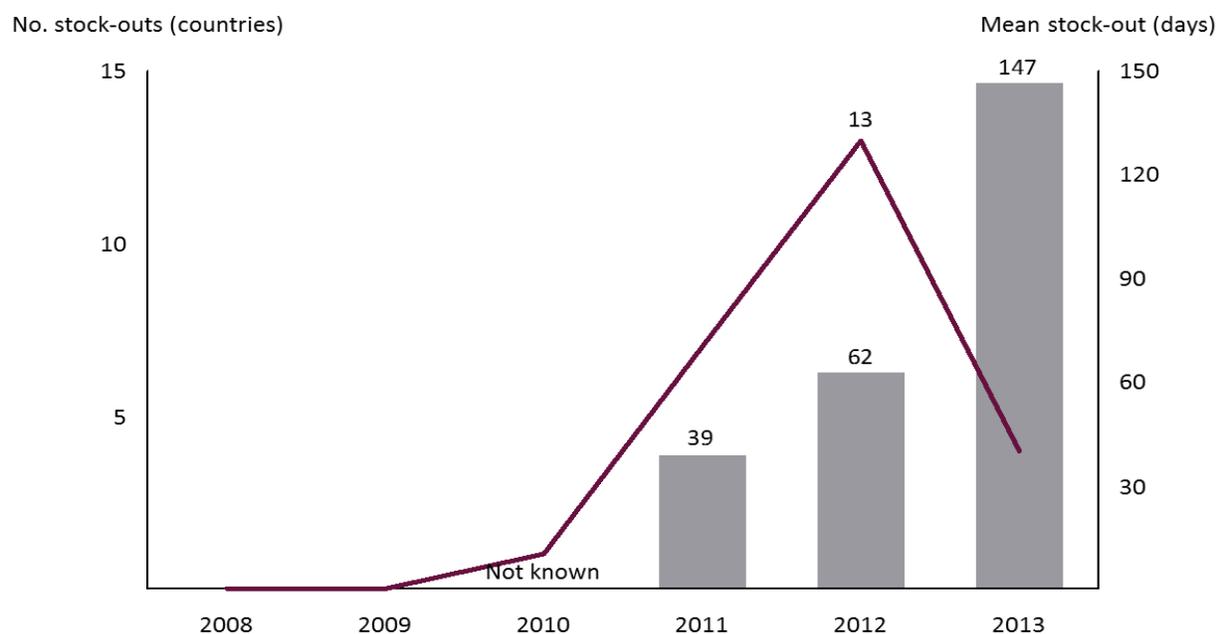
Year	Targeted number of treatments	% coverage of annual incidence
2007-2008	216,033	24%
2008-2009	248,438	25%
2009-2010/11	285,704	26%
<b>Total</b>	<b>750,175</b>	

#### 4.2.2 In the five focus countries, stock-outs were rare but increased significantly in 2011

GDF define stock-outs as “the number of days that a product was not present in a warehouse or health facility over a recent 12-month period (usually the 12 months preceding the one during which the monitoring takes place)”<sup>10</sup> meaning that reporting on stock-outs can only start in the second year of the project. Between 2008 and 2010, stock-outs were very rare. The first stock-out reported by a country procuring through GDF was not until 2010, in Niger. However in 2011 stock-outs rapidly increased, peaking in 2012.

The rise in stock-outs during the second half of the project appears to coincide with some countries finishing their 3-year grants and not transitioning to alternative funding sources in time. During this period, uncertainty over procurement processes, issuing of LTAs, and increased lead times may have also increased the incidence and duration of stock-outs. For further information on procurement efficiency and funding transition, see later sections.

**Figure 4: Number and duration of stock-outs between 2008 and 2013**



Please note: X axis refers to year reported; actual stock-out may have occurred at any point in the preceding 12 months. Data is collected by GDF using monitoring mission reports. Length of stock-out is not always reported and reporting is not always specific (e.g. “a few weeks”).

<sup>9</sup> Final Report on GDF/UNITAID Paediatric TB 2007-2013, Stop TB Partnership Global Drug Facility (2014)

<sup>10</sup> 2010 Report on GDF/UNITAID Paediatric TB Grant 2006-2013, Stop TB Partnership Global Drug Facility

### 4.2.3 The project helped to catalyse the development of child-friendly TB formulations

As mentioned in the ‘relevance’ section, there were no paediatric TB treatments available before the project began. It is difficult to precisely attribute development of new drugs to one particular stakeholder or project, but it is nonetheless likely that this project contributed to the development of new formulations.

Before the start of the project, GDF was in discussions with potential manufacturers of paediatric formulations and, in 2007, GDF procured three quality-assured paediatric formulations using UNITAID funding. According to interviewees, these formulations were newly developed by manufacturers specifically with the UNITAID-GDF program in mind. By 2009, five formulations were available, all of which could be purchased in preferred blister pack packaging (rather than LDPE bags). Furthermore, in 2009, Macleods became a WHO prequalified supplier of dispersible formulations for RH 60/60, RH 60/30, and RHZ 60/30/150. See

Table 3 for details on GDF-procured formulations and manufacturers.

**Table 3: Paediatric product shipments by supplier (for delivery between 2007 and 2013)<sup>11</sup>**

	2007	2008	2009	2010	2011	2012	2013
<b>RHZ 60/30/150</b>	Macleods	Macleods Sandoz	Lupin Macleods	Macleods Lupin	Macleods Lupin	Macleods Lupin	Macleods Lupin
<b>RH 60/60</b>		Macleods Sandoz	Macleods	Macleods	Macleods	Macleods	Macleods
<b>RH 60/30</b>	Macleods	Macleods Sandoz	Lupin Macleods	Macleods Lupin	Macleods Lupin	Macleods Lupin	Macleods Lupin
<b>H 100</b>	Lupin	Lupin Cadila	Lupin Cadila Macleods	Lupin Cadila Macleods	Lupin Macleods	Macleods	Lupin Macleods
<b>E100</b>			Fatol Lupin	Fatol	Fatol Macleods	Fatol Macleods	Fatol Labatec Macleods

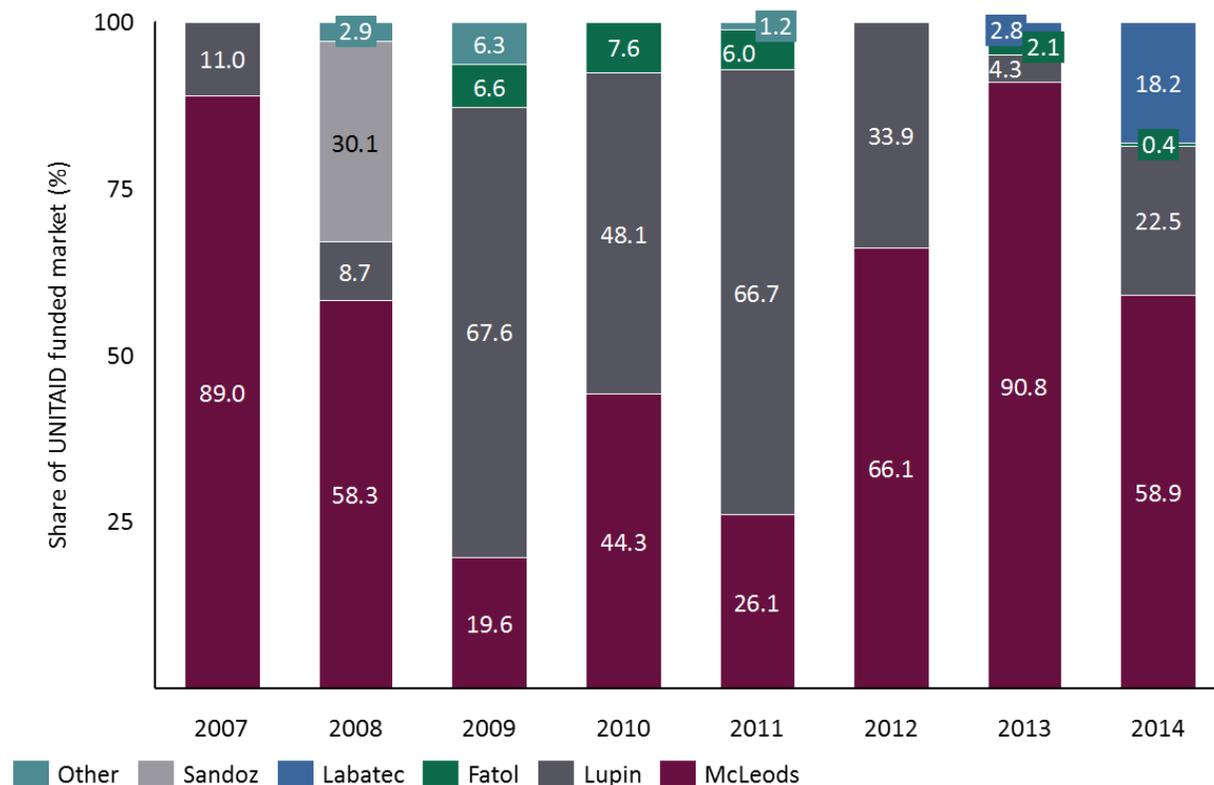
### 4.2.4 GDF procured quality-assured products from six different manufacturers in total, but more than 85% came from two suppliers (Macleods and Lupin)

In the first year of the project, GDF procured treatments from two eligible manufacturers. By 2009, GDF was procuring from four manufacturers with quality-assured medicines. From 2010 onwards, there were no new market entrants (except for Labatec in 2013 for E100), and the market became largely dominated by Macleods and Lupin. In fact, over the duration of the project, 87% of all UNITAID funding was used for treatments supplied by Lupin or Macleods. The precise manufacturer share varies by product and by year (and can be seen in more detail in Annex H). In particular, Macleods obtained more than half of the UNITAID-funded market post 2011, as shown in

<sup>11</sup> UNITAID-GDF procurement database, as supplied by Fabienne Jouberton on November 21<sup>st</sup> 2014

Figure 5. The breakdown of manufacturer share of UNITAID funding by formulation is included in Annex H.

**Figure 5: Destination of UNITAID procurement funds by supplier between 2007 and 2014**



Source: UNITAID-GDF procurement database, as supplied by Fabienne Jouberton on November 21st 2014

While the concentration in the supply-base suggests that competition was limited, it is important to note that a low-volume market with more manufacturers does not always exhibit more desirable market dynamics from a public health standpoint. In markets with small volumes (such as most paediatric TB treatments), there may not be sufficient economies of scale, per manufacturer, to achieve the lowest possible price. In that scenario, the procurement agent must decide between i) allocating procurement to more manufacturers, with a higher average price but greater incentive for more manufacturers to participate in the following year, versus ii) allocating to fewer manufacturers, with a lower average price but less incentive for more manufacturers to participate in the following year. Further analysis into the production economics of paediatric TB treatments would be useful to establish the optimal (but still hypothetical) number of manufacturers that equate to maximum public health outcomes.

In addition, stakeholders offered two additional explanations for the lack of market penetration from other manufacturers.

**WHO Guidelines changed in 2010.** In 2010, the WHO released updated guidelines on the treatment of tuberculosis in children. This advice gave an updated recommendation on the different quantities of

each treatment required in the dosage (see Table 4). As a result, the FDCs produced by each supplier were not in full alignment with these recommendations.

**Table 4: Comparison of Previous and Current WHO Recommendations<sup>12</sup>**

	Previous recommendation (mg/kg/d)	Current recommendation(mg/kg/d)
Rifampicin	8 to 12	10 to 20
Isoniazid	4 to 6	10 to 15
Pyrazinamide	20 to 30	30 to 40
Ethambutol	15 to 20	15 to 25

It was generally accepted therefore that the market lifetime of existing formulations was limited and new FDCs would be needed in the near future to cater to the 2010 guidelines. This acted as a disincentive to potential manufacturers to enter or even remain in the paediatric TB treatment market.

**Absence of formal tenders and LTAs until 2010/11.** Between 2007 and 2010, supplier arrangements were established on an informal basis and long-term agreements were only signed with manufacturers in 2011 (aside from an aborted LTA process in 2010). Several interviewees mentioned that the impact of this was to reduce demand certainty for suppliers, discouraging them from supplying to this market. This is discussed further in Section 4.2.6.

#### **4.2.5 Prices for the two most procured products reduced dramatically over time, whilst prices for other products increased**

In 2007, initial price assumptions (used to calculate coverage targets) were taken from a single market quote from Sandoz in 2006. However, in reality, the prices offered by manufacturers in 2007 were significantly lower than anticipated (approximately 25% of the expected price). Over time, it is clear that products which experienced significant demand increases, also experienced significant price decreases. Those products where demand remained relatively small, saw price increases.

Specifically, procurement of RHZ 60/30/150 increased from around USD 150,000 in 2007 to almost USD 800,000 in 2009. (In total RHZ 60/30/150 accounted for 30% of total UNITAID funding). Over the course of the project, the price was reduced by 88% from USD 0.23 per pill to 3 cents. Similarly for RH 60/30, procurement increased from USD 65,000 in 2007 to over USD 1,000,000 in 2009. (In total, RH 60/30 accounted for 39% of UNITAID funding). During this period prices decreased by 89% from USD 0.16 per pill to just 2 cents.

The one exception to this rule is RH 60/60. Procurement increase dramatically from around USD 30,000 in 2012 to USD 713,148 in 2014. However, prices have remained constant at 4 cents. Throughout this period, there was one supplier of this product, and price stability could be the result of a lack of competition for this specific formulation.

<sup>12</sup> Dosing instructions for the use of currently available fixed-dose combination TB medicines for children: [http://www.stoptb.org/assets/documents/gdf/whatis/Interim%20Paediatric%20FDCs%20dosing%20instructions%20for%20prescribers\\_Sept09.pdf](http://www.stoptb.org/assets/documents/gdf/whatis/Interim%20Paediatric%20FDCs%20dosing%20instructions%20for%20prescribers_Sept09.pdf)

**Table 5: Average price by product (2007-2013)**

USD	2007	2008	2009	2010	2011	2012	2013	Change to 2013 vs first year
<b>RHZ 60/30/150</b>	0.213	0.053	0.032	0.029	0.034	0.026	0.026	-0.187 (-88%)
<b>RH 60/60</b>		0.004	0.023	0.024	0.025	0.036	0.036	0.032 (748%)
<b>RH 60/30</b>	0.158	0.043	0.024	0.021	0.026	0.018	0.018	-0.140 (-89%)
<b>H 100</b>	0.001	0.001	0.007	0.006	0.006	0.020	0.010	0.009 (707%)
<b>E 100</b>			0.031	0.029	0.032	0.033	0.033	0.002 (8%)

It should be noted that several interviewees felt that, although prices varied (both up and down) over the course of the project, products were always affordable.

#### **4.2.6 The project faced significant challenges in implementing efficiency procurement processes, although this improved during the project**

Initial supplier tender processes did not follow the terms proposed in the original agreements and subsequent amendments and there is some (predominantly anecdotal) evidence about the poor performance of procurement agents and a lack of transparency in the first years of the project. That said, there are several important caveats such as the project’s increase in scale, the GDF’s attempt to align QA policy with the Global Fund, and the adjustment to WHO guidelines in the middle of the project. Interviewees from all areas of the project expressed satisfaction with the improved performance of procurement agents in the last years of the project.

GDF selected procurement agents, through a competitive process, according to WHO/GDF procedures and approved by the WHO’s Contracts Review Committee. Between 2006 and 2009, GTZ were GDF’s procurement agent for paediatric drugs. In 2010, PFSCM was the procurement agent but its contract was terminated after 6 months and it was replaced by GIZ (formerly GTZ). The IDA Foundation was selected as the procurement agent for all TB products (including adult) in 2013.

GDF agreed to run a competitive tender, acting through the procurement agent, for the selection of suppliers and the institution of Long Term Agreements (LTAs). During this project, the process for instituting LTAs did not commence until July 2010 and did not come in to effect with manufacturers until May 2011. These LTAs were annulled by new LTA agreements less than a year later in December 2011, after an intervention by GDF.

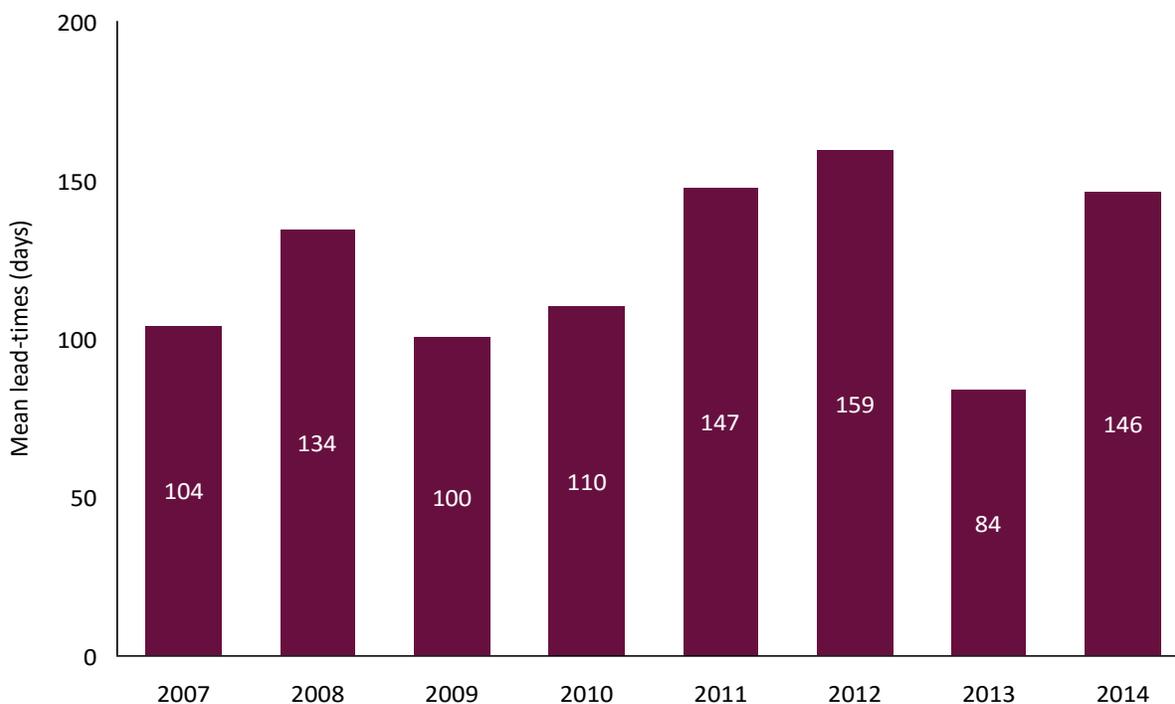
The delays in the procurement process meant the majority of UNITAID funded drugs were not supplied under Long Term Agreements (LTAs) but rather “informal, non-binding, 1-year contracts” with manufacturers. While this was allowed under the original agreement, UNITAID and GDF agreed that “GTZ [now GIZ] will issue a tender no later than end Q2 2007” and that this will be a “competitive tender” resulting in “long term agreements.”<sup>13</sup> GDF reported in 2009 that “the extension period for the current agreements may seem to have been exhausted with respect to accepted public procurement practice ensuring competitiveness, transparency, fairness and best value for money.”<sup>14</sup>

<sup>13</sup> GDF-UNITAID Original Agreement (2006)

<sup>14</sup> 2009 Report on GDF/UNITAID Paediatric TB Grant 2006-2013, Stop TB Partnership Global Drug Facility

In particular, the performance of PFCSM and GIZ appears to have hindered the implementation of LTAs. GDF terminated PFCSM’s contract as a result of their inability to meet internal and external deadlines<sup>15</sup>. Similarly, GDF reported that the LTAs signed by GIZ in May 2011 did not “foresee business share allocations to suppliers”. This increased demand uncertainty for suppliers and appears to have led to longer product lead-times (see Figure 6). A key negative externality that needs to be acknowledged here is that MacLeods, whose PQ product was significantly more expensive than the ERP equivalents, had to be included under the agreements. The aim in not setting supply allocations was to avoid having to procure significantly more expensive products from MacLeods. In reality, the lack of allocations had a negative effect on market confidence and GDF were forced to re-run the bidding process for LTAs using a process that allowed a primary supplier to be ERP, even if a PQ product existed. GDF reported at the end of 2011 that they were “working on restoring faith with suppliers in the competitive processes held by GDF and its Procurement Agent.”<sup>16</sup>

**Figure 6: Average lead-time between 2008 and 2013**



Source: UNITAID-GDF procurement database, as supplied by Fabienne Jouberton on November 21st 2014

It is ultimately difficult to ascertain the full impact of a lack of a competitive tender process on the market. There is evidence that manufacturers were frustrated over the process, and that uncertainty over tenders might have had a negative impact on suppliers’ ability to predict demand. This might have reduced the incentives to pursue pre-qualification; produce new formulations; or stay in the market. However it is has not been possible under the scope of this evaluation to verify, or quantify, the market impact of these factors.

<sup>15</sup> Final Report on GDF/UNITAID Paediatric TB 2007-2013, Stop TB Partnership Global Drug Facility (2014)

<sup>16</sup> 2011 Report on GDF/UNITAID Paediatric TB Grant 2006-2013, Stop TB Partnership Global Drug Facility

It is also important to caveat these observations by acknowledging some of the underlying factors that help to explain the delay in issuing the tender. The amendments to the original agreement significantly altered the scale of the project and the scale of the tender agreements with suppliers. GDF's aim to harmonize their QA policy with the Global Fund caused further delays. Additionally, by 2009, the expected changes to WHO paediatric formulations in 2010 are likely to have adversely impacted the entry of manufacturers in the market (see manufacturer sections) and therefore the viability of a competitive tender for each product.

The situation appears to have improved over the final years of the project. Multiple interviewees identified recent changes to GDF's procurement processes and the choice of the IDA Foundation as the procurement agent of all TB products (including adult formulations) has significantly improved the relationship between GDF and suppliers as well as decreasing procurement agent fees.

#### **4.2.7 Additional donors scaled-up funding for paediatric TB treatments during the project**

The grant by UNITAID to GDF appears to have successfully contributed to increasing donor interest and funding for paediatric TB treatments.<sup>17</sup> In 2007, UNITAID funded 52,128 paediatric TB treatments but by the end of the project in 2013, there were four funders supplying 179,851 treatments (presumably at the higher price experienced in 2013). A year after the end of the project, an estimated 526,219 treatments were supplied by funders, more than 10 times the amount 7 years earlier (see Figure 3). It is difficult to precisely attribute the entry of new funders in to paediatric TB to one particular stakeholder or project, but it seems likely that this project played a role in catalysing new funding sources.

#### **4.2.8 There were no issues relating to diversion of products, counterfeiting or substandard drugs being procured, however cheaper ERP products were procured in place of PQ products**

Several stakeholders, including NTPs, CSOs and GDF HQ staff were asked about the possibility of countries procuring substandard drugs through GDF using UNITAID grant funding. No problems were reported relating to counterfeiting, diversion of products or procurement of drugs that were not quality assured through WHO PQ, SDRA (Stringent Drug Regulatory Authority) or ERP (Expert Review Panel). On one occasion, in 2011, a competitive tender process run by GDF and the Procurement Agent awarded a procurement agreement to the supplier of a ERP product ahead of the supplier of a WHO PQ product.<sup>18</sup>

Generally, GDF policy is to prioritise quality over price, meaning GDF aim to procure WHO PQ products ahead of ERP-approved products, although both fulfil minimum quality standards. It should be noted that where this aim was not achieved, GDF were able to secure significantly lower prices.

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<sup>17</sup> It is important to note that it is impossible to entirely isolate the impact of this project from concurrent catalysts for increased donor funding (e.g. an increased focus on HIV co-infections in children).

<sup>18</sup> UNITAID-GDF procurement database, as supplied by Fabienne Jouberton on November 21<sup>st</sup> 2014; WHO PQ database, accessed November 21<sup>st</sup> 2014

### **4.3 Impact and reporting**

*Final review rating: MEDIUM/HIGH*

#### **4.3.1 UNITAID funding provided 526,508 curative and 776,980 prophylactic treatments under the grant, however public health impact is not directly measured**

The project supplied 526,508 curative treatments and 776,980 prophylactic treatments to countries during the grant period. This figure refers to the number of treatments supplied rather than number of children treated but it is recognised that this falls beyond the scope of the agreement between UNITAID and GDF.

As indicated early in the project, it is not possible for the grantee to report on the health impact of the project in terms of children treated or treatment outcomes. GDF perform monitoring missions on an annual basis that assess the quality of implementation by countries, however the scope of these reports does not allow for the comprehensive tracking of health outcomes.

Anecdotal evidence from interviewees suggests that in high-burden countries, the ability of clinicians to diagnose and treat TB is a major barrier to ensuring all treatments delivered are used, and used appropriately.

#### **4.3.2 Transition to alternative funding sources was slower than expected**

At the end of the standard three-year grant terms many countries struggled to secure alternative funding in order to sustain their paediatric TB procurement. In some cases, monitoring mission reports suggest that countries began to stock-out of drugs at this stage. In order to avoid this, GDF granted emergency funding from other sources to bridge the gap before planned funding from alternative sources became available. In the case of twelve countries, alternative funding could not be found and UNITAID funding provided support for an additional year in 2013 (under a further amendment). At the time of the final GDF report to UNITAID (2014), 40 countries had either secured second-term (T2) funding from GDF or were directly procuring through GDF using alternative donor funding sources.

Emergency funding and grant extensions, as well as support to transition to other funding sources helped to avoid a number of countries from procuring substandard drugs; using adult formulations; or not treating children at all. However, the need for emergency funding suggests that countries under the GDF grant were sometimes not prepared for transition or could not secure funding that commenced before UNITAID grants came to an end. GDF appears to have a lack of visibility on the future funding sources for 24 countries under the programme which is a concern when considering the long term impact of the grant on building a stable quality-assured market.

**Table 6: Transition status (2014)**<sup>19</sup>

	Country	Transition status
1	Afghanistan	2013: GDF direct procurement 2014: GDF grant
2	Bangladesh	GDF grant
3	Benin	Alternative process
4	Burkina Faso	Alternative process
5	Burundi	2013: GDF direct procurement 2014: GDF grant
6	Cabo Verde	GDF grant
7	Cambodia	GDF direct procurement
8	Cameroon	Alternative process
9	Congo, Rep.	GDF direct procurement
10	Côte d'Ivoire	GDF direct procurement
11	Djibouti	GDF grant
12	Egypt, Arab Rep.	GDF grant
13	Eritrea	Unknown
14	Ethiopia	Unknown
15	Gambia, The	GDF direct procurement
16	Georgia	Alternative process
17	Guinea	GDF grant
18	Guinea-Bissau	Alternative process
19	Indonesia	Alternative process
20	Iraq	GDF direct procurement
21	Jordan	GDF direct procurement
22	Kazakhstan	Alternative process
23	Kenya	GDF grant
24	Kiribati	Alternative process
25	Korea, Dem. Rep.	GDF grant
26	Kyrgyz Republic	GDF grant
27	Lebanon	GDF direct procurement
28	Lesotho	GDF grant
29	Macedonia, FYR	GDF grant
30	Madagascar	GDF grant
31	Malawi	GDF direct procurement
32	Mali	Alternative process
33	Mauritania	Alternative process
34	Mongolia	Alternative process
35	Morocco	GDF grant
36	Mozambique	GDF direct procurement
37	Myanmar	GDF grant

<sup>19</sup> Final Report on GDF/UNITAID Paediatric TB 2007-2013, Stop TB Partnership Global Drug Facility (2014). "GDF grant" means funded by GDF grant (unspecified donor); "GDF direct procurement" means funded by alternative source, directly procured through GDF mechanisms; Grey boxes indicate that GDF is no longer involved; "Alternative process" means funded by alternative source through alternative procurement processes

38	Nepal	GDF direct procurement
39	Niger	GDF grant
40	Nigeria	GDF direct procurement
41	Pakistan	GDF direct procurement
42	Papua New Guinea	Alternative process
43	Philippines	Alternative process
44	Rwanda	Alternative process
45	Senegal	Alternative process
46	Sierra Leone	GDF direct procurement
47	Somalia	Alternative process
48	South Sudan	GDF grant
49	Sri Lanka	GDF grant
50	Sudan	GDF grant
51	Swaziland	Alternative process
52	Tajikistan	GDF grant
53	Tanzania	GDF direct procurement
54	Thailand	Alternative process
55	Togo	Alternative process
56	Turkmenistan	Alternative process
57	Uganda	GDF direct procurement
58	Vietnam*	Alternative process
59	Yemen, Rep.	GDF direct procurement
60	Zambia	GDF grant
61	Zimbabwe**	Alternative process

\* Application rejected by TRC

\*\* Country never applied

#### **4.3.3 Reporting and feedback was inconsistent throughout the project**

Inconsistencies in reporting, adjustments to the monitoring and evaluation frameworks and the late addition of a logframe, make it difficult to track the performance of the grantee throughout the project.

Reporting by GDF between 2007 and 2010 was largely comprehensive and informative (with the caveat that the 2007 annual report could not be provided for review). During this period, GDF raised some issues that do not appear to be addressed in the intervening year. For example, whether GDF could and should have continued to report health outcomes to UNITAID.

In 2011, there was a substantial shift in the style and format of GDF reporting after the introduction of the first logframe. In particular, annual reports do not include explanations for underperformance on a subset of targets (for example, lead-time). Project documentation suggests that UNITAID gave feedback on the 2011 report to seek clarification regarding these missing explanations. The final report for the grant does not systematically report on all of the indicators tracked across the project (for example, stock-outs) and there are some discrepancies between GDF reports and information gathered during this evaluation. For example, the number of suppliers to GDF each year.

UNITAID did not complete a mid-term evaluation of the project. This suggests that there was little independent assessment of the performance of UNITAID and GDF during the project and makes it

difficult to ascertain if recommendations for the improvement of the programme were made during the grant and acted upon by any of the parties.

## 5 Recommendations for design of future initiatives

This document is a final evaluation of the GDF paediatric TB project, and as such its purpose is not to direct the course of the GDF project, which has concluded, but rather to enable UNITAID to inform and improve other projects and efforts. This section attempts to distil insights that will support this goal.

### *Project monitoring and evaluation*

**Develop measurable and consistent targets.** It was difficult to assess this grant's overall level of success over the course of this evaluation. Firstly, some targets were set without due consideration to the feasibility of measuring them (e.g. number of children treated with QA paediatric treatments). Secondly, some targets were changed throughout the project, making it difficult to know the most appropriate comparator (e.g. target coverage of notified cases, by country). In the future, all stakeholders should agree on the theory of impact, the way in which progress will be measured, and the attribution methodology. Furthermore, where public health impact is difficult or costly to measure, stakeholders should explicitly decide whether to exclude this metric or make the investment and build the capacity to measure it.

### *Procurement processes*

**Analyse the benefit of using one procurement agent across multiple products.** In markets where transaction costs are particularly high (e.g. markets with short shelf-life products and low shipment volumes), it is important to identify efficiency improvements wherever possible. For GDF, using one procurement agent across multiple products improved efficiency and lowered cost. UNITAID should assess whether there are opportunities within and between other product markets to adopt a similar approach.

**Recognize and prevent actions that needlessly reduce supplier confidence.** A lack of certainty or confidence for suppliers might prevent them from entering a market, cause them to exit prematurely, or result in sub-optimal and inefficient production planning. This lack of certainty can be caused by a lack of clarity or inconsistencies when assessing supplier bids, or when communicating potential expected volume allocations. In addition, there is likely a "quick win" in creating clear guidelines on potential trade-offs between quality assurance and pricing.

**Inform targets through economic and epidemiological analysis of how many suppliers a healthy market can sustain.** Setting targets as part of future market interventions should consider the production economics of each market to ensure they incentivize the most appropriate market outcomes. For example, in markets with low demand but high fixed costs, the relatively high minimum efficient scale might reduce the feasibility for several competitors to enter the market. As such, any targets for manufacturer entry should take this into account.

### *Interaction with national programs*

**Support national program to streamline procurement processes.** GDF uses Country Support Officers to provide assistance to national programs during the project. There were several occasions when country processes took several months to approve quotations, leading to lengthy delays in treatment delivery, and ultimately, a reduced public health outcome. In future programs, UNITAID should work to identify

and address such delays as part of the projects core activities. For example, there might be a way for GDF to pre-agree price ranges with country programs, before running tenders. Recognizing that UNITAID and its grantees have a pre-defined scope, this could be achieved by collaborating with other partners to help maximize the impact of UNITAID interventions.

**Plan for and support grantee transition to sustainable funding models.** The transition away from UNITAID funding towards either Global Fund or domestic resources is important to boost the sustainability of the project's impact. In future, UNITAID should aim to kick-start this process early-on, identify which countries are likely to require additional support, and assess the risks of failure. There are inherent limitations to UNITAID's potential role here so this could require collaboration with other partners.

#### *New formulations*

**Assess the need to support the introduction of new formulations into grantee countries.** Several countries have transitioned to alternative sources of funding for quality-assured paediatric TB treatments (via the Global Fund), whilst others have not yet done so. According to interviewees during this project, those countries which now rely on Global Fund resources for paediatric TB treatment procurement may wait for new formulations to become available, before applying to update their Global Fund-funded portfolio. If countries receive grants and procurement support, uptake of new formulations might be accelerated. For countries without alternative sources of funding, grants for procurement of new formulations would of course be a valuable opportunity. Firstly, this would potentially improve public health outcomes by increasing coverage and avoiding purchase of non-quality-assured medicines. Secondly, it would provide additional time for countries to seek alternative sources of long-term funding for paediatric TB treatment procurement. That said, the existence of a need does not necessarily mean that UNITAID should play that role and provide that support. As such, this is a decision to be made as part of UNITAID's wider strategy.

## 6 Annex A – Methodology

This annex provides an overview of the scope of the final review along with the approach taken to pursue the review's objectives. As stated in Section 3.2, the objectives of this independent evaluation are threefold:

- To assess the extent to which the project has achieved the agreed objectives
- To assess the effectiveness and efficiency of project implementation in achieving said objectives
- To recommend ways in which lessons from the project could be used to improve future UNITAID projects.

### A1.1 Scope

In order to meet the review's objectives, Dalberg was engaged to perform the following activities:

- Review all provided documentation covering the lifetime of the project
- Engage key stakeholders in discussion of the project's successes, challenges, and lessons learned
- Rate the project's performance against its objectives and intended impact
- Describe lessons learned over the lifetime of the project that could inform future UNITAID projects.

### A1.2 Approach

The final review of the A2S2 project was implemented in three phases:

**First phase:** Preliminary planning. The evaluation team:

- Finalized the evaluation framework, including: evaluation questions and methodology
- Requested project documents and other relevant materials from UNITAID and GDF
- Developed interviewee list and compiled interview guide
- Submitted an inception report to UNITAID on planned approach.

**Second phase:** Preliminary assessment and analysis. The evaluation team:

- Interviewed project stakeholders and experts
- Reviewed provided project documents
- Conducted a preliminary assessment of project efforts.

**Third phase:** Final assessment. The evaluation team:

- Drafted final report, refining analyses and findings
- Developed recommendations based on lessons learned
- Shared the draft review with UNITAID for feedback and GDF for fact-checking
- Addressed and incorporated all feedback and submitted final report.

During the first phase of the evaluation, the UNITAID and the evaluation team agreed on the following evaluation questions:

**Figure 7: Methodology for final evaluation**

<b>Relevance</b>	<ul style="list-style-type: none"> <li>• Are the outcome(s) and impact(s) of the grant aligned with UNITAID's overall mission to contribute to the scale up of and access to treatment for HIV/AIDS, malaria and TB for the most disadvantaged populations in developing countries using innovative global market based approaches?</li> <li>• How does the grant contribute to one or more of UNITAID's six strategic objectives?</li> </ul>
<b>Effectiveness</b>	<ul style="list-style-type: none"> <li>• Are the outputs of the grant consistent with the objectives and expected outcomes as described in the project plan? If changes have been made, has the UNITAID Secretariat been involved in discussions about the changes?</li> <li>• Were the outputs of the project achieved within the timeframe specified in the initial project plan?</li> <li>• What are the main factors influencing the achievement or non-achievement of the outputs or overall outcomes across all countries and within each beneficiary country?</li> <li>• What factors have been considered to ensure that value for money has been achieved?</li> </ul>
<b>Efficiency</b>	<ul style="list-style-type: none"> <li>• Can the grant Implementers and their partners demonstrate that national authorities are aware and participating in grant activities at the national level?</li> <li>• How cost efficient and cost effective is grant implementation?</li> <li>• Were challenges raised with the UNITAID Secretariat in a timely manner and did the Secretariat participate in resolving these challenges?</li> <li>• Was the grant's procurement model designed to identify and solve procurement-related problems (where applicable)? <ul style="list-style-type: none"> <li>• Have the supplier selection and other procurement processes and activities used for the Projects been consistent with the (i) agreements between the Grantee and UNITAID</li> <li>• Have procurement processes been efficient and effective in accomplishing the Projects' objectives, notably achieving price reduction of products, increasing access to treatment, making effective use of the existing supplier base, and encouraging new suppliers to enter the market?</li> <li>• Has the Grantee optimized use of the supplier base to encourage competition in the market? When there are multiple manufacturers of the same quality assured product, what is the split of the business between them and how is it determined?</li> </ul> </li> <li>• Were there any issues related to potential diversion of products, counterfeit or quality?</li> <li>• Is the grantee implementation arrangement efficient?</li> <li>• Did the availability of Paeds TB project help to bring in more donor funding in this area of Paeds Tb drugs? What transition arrangements were negotiated in sample countries?</li> </ul>
<b>Impact</b>	<ul style="list-style-type: none"> <li>• Can the grantee report on impact as originally framed in the project plan and LogFrame? If not, has the grant impact been measured in another way?</li> <li>• Where relevant, can the grantee attribute UNITAID's financial support for medicines, diagnostics or preventive products purchased to patients tested or treated in each beneficiary country?</li> </ul>
<b>Learning &amp; risk mitigation</b>	<ul style="list-style-type: none"> <li>• Have lessons learnt been documented and widely disseminated by grantees and UNITAID?</li> <li>• Have programmatic and financial risks been identified and tracked over the course of grant implementation?</li> <li>• Have the findings and recommendations of mid-term evaluations or audits (where relevant) been used to improve grant performance</li> </ul>

During the second phase of the evaluation, the evaluation team reviewed 31 project related documents and interviewed 18 stakeholders. Stakeholders interviewed include representatives of UNITAID, GDF, paediatric TB treatment manufacturers, procurement agents, country programmes and CSOs. A

complete list of documents reviewed and interviews conducted as part of this review can be found in Annex B and Annex D. The interview guide can be found in Annex C.

During the second and third phases of the evaluation, the evaluation team developed and refined findings. A summary of these findings can be found in Section 4. These findings have been grouped in the following categories:

- **Relevance.** Assessment of whether or not the goals of the project, if achieved, would have contributed to UNITAID's objectives and wider efforts to improve the treatment of paediatric TB.
- **Effectiveness & Efficiency.** Evaluation of project outputs compared with those envisioned in the original agreement and subsequent amendments.
- **Impact & Reporting.** Review of the market or health impact (either positive or negative) generated by the project's activities and assessment of the efforts made toward ensuring that the impact of the project will remain after UNITAID funding is withdrawn. Evaluation of the quality of grantee reporting and UNITAID feedback during the project.

For each category, a rating in the range of low to high is provided by the evaluation team. This rating is based on interpretation of key findings and demonstrated progress towards agreed project objectives.

Lessons learned from the project and recommendations for the design of future initiatives are presented in Section 5. This includes lessons and recommendations that are relevant to the design of future projects of a similar type, as well as recommendations relevant to the management of any future project.

## 7 Annex B - Project interview list

This annex provides an overview of the project stakeholders approached and interviewed during the evaluation.

Group	Organization	Name	Title / Affiliation	STATUS
Internal	UNITAID	Lorenzo Witherspoon	Supply officer	Interviewed
Internal	UNITAID	Robert Matiru	TB portfolio manager	Unavailable
Internal	UNITAID	Irina Avchyan	Finance officer	Interviewed
Internal	UNITAID	Yamuna Mundade	Technical officer, TB portfolio	Interviewed
External	Global Fund	Silas Holland		Interviewed
External	Stop TB	Joel Keravec	Manager	Interviewed
External	Stop TB	Andrea de Lucia	Technical officer	Interviewed
External	Stop TB	Nigorsulton Muzafarova	Quality assurance officer	Interviewed
External	Stop TB	Fabienne Jouberton	Procurement officer	Interviewed
Manufacturer	Lupin	Mr. Shrikant Kulkarni	VP of International Business	No response
Manufacturer	Macleods	Mr. Vijay Agarwal	President	Interviewed
Manufacturer	Svizzera	Mr. Boudwin Ploos van Amstel	CEO	Interviewed
Procurement	IDA foundation	Edwin de Voogd	President	Interviewed
CSO	WHO	Andrea de Lucia	Cambodia	See above
CSO	WHO	Elena Mochinova	Tajikistan	Unavailable
RSO	WHO	Caroline Bogren	Bangladesh	Interviewed

CSO	WHO	Alessio Mola	Bangladesh and Mozambique	Interviewed
CSO	WHO	Annette Kasi Nsubuga	Ethiopia	No response
In-country	Cambodia NTP		Not provided by GDF	NA
In-country	Tajikistan NTP	Dr Oktam Bobokhojaev	Director	Interviewed
In-country	Tajikistan NTP	Gulnora Jalilova	Drug Coordinator	Interviewed
In-country	Bangladesh NTP	Dr Md. Quamrul Islam	Manager	Interviewed
In-country	Bangladesh PSM	Dr Md. Abdul Hamid	GDF focal point	No response
In-country	Ethiopia MoH	Mr. Sufyan Abdulber	Pharmaceutical Logistics Management Unit Coordinator	No response
In-country	Mozambique NTP	Dr Ivan Manhica	Manager	No response
In-country	Mozambique MoH	Dr Carla Matos	Program Management Unit Coordinator	Interviewed
Expert		Professor Robert Gie	Paediatrician and GDF advisor	Interviewed

## 8 Annex C – Interview guide

This annex details the interview guide used during interviews with project stakeholders. Please note that the final interview structure and content was adjusted for each individual, depending on their experience.

### General

1. How and why did UNITAID and GDF initiate the project?
2. What impact did UNITAID and GDF expect to have?
3. What were the major successes of the project?
4. What the major challenges faced by project?

### Areas of discussion

#### **GDF contracting**

- Grants
  - What is the process to approve and renew grants?
  - What activities were covered by grants?
- LTAs
  - What is process to approve and renew LTAs?
  - What activities were covered by LTAs?

#### **Procurement and delivery**

- Procurement agent contracting
  - What were the criteria and process for selecting procurement agents?
  - Which organizations were contracted?
  - How did they perform? (linked to following questions)
- GDF / procurement agents activities and performance
  - Procurement
    - What was the process for procurement?
    - What were the approval and oversight mechanisms?
  - Distribution
    - How were responsibilities allocated between different actors?
    - What was the lead time and which factors impacted lead time?
    - Was any wastage (or any other issue) reported during this process?
  - Prices
    - How were baseline prices calculated
    - What prices were achieved over the course of the project?
    - To what extent to these prices represent value for money?
  - Volumes
    - How many paediatric TB drugs were procured? [*by country, manufacturer, formulation*]
    - How did this compare to country need?
  - Formulations
    - How were formulations chosen? How did this change over time?
    - How did GDF engage with manufacturers to promote new formulations?

- Quality
  - What were the quality requirements and how were quality checks made?
  - What was the quality performance?
  - Were there any issues relating to counterfeiting?
- Allocation between manufacturers
  - What method did GDF use to allocate volumes to manufacturers?
    - Did this method encourage competition?
    - Did this method encourage new supplier market entry?
  - What was the allocation between manufacturers?
  - How did this compare with the log frame and original project objectives? If different, why?

#### **Final use**

- How many treatments were used?
- How were treatments used?
  - How many treatments were used in alignment with guidelines?
  - How did GDF ensure appropriate use of paediatric treatments in-country?
- What were the challenges associated with reporting usage?

#### **Reporting**

- How does GDF verify data provided by countries and contracted agents?
- Does reporting provide clear indicators of success and failure based on originally agreed metrics?
- Do subsequent communications clearly outline progress towards recommendations?

## 9 Annex D – Document list

This annex provides an overview of the project documentation provided and reviewed during the evaluation.

Document	Section	Reviewed
Original agreement	Contract	Yes
	Project plan	Yes
	Annexes	Not available/provided
1 <sup>st</sup> amendment	Contract	Yes
	Project plan	Not available/provided
	Annexes	Not available/provided
2 <sup>nd</sup> amendment	Contract	Yes
	Project plan	Yes
	Annexes	Yes
3 <sup>rd</sup> amendment	Contract	Yes
	Annexes	Yes
4 <sup>th</sup> amendment	Contract	Yes
	Annexes	Yes
Cost-extension	Memo	Yes
Inception report	ALL	Not available/provided
2007 interim report	ALL	Yes
2007 annual report	ALL	Not available/provided
2008 annual report	ALL	Yes

2009 annual report	ALL	Yes
2010 annual report	ALL	Yes
2011 annual report	Data & analysis	Yes
	Feedback	Yes
2012 annual report	Data & analysis	Yes
2013 annual report	ALL	Not available/provided
Final report	ALL	Yes
Mid-term evaluation	ALL	Not available/provided
Procurement agent contracts (CONFIDENTIAL)	2013 (example)	Yes
	2007-2012	Not available/provided
Supplier contracts (CONFIDENTIAL)	2014 (example)	Yes
	2007-2013	Not available/provided
BID evaluation report (CONFIDENTIAL)	2011	Yes
Monitoring mission reports	Mozambique	Not complete (2)
	Bangladesh	Yes (4)
	Ethiopia	Not available/provided
	Cambodia	Yes (3)
	Tajikistan	Not available/provided

## 10 Annex E – UNITAID strategic objectives

This annex provides an overview of strategic objectives of UNITAID.

**Strategic Objective 1:** Increase access to simple, POC diagnostics for HIV/AIDS, TB, and malaria

**Strategic Objective 2:** Increase access to affordable, paediatric medicines to treat HIV/AIDS, tuberculosis, and malaria

**Strategic Objective 3:** Increase access to emerging medicines and/or regimens, as well as new formulations, dosage forms, or strengths of existing medicines that will improve the treatment of HIV/AIDS and co-infections such as viral hepatitis.

**Strategic Objective 4:** Increase access to artemisinin-based combination therapies (ACTs) and emerging medicines, that, in combination with appropriate diagnostic testing, will improve the treatment of malaria

**Strategic Objective 5:** Secure supply of second-line TB medicines, and increase access to emerging medicines and regimens that will improve treatment of both drug-sensitive and multi drug-resistant TB

**Strategic Objective 6:** Increase access to products for the prevention of HIV, TB, and malaria

## 11 Annex F – 2011 logframe

This annex includes the 2011 project logframe

Project Description	Verifiable Indicators	Means of Verification	Assumptions and risks	Reporting Frequency
<b>Goal (Impact): CONTINUING ACCESS TO EXISTING QUALITY ASSURED PAEDIATRIC TB DRUGS PENDING THE AVAILABILITY ON THE MARKET OF THE NEW RECOMMENDED FORMULATIONS</b>				
Indicator G1.1	Estimated number of children treated with quality-assured paediatric TB drugs through this project.	Web based live report (data source: Order Management System)		Annual & Semi-Annual Reporting
Indicator G1.2	Percentage of time that paediatric TB drugs are not available by eligible countries	Manual report through monitoring mission reports		Annual & Semi-Annual Reporting
<b>Purpose (Outcome): SUSTAINED DEMAND FOR PAEDIATRIC TB DRUGS TO KEEP MANUFACTURERS ENGAGED</b>				
Indicator P1.1	EXW and All fee included value of UNITAID paediatric grants (order placed and delivered) per country and in total	Web based live report (data source: Order Management System)		Annual & Semi-Annual Reporting
Indicator P1.2	Number of orders placed and delivered for each eligible country and in total	Web based live report (data source: Order Management System)		Annual & Semi-Annual Reporting
Indicator P1.3	Number of Paediatrics patient treatments ordered and delivered through GDF by country	Web based live report (TB implemented)		Annual & Semi-Annual Reporting
<b>Output 1: Pool-procurement of existing quality-assured paediatric TB drugs for 58 eligible countries under GDF policies and processes for procurement and monitoring &amp; support</b>				
Indicator O1.1	Number of LTAs per key product signed with manufacturers	Web based live report (data source: Order Management System)	Assumption is that products procured & supplied are meeting GDF Quality-Assurance Policy	Annual & Semi-Annual Reporting
Indicator O1.2	Range, interquartile range and median price by product compared with baseline prices	Web based live report (data source: Order Management System)		Annual & Semi-Annual Reporting
Indicator O1.3	Median lead time from order placed to first delivery per country and globally by manufacturer for UNITAID supported Programmes	Web based live report (data source: Order Management System)		Annual & Semi-Annual Reporting
<b>Activity A1.1: Sign grant agreements with the 58 national TB programmes eligible under this Project that meet programmes requirements (type of drugs &amp; quantities and anticipated order timeline)</b>				
Indicator 1	Number of grant agreements signed	manual report	Risk of change in World Bank income classification of eligible countries that may create non-adherence to UNITAID budget allocation requirements ( 85% to LIC;> 10% to LMIC; > 5% to UMIC)	Annual & Semi-Annual Reporting
<b>Activity A1.2: On the basis of a pooled demand, issue tender to or directly negotiate with manufacturers of quality-assured paediatric TB drugs, and conclude long term agreements (LTAs) with suppliers at affordable prices</b>				
Indicator 1	Number of LTAs signed with manufacturers for supply of paediatric TB treatments	Web based live report (data source: Order Management System)	Assumption is that products procured & supplied are meeting GDF Quality-Assurance Policy	Annual & Semi-Annual Reporting
Indicator 2	GDF secured cost per patient treatment compared to baseline cost	Web based live report (data source: Order Management System)		Annual Reporting
<b>Activity A1.3: Procure and supply approx. 750,176 treatments to the 58 countries according to grant agreements</b>				

Project Description	UNITAID: Key Performance Indicator
Goal (Impact): CONTINUING ACCESS TO EXISTING QUALITY ASSURED PAEDIATRIC TB DRUGS PENDING THE AVAILABILITY ON THE MARKET OF THE NEW RECOMMENDED FORMULATIONS	Area 1 : Impact of UNITAID on the market for products to treat, diagnose and prevent HIV/AIDS, TB and malaria
Purpose (Outcome): SUSTAINED DEMAND FOR PAEDIATRIC TB DRUGS TO KEEP MANUFACTURERS ENGAGED	Area 1 : Impact of UNITAID on the market for products to treat, diagnose and prevent HIV/AIDS, TB and malaria
Output 1: Pool-procurement of existing quality-assured paediatric TB drugs for 58 eligible countries under GDF policies and processes for procurement and monitoring & support	Area 3 Action 1: Track treatments, diagnostics and related products delivered and estimated patients treated by UNITAID funded projects by beneficiary country and over time
#REF!	Area 1 Action 3: Improve quality of medicines, diagnostics and related products

A5: Risk Assessment			
Project Description	Risk	Probability of Occurrence	Magnitude of Impact
Purpose (Outcome): SUSTAINED DEMAND FOR PAEDIATRIC TB DRUGS TO KEEP MANUFACTURERS ENGAGED	Eligible countries may not request their grants and/or their grants may not be approved under the GDF monitoring and review processes for grant renewal (i.e. meet GDF terms and conditions for grant approval, including programmatic and WHO standards requirements)	Medium	Low
Output 1: Pool-procurement of existing quality-assured paediatric TB drugs for 58 eligible countries under GDF policies and processes for procurement and monitoring & support	Risk not to be able to sustain manufacturers interest in the perspective of changes in formulations guidelines	Low	High
#REF!	Risk 1: formulations development may not be eligible for UNITAID funding Risk 2: WHO/EMP may not submit a separate proposal addressing the need for paediatric TB formulations development	Low	High

## **12 Annex G - Project amendments**

This annex provides an overview of the original agreement and subsequent amendments between UNITAID and GDF, as provided in the project's final report.

Recognizing this untackled disease burden, UNITAID concluded an agreement coordinated by the Global Drug Facility (GDF) of the Stop TB Partnership on 10 January 2007 for the 'Project Support for Paediatric TB 2006 Q4 and 2007'. This agreement provided USD 5,665,000 through UNITAID to GDF for the supply of 150,000 paediatric ant-TB treatments for children in 20 countries.

### **1st Amendment**

In December 2007, a 1st Amendment (no-cost extension) was signed which expanded and extended the Paediatric Project from 20 countries and 150,000 paediatric patient treatments to 40 countries and up to 600,000 paediatric patients treatments. It further extended the project timeframe from 31 December 2007 to 31 December 2010. The increase in countries and patient treatments were a direct result of cost savings due to pooled procurement. The increased timeframe of the project further allowed for the project's activities to be built into GDF's regular 3 year grants. A revised target for this amendment was to supply at least 25% of the estimated global paediatric incidence per year from 2007 – 2010.

### **2nd Amendment**

In December 2008, a 2nd Amendment (cost-extension) was concluded to extend the project timeframe until December 2011 and increase the project budget to USD 11,288,409. The reason for the request for additional funds were to cover the underestimation at the start of the Project of the optimal number of countries constituting the minimum threshold of demand aggregation required to positively influence market dynamics for paediatric anti-TB drugs. Other programmatic justifications for the increase were provided in the 2nd Amendment request. This Amendment also increased the number of countries included in this project to 61 countries.

### **3rd Amendment**

In December 2011, the 3rd Amendment was signed as a no-cost extension for the project until 31 December 2012 to allow for the completion of the grant terms (3-year cycle) for approved countries. Further, the project logframe was revised along with a re-programming of the Budget, as there was a cost-savings of USD 934,300 (Table 5)

### **Extension Paediatric TB Project**

In 2010, GDF submitted a proposal to UNITAID Executive Board for the increase in drug costs related to applying the new treatment guidelines for children (2009). As new formulations did not exist to allow for the easy implementation of the dosing requirements, countries would need to use more of the current drugs to meet the recommended dosages. In turn, it was foreseen an increase in treatment costs

requiring more funding. The 12th Session of the Executive Board approved the increase of USD 2,207,486 for this purpose.

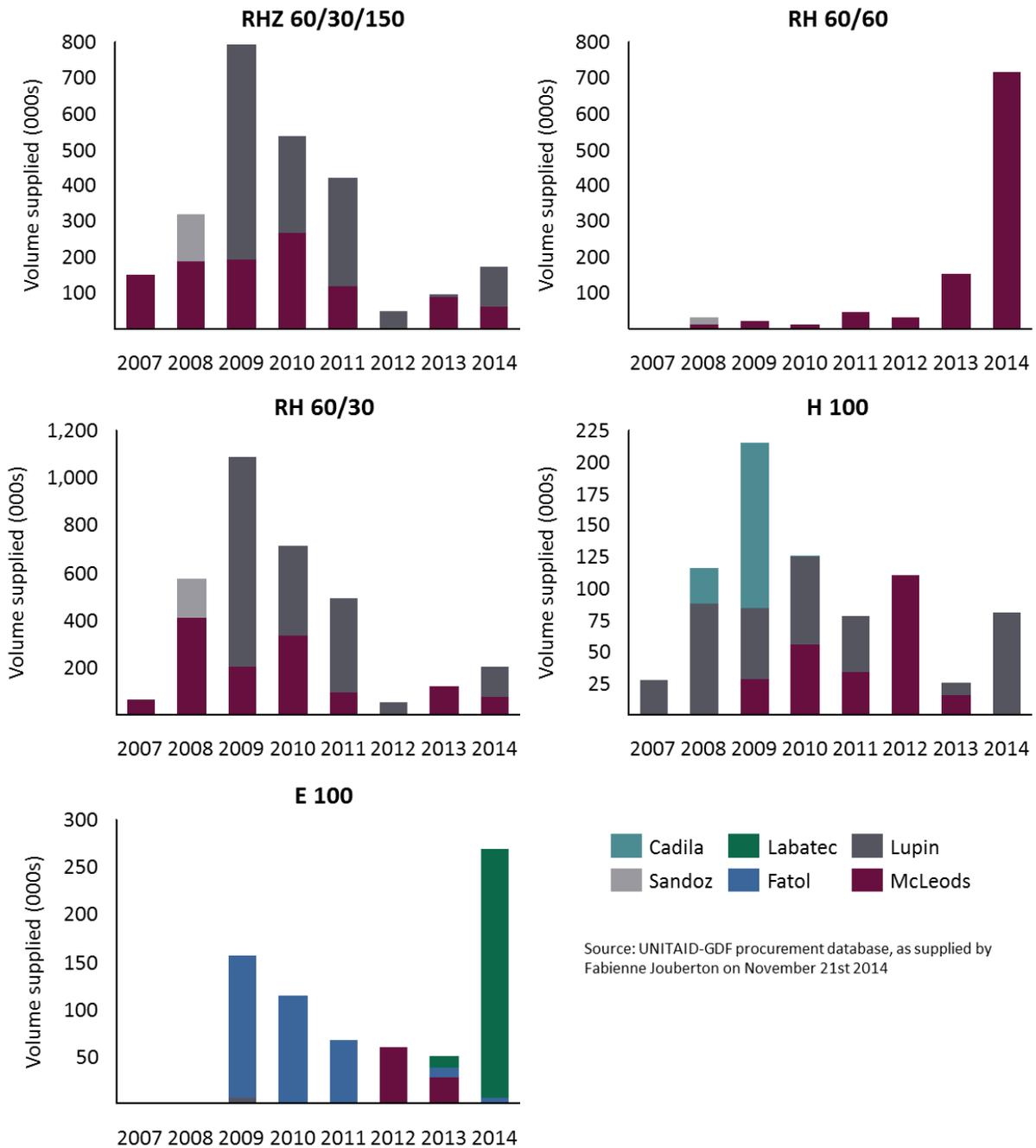
#### **4th Amendment**

In March 2013, a 4th Amendment cost-extension was concluded between UNITAID and Stop TB Partnership, which provided continued funding (additional 1 year grants) for 12 countries (from the originally approved 61 countries) and an additional USD 1,534,696 to cover this support.

The additional funding came from an original approval in June 2010 by the UNITAID 12th Executive Board to grant an additional USD 2,207,486 to reduce the risk of treatment disruption due to the associated drug costs of additional medicines needed to follow the new paediatric treatment recommendation (See section on Milestones 2009, 2010). As there was a slower than expected transition to the new treatment guidelines, GDF had not asked for the disbursement of this money prior to the end of the project.

### 13 Annex H – Manufacturer market share by product

This annex provides a detailed breakdown of manufacturer shares, by paediatric TB product, for the duration of the project.



Source: UNITAID-GDF procurement database, as supplied by Fabienne Jouberton on November 21st 2014