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# Stop TB Partnership

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Partnership profile  
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## List of acronyms

CDC	US Centers for Disease Control and Prevention
CIDA	Canadian International development Agency
DOTS	Directly Observed Treatment, Short course
EDB	Singapore Economic Development Board
GDF	Global Drug Facility
GFATM	Global Fund to fight AIDS, TB and Malaria
GLC	Green Light Committee
GPPI	Global Public-Private Initiative
HBC	High-Burden Country (i.e. high TB disease burden)
IPPPH	Initiative on Public-Private Partnerships for Health
IUATLD	International Union Against Tuberculosis and Lung Disease
KNCV	Royal Netherlands Tuberculosis Association
MDR-TB	Multi-Drug Resistant TB
MSF	Médécins Sans Frontières
NGO	Non-Governmental Organization
NITD	Novartis Institute of Tropical Diseases
NTP	National TB Control Programme
OSI	Open Society Institute
PPP	Public-Private Partnership
RBM	Roll Back Malaria
RIVM	National Institute of Public Health and Environmental Protection
STAG	WHO Strategy & Technical Advisory Group
TB	Tuberculosis
TB Alliance	Global Alliance for TB Drug Development
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
WEF	World Economic Forum
WHO	World Health Organization

## Introduction

This report forms part of a broader research project on the role of companies in public-private partnerships (PPPs). Such collaborations have become an increasingly important way to stimulate sustainable development. The research project aims to contribute to a better understanding of the rationale, functioning and effectiveness of these partnerships.

This report describes and analyses the Stop TB Partnership, a Global Public-Private Initiative (GPPIs) for health. GPPIs are a specific type of public-private partnerships. The report focuses on the role of private sector partners in the operations and governance of Stop TB. It does not evaluate outcomes or effectiveness in much detail, nor does it provide an analysis of each company's approach to GPPIs for healthcare in general. These issues are addressed in separate reports by SOMO, including three reports on individual companies (Aventis, GlaxoSmithKline, Merck & Co).<sup>1</sup> These reports relate their involvement with GPPIs to the core-business of the companies and to broader company strategies and policies for corporate social responsibility. Field studies on the implementation of the GPPIs in developing countries, conducted by partner organizations of WEMOS, form part of the broader research project.<sup>2</sup>

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<sup>1</sup> See <http://www.somo.nl>.

<sup>2</sup> At the release of this report, the reports of the field studies were still being edited. When they are finished, they will be placed on the WEMOS website, <http://www.wemos.nl>.

## 1 Short description of Stop TB

Stop TB is a campaign as well as a partnership. The Stop TB Partnership was established by the World Health Organization (WHO) in November 1998 as a broad-based social movement to fight tuberculosis. It started as a collaboration between a small number of agencies working on TB control. Since its establishment, it has grown rapidly and evolved into a broader global movement, sometimes called the Global Partnership to Stop TB.<sup>3</sup> The Stop TB Partnership is an example of a Global Public-Private Initiative (GPPI) or public-private partnership.

In 2001 the Partnership launched the Global Plan to Stop TB, a strategic plan shared by all partners. It aims to reduce the global TB burden in half by 2010 relative to 2000 levels, and sets targets with required inputs and measurable outcomes. The most important global targets are detecting 70% of people with infectious TB and curing 85% of those detected by 2005.<sup>4</sup> For treatment of TB, the so-called Directly Observed Treatment, Short course (DOTS) programme is recommended. This treatment programme has a 95% cure rate and prevents the development of drug resistance.<sup>5</sup> DOTS expansion, the introduction of DOTS programmes where they are not yet implemented, therefore forms an important part of the Stop TB strategy. However, in March 2004 the WHO estimated that only 27% of people with infectious TB were treated in DOTS programs. Unless there is a rapid acceleration of DOTS expansion, the global targets for 2005 will not be met until 2013.<sup>6</sup>

The Stop TB Partnership coordinates and guides the efforts of individual partners and separate partnerships, which are responsible for the implementation of TB programmes and for providing the resources required for these programmes. An example of a separate partnership is the Global Alliance for TB Drug Development (TB Alliance). The TB Alliance supports R&D programmes for new TB drugs. Hence, many activities to fight TB are coordinated within Stop TB, but not implemented by Stop TB itself. Much of the coordination between partners takes place in the six Working Groups of the Stop TB Partnership.

Apart from coordination and overall strategic guidance, the Stop TB Partnership also provides first-line TB treatments to developing countries through the Global Drug Facility (GDF). The GDF donates these drugs to the poorest countries and since 2003, the GDF also has a direct procurement mechanism. This mechanism enables other governments, Non-

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<sup>3</sup> STOP TB website, [http://www.stoptb.org/world.tb.day/WTBD\\_2003/News/Press\\_Release\\_Partnership.htm](http://www.stoptb.org/world.tb.day/WTBD_2003/News/Press_Release_Partnership.htm), accessed in August 2004; IPPPH website, <http://www.ippph.org>, accessed in August 2004.

<sup>4</sup> Stop TB website, [http://www.stoptb.org/world.tb.day/WTBD\\_2003/News/Press\\_Release\\_Partnership.htm](http://www.stoptb.org/world.tb.day/WTBD_2003/News/Press_Release_Partnership.htm), accessed in August 2004.

<sup>5</sup> WHO website, <http://www.who.int/gtb/dots/whatisdots.htm> accessed in September 2004.

<sup>6</sup> Novartis website, [http://www.novartis.com/special/WorldTB\\_day\\_04.shtml](http://www.novartis.com/special/WorldTB_day_04.shtml), accessed in August 2004.

Governmental Organizations (NGOs) and donors that purchase first-line drugs to benefit from the cost savings, quality assurance and technical assistance of the GDF.<sup>7</sup>

One of the Working Groups of the Stop TB Partnership develops guidelines for the treatment of Multi-Drug Resistant TB (MDR-TB). The Green Light Committee (GLC), an independent group of experts linked to this Working Group and part of Stop TB, approves MDR-TB pilot programmes. Second-line drugs, required for the treatment of MDR-TB, are provided through the Working Group to GLC-approved programmes at heavily discounted prices.<sup>8</sup>

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<sup>7</sup> Stop TB website, [http://www.stoptb.org/gdf/whatis/facts\\_and\\_figures.html](http://www.stoptb.org/gdf/whatis/facts_and_figures.html), accessed in August 2004.

<sup>8</sup> WHO (2004). *Fourth annual meeting of the Stop TB Working Group on DOTS-Plus for MDR-TB*. Paris, France, 27-28 October 2003. WHO/HTM/TB/2004.341.

## 2 Partnership policy

### 2.1 Partners involved

Started as a collaboration between a small number of organizations, membership of Stop TB has rapidly expanded since its foundation. As of end-2003, there were over 300 partners involved with the Stop TB Partnership.<sup>9</sup> Main partners include:<sup>10</sup>

- **United Nations organizations:** WHO, World Bank, United Nations Children's Fund (UNICEF), United Nations Development Programme (UNDP), Joint United Nations Programme on HIV/AIDS (UNAIDS);
- **Private foundations:** Global Fund to fight AIDS, TB and Malaria (GFATM), Rockefeller Foundation, Soros Foundation;
- **NGOs:** International Union Against Tuberculosis and Lung Disease (IUATLD), Royal Netherlands Tuberculosis Association (KNCV), National Institute of Public Health and Environmental Protection (RIVM) from The Netherlands, American Lung Association, Management science for Health, Task force for Child Survival and Development and many other Non-Governmental Organizations (NGOs);
- **Donor Governments:** the US Centers for Disease Control and Prevention (CDC), the UK, Canadian, the Netherlands (Ministry of Foreign Affairs) and other bilateral donors;
- **Pharmaceutical corporations:** Aventis, Novartis, Eli Lilly and other.

### 2.2 Partnership policy and expansion

Stop TB uses the following definition of a partner: '*A partner is an organization that declares with reason(s) and substantiation interest and commitment to global TB control*'.<sup>11</sup> Partners are classified according to the geographical scope of their activities. Three geographical levels are distinguished: the global, regional and national level.

- The global partnership is organized as the Stop TB Partners Forum and supported by the Partnership Secretariat.<sup>12</sup>
- The regional partnerships are based on WHO regions. The WHO regional offices have a central role in the creation and maintenance of these partnerships. They act as the secretariats of these partnerships. Regional partnerships do not exist in all regions yet.
- National partnerships are led by governments and focus on the implementation of National DOTS Expansion Plans.<sup>13</sup>

<sup>9</sup> IPPPH website, <http://www.ippph.org>, accessed in August 2004.

<sup>10</sup> Global Partners, Partners Directory (August 2004). See Stop TB website, <http://www.stoptb.org/partners/default.asp>, accessed in August 2004.

<sup>11</sup> *Joining the Stop TB Partnership*. See Stop TB website, [http://www.stoptb.org/partners/partner\\_application.asp](http://www.stoptb.org/partners/partner_application.asp), Partnership Policy. Accessed in September 2004

<sup>12</sup> See page 16 for more information on the Stop TB Partners Forum and Partnership Secretariat.

<sup>13</sup> *Joining the Stop TB Partnership*. See Stop TB website, [http://www.stoptb.org/partners/partner\\_application.asp](http://www.stoptb.org/partners/partner_application.asp), accessed in September 2004.

Similar to the Roll Back Malaria (RBM) Partnership, Stop TB aims to strengthen commitments and political support and therefore seeks to bring in as many partners as possible. Stop TB has an open door policy for joining the initiative and stresses that this should be maintained in order to continue the expansion of membership.<sup>14</sup> Apparently, being a partner is in itself of little value for company image. In contrast to other GPPs, including those related to Stop TB, companies like Aventis and Eli Lilly do not usually mention that they are a Stop TB partner in public communications.

Organizations can apply for joining the Stop TB partnership via the Stop TB website. Decisions about applications are taken at different levels, depending on the geographical level of membership.

- The Secretariat, on behalf of the Board, decides on applications for global membership.
- The WHO regional offices have the authority to decide on applications for regional membership.
- The national partnerships have the authority to decide on applications for national membership.<sup>15</sup>

When applying for membership, organizations have to fill a form describing the organization and its work on TB. Furthermore, it is required to describe any real, potential or apparent conflict of interests, and agree on the partnership policy of Stop TB. The information describing conflicts of interests will only be available to the Executive Secretary and his designee and not disclosed to anyone else. The existence of conflicts of interests is usually not considered to determine membership of the Stop TB Partnership. However, the Executive Secretary may disallow participation in a specific project or activity on the basis of the submitted information. Members can appeal to the Coordinating Board to reconsider the decision.<sup>16</sup> The Secretariat did not provide information on such decisions, but indicated that on a few occasions it rejected membership applications from companies, because they did not provide information related to conflicts of interests.<sup>17</sup>

In 2000, the WHO secretariat adopted a set of internal guidelines in order to deal with (potential) conflicts of interests when working with private sector partners. They recommend that the WHO *'should always consider whether a proposed relationship might involve a real or perceived conflict of interests'* and call for a *'step-by-step evaluation of the commercial enterprise'*.<sup>18</sup> This contrasts with the Stop TB policy of relying on the

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<sup>14</sup> *Joining the Stop TB Partnership.*

<sup>15</sup> *Joining the Stop TB Partnership.*

<sup>16</sup> *Joining the Stop TB Partnership.*

<sup>17</sup> Correspondence with M. Hayakawa, Stop TB Secretariat, on 25 August 2004.

<sup>18</sup> WHO (30 November 2000). *Guidelines on working with the private sector to achieve health outcomes*, annex.



information provided in the application form. The WHO guidelines call for a more active approach and an evaluation by the WHO instead of the companies themselves. However, the Partnership is not part of the WHO and applications are reviewed by the Stop TB Secretariat, not by the WHO.<sup>19</sup> If the WHO guidelines were not applied for that reason, it means the present structure of many GPPIS severely limits their use.

### 2.3 Roles and contributions of pharmaceutical companies

Large pharmaceutical companies involved with the Stop TB Partnership include Aventis, Novartis and Eli Lilly. Other companies are indirectly involved as well, for example Chiron participates in the TB Alliance. However, it is not clear whether they are also Stop TB members, as the list on the website is not complete. In general, companies do not contribute directly to the core operations of the Stop TB Partnership, but provide their support through various Working Groups of the partnership.<sup>20</sup> As the Stop TB Partnership is not a legal entity, contributions of companies are formally made to national partnerships, governments, the WHO or other Stop TB partners, not to the global partnership as a whole.<sup>21</sup>

Being a member of Stop TB does not impose any specific obligations or responsibilities. The roles of different (groups of) partners have not been formally described. However, cooperation between various partners existed already long before Stop TB was established. It is therefore perceived that the role and responsibilities of partners would be relatively clear.<sup>22</sup> The Stop TB Partnership Secretariat explains that private sector contributions include *'information sharing, advocacy for TB control, resource mobilization, alliance building, and cash and in kind donations'*.<sup>23</sup> Eli Lilly thinks it is crucial that the private sector becomes more involved.<sup>24</sup>

#### **Aventis**

Aventis is indirectly contributing to the Stop TB Partnership only. Aventis South Africa is a member of the global Stop TB Partnership.<sup>25</sup> In 2002, Aventis initiated a separate public-private partnership called TB Free, which aims to improve the health situation of people with tuberculosis in South Africa. TB Free is implemented by the Nelson Mandela Foundation in coordination with the South African government, and receives support from Aventis and the Gates Foundation. The programme trains people to support compliance with the complicated 6-month treatment regime. The goals of TB Free are based on the Global Plan to Stop TB, for instance, the detection of 70% of all new TB cases and the cure

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<sup>19</sup> Correspondence with M. Hayakawa, Stop TB Secretariat, on 25 August 2004.

<sup>20</sup> Interview with J. Broekmans, KNCV, 23 August 2004.

<sup>21</sup> Correspondence with M. Hayakawa, Stop TB Secretariat, on 25 August 2004.

<sup>22</sup> Interview with H. Schooten, 27 May 2004.

<sup>23</sup> Correspondence with M. Hayakawa, Stop TB Secretariat, on 25 August 2004.

<sup>24</sup> Interview with P. Carlevaro, Eli Lilly, 24 August 2004.

<sup>25</sup> Global Partners, Partners Directory (August 2004). See <http://www.stoptb.org/partners/default.asp>.

of 85% of all detected cases.<sup>26</sup> Although the TB Free programme follows the framework offered by the Stop TB Partnership, it is operating independently and has its own governance structure.

Furthermore, a plant of Aventis in Bangladesh is a pre-qualified supplier of TB drugs to the GDF, which centrally procures drugs for TB programmes in poor countries.<sup>27</sup> In this relationship with Stop TB, Aventis Bangladesh is a commercial supplier.

### **Novartis**

Novartis is involved with the Stop TB Partnership in different ways. A South African plant of Sandoz, the generics division of Novartis, is a pre-qualified supplier of TB drugs to the GDF.<sup>28</sup> Like Aventis Bangladesh, this involves a commercial supplier relationship with Stop TB. Yet Novartis also donates drugs to the GDF. In December 2003, the company announced a 5-year donation of TB drugs to the GDF. Novartis will also provide the necessary funds for related logistics and independent quality control. The donation consists of rifampicin-based fixed-dose combinations for half a million patients.<sup>29</sup>

Novartis is also a member of the global Stop TB Partnership through the Novartis Institute of Tropical Diseases (NITD).<sup>30</sup> The NITD is itself set up as a public-private partnership, between Novartis and the Singapore Economic Development Board (EDB). The institute performs R&D on tropical diseases with a focus on dengue fever and TB. The NITD is a non-profit organization, yet it is at the same time an affiliate of Novartis and part of Novartis Corporate Research.<sup>31</sup>

Novartis India is a partner of the TB Alliance, the leading organization of the Working Group on new drug development of the Stop TB Partnership.<sup>32</sup> The TB Alliance is an independent public-private partnership with its own governance structure.

### ***Eli Lilly***

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<sup>26</sup> Aventis and Aventis Foundation websites, <http://www.ventis.com> and <http://www.ventis-foundation.org/en/keyprojects/civilsociety/tbfree/index.html>, accessed in September 2004.

<sup>27</sup> Stop TB website, [http://www.stoptb.org/gdf/drugsupply/procurement\\_quality\\_sourcing\\_process.html](http://www.stoptb.org/gdf/drugsupply/procurement_quality_sourcing_process.html), accessed in September 2004.

<sup>28</sup> Stop TB website, [http://www.stoptb.org/gdf/drugsupply/procurement\\_quality\\_sourcing\\_process.html](http://www.stoptb.org/gdf/drugsupply/procurement_quality_sourcing_process.html), accessed in September 2004.

<sup>29</sup> Novartis website, [http://www.novartis.com/special/WorldTB\\_day\\_04.shtml](http://www.novartis.com/special/WorldTB_day_04.shtml), accessed in September 2004; WHO website, [http://www.who.int/gtb/archives/homepage/end\\_20jan04\\_gdf.htm](http://www.who.int/gtb/archives/homepage/end_20jan04_gdf.htm).

<sup>30</sup> Stop TB website, <http://www.stoptb.org/partners/default.asp>, accessed in September 2004.

<sup>31</sup> NITD website, <http://www.nitd.novartis.com/home.shtml>, accessed in September 2004.

<sup>32</sup> IPPPH website, <http://www.ippph.org>, accessed in September 2004; TB Alliance website, [http://www.tballiance.org/1\\_2\\_2\\_stakeholders.asp](http://www.tballiance.org/1_2_2_stakeholders.asp), accessed in September 2004.

Eli Lilly is a member of the global Stop TB Partnership and supports the resource mobilization efforts of the partnership.<sup>33</sup> The company got involved with Stop TB in 1999-2000 through a discussion with Médecins Sans Frontières (MSF). MSF worked in Russia, where Eli Lilly was the only reliable supplier of second-line drugs for MDR-TB. These drugs were provided at preferential prices.<sup>34</sup> At present, Eli Lilly supplies its second-line TB drugs Cycloserine and Capreomycin drugs at discounted prices to all GLC-approved MDR-TB programmes that use these drugs. The company agreed to supply 1.2 million capsules of Cycloserine and 1.8 million vials of Capreomycin for the first phase of two years, which started in 2002, and double quantities for the second phase. The company expanded a manufacturing facility to double its production capacity for Capreomycin.<sup>35</sup>

According to Eli Lilly, the price for the discounted drugs supplies is set below manufacturing cost. The company is making a loss and is in fact subsidizing the drugs.<sup>36</sup> This becomes apparent when comparing Eli Lilly's prices with those of generic producers. Eli Lilly charges \$1.00 per vial of Capreomycin, compared to a generic price of \$4.00 per vial, and \$13.65 for 40 capsules of Cycloserine, compared to a generic price of \$60.00 per 100 capsules (which is 76% higher per capsule).<sup>37</sup> Using these data, it can be calculated that the discounts compared to generic prices are worth approximately \$10 million over the first four years. Eli Lilly estimates that the value of the discounts is approximately \$25 million over six years,<sup>38</sup> but it is not clear on which price levels and total donation quantities this estimate is based.

In June 2003, Eli Lilly established a separate GPPI with the WHO and other partners, called the Eli Lilly MDR-TB Partnership. In this initiative, Eli Lilly will invest US\$ 70 million to transfer technology for the manufacturing of Cycloserine and Capreomycin, with the aim to increase supplies from low-cost producers.<sup>39</sup> The first three companies selected to receiving technical assistance from Eli Lilly were Shasun Chemical and Drugs (India), Aspen Pharmacare (South Africa), and Zhejiang Hisun Pharmaceutical (China). As of mid-2004, the companies were in various stages of facility conversion and initial production.<sup>40</sup> The first supplies from Aspen Pharmacare are expected by 2005. Eli Lilly explains that it will also continue to produce the two drugs itself. Even with technology transfer to new producers and expanded internal production capacity, second-line TB drug supplies will be

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<sup>33</sup> IPPPH website, <http://www.ippph.org>, accessed in September 2004.

<sup>34</sup> Interview with P. Carlevaro, Eli Lilly, 24 August 2004.

<sup>35</sup> Eli Lilly website, [http://www.lilly.com/products/access/international\\_initiatives.html](http://www.lilly.com/products/access/international_initiatives.html), accessed in August 2004.

<sup>36</sup> IPPPH website, <http://www.ippph.org>, accessed in September 2004.

<sup>37</sup> WHO & IDA (June 2004). *Procurement manual for the DOTS-Plus projects approved by the Green Light Committee*. WHO/HTM/TB/2003.328 Rev.1.

<sup>38</sup> Eli Lilly website, [http://www.lilly.com/products/access/international\\_initiatives.html](http://www.lilly.com/products/access/international_initiatives.html).

<sup>39</sup> IPPPH website, <http://www.ippph.org>, accessed in September 2004.

<sup>40</sup> Eli Lilly website, [http://www.lilly.com/products/access/international\\_initiatives.html](http://www.lilly.com/products/access/international_initiatives.html), accessed in August 2004; Interview with P. Carlevaro, Eli Lilly, 24 August 2004.

falling short for all MDR-TB patients. The WHO estimates the number of MDR-TB patients worldwide at 300,000 to 400,000.<sup>41</sup>

## 2.4 Motivation and interests of pharmaceutical industry partners

The Stop TB Secretariat believes social responsibility and corporate citizenship to be key motivations for the contributions of private sector partners. Yet the Secretariat also recognizes that the involvement of companies with Stop TB has a positive impact on their own business. Notwithstanding the ethical character of key motivations, business benefits are regarded a precondition for effective partnership, because *'sustainable and effective partnership is always equal and mutually beneficial'*.<sup>42</sup>

Companies like Aventis and Eli Lilly do not frequently mention in public communications that they are Stop TB partners. This contrasts with other GPPIs, including those related to Stop TB, such as TB Free and the Eli Lilly MDR-TB Partnership. Apparently, being a partner is in itself of little value for company image, because it does not stand for any specific commitments.

Unlike other companies, Ortho McNeil Pharmaceutical (part of Johnson & Johnson) does not provide its second-line anti-TB drugs at preferential prices. Probably because this is because they do not have a similar 'corporate ethics' policy like the other companies.<sup>43</sup>

Some indicate that in other GPPIs business interests play a large role for pharmaceutical companies. For Stop TB, this is much less the case because first-line TB drugs do not constitute an interesting market for the companies. Hence, the motivation of pharmaceutical industry partners for involvement with Stop TB is relatively sound.

Eli Lilly indicates that the subsidized second-line TB drug supplies are a philanthropic initiative. The Eli Lilly MDR-TB Partnership is the single largest corporate programme of this type and was decided upon by senior management. The partnership is considered a good investment for public health, not for the company, because it loses money on it. However, internally the contributions generate a feeling of proud, and the company hopes that its contributions are recognized. Eli Lilly explains that high commitment to such initiatives forms part of the company culture, and that it is not interested in drug promotion or in entering other markets through the partnership.<sup>44</sup>

The technical assistance provided by Eli Lilly helps to drive up quality and lower prices of the MDR-TB drugs. Yet for the generic producers that receive assistance, there will be an influence beyond the manufacturing of MDR-TB drugs alone. The required employee

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<sup>41</sup> IPPPH website, <http://www.ippph.org>, accessed in September 2004.

<sup>42</sup> Correspondence with M. Hayakawa, Stop TB Secretariat, on 25 August 2004.

<sup>43</sup> Interview with G. Elzinga, RIVM, 1 September 2004.

<sup>44</sup> Interview with P. Carlevaro, Eli Lilly, 24 August 2004.

training and support for manufacturing processes for capsules, quality control, etc. is also useful for the production of other drugs. Eli Lilly explains that this could have an indirect positive effect on its business, because it creates more opportunities for commercial outplacement of the production of branded drugs to external manufacturers.<sup>45</sup>

## 2.5 Conditions of cooperation

Following the donation of TB drugs by Novartis, the Coordinating Board of Stop TB approved a set of guidelines for drug donations to the GDF at its meeting on March 2004. These refer to the standard WHO Guidelines for Drug Donations, which apply Tb drug donations for that are made directly to national programmes.<sup>46</sup> The guidelines for donations to the GDF are stricter and more specific. For example, they specify that the drugs must have a remaining shelf life of at least two years after arrival in the recipient country. For accounting purposes the declared value of the donation should be based on the price levels of GDF tenders.<sup>47</sup>

The Board of Stop TB also called for the development of an ethical policy for accepting financial donations.<sup>48</sup> This ‘ethical grants policy’ would apply to all grants that do not come from donor governments. The policy is intended to prevent conditions attached to grants that have a negative impact on Stop TB. However, while some indicate that bilateral donors may have conflicts of interests too, there has been no discussion yet about the grants from donor governments.

### **Novartis donation**

The conditions of the Novartis donation were laid down in a Memorandum of Understanding, signed on 19 December 2003, between Novartis and the WHO. As the Stop TB Partnership is not a legal entity, formal commitments of companies are made to national partnerships, governments, the WHO or other Stop TB partners.<sup>49</sup> To be eligible for donated drugs, a country must be receiving support for TB control from the GFATM, and the donation should cover a significant part of the drug requirements of the country. Applications are reviewed by the GDF Technical Review Committee on technical grounds. Country selection started in April 2004.<sup>50</sup>

<sup>45</sup> Interview with P. Carlevaro, Eli Lilly, 24 August 2004.

<sup>46</sup> See *Guidelines for Drug Donations* (revised version of 1999), See WHO website, <http://www.who.int/medicines/library/par/who-edm-par-1999-4/who-edm-par-99-4.pdf>.

<sup>47</sup> See *Draft Paper for Stop TB Partners review: Guidelines for Drug Donations to the GDF*, available at <http://www.stoptb.org/coordinatingboard/meetings/20040322/Default.asp>.

<sup>48</sup> Board Meeting 22-23 March 2004: *Summary of decisions and actions*.

<sup>49</sup> Correspondence with M. Hayakawa, Stop TB Secretariat, on 25 August 2004.

<sup>50</sup> Novartis website, [http://www.novartis.com/special/WorldTB\\_day\\_04.shtml](http://www.novartis.com/special/WorldTB_day_04.shtml), accessed in September 2004; WHO website, [http://www.who.int/gtb/archives/homepage/end\\_20jan04\\_gdf.htm](http://www.who.int/gtb/archives/homepage/end_20jan04_gdf.htm), accessed in September 2004.

## *Eli Lilly*

The cooperation agreements for the Eli Lilly MDR-TB Partnership are not publicly disclosed. The company says that these are very simple. There are agreements for a period of two years that specify the amount of subsidized drug supplies. These 1.2 million capsules of Cycloserine and 1.8 million vials of Capreomycin for the first phase of two years and double quantities for the second phase. The programmes that benefit from these supplies have to be approved by the Graan Light Committee (GLC)<sup>51</sup>. According to Eli Lilly, no other conditions apply.<sup>52</sup>

### **2.6 Added value of the partnership**

The added value of the Stop TB Partnership is clear and mainly in the coordination of partners' activities. There seems to exist a consensus among Stop TB partners that this is functioning well. Some partners also indicate that the partnerships has increased resource mobilization for TB and political priority for the disease.<sup>53</sup> In financial terms, the Global Drug Facility (GDF) and Green Light Committee (GLC) have considerably brought down the prices of TB drugs. Furthermore, it is appreciated that Stop TB offers a platform to jointly develop policies.<sup>54</sup> In fact, some partners even remark that it is strange that a PPP was not established earlier.<sup>55</sup>

One partner perceives a problem about large partnerships like Stop TB as well. Organizations and companies like it very much to announce the start of a collaboration, but there is usually a 'day-after' effect: after the announcement, there will be some disappointment about the commitments to a project and its results.<sup>56</sup>

### **2.7 Transparency**

Transparency about the partnership policy and membership is high. However, transparency about conditions of cooperation with industry partners is rather low. The Memorandum of Understanding between Novartis and the WHO is not publicly disclosed. Neither are the cooperation agreements for a number of implementation partnerships related to Stop TB, including the Eli Lilly MDR-TB Partnership. Furthermore, there is no transparency about potential conflicts of interests, as the information on this issue (provided the companies themselves) is only available to the Executive Secretary.

Although the Stop TB Partnership has a central website, a study in South Africa showed that it was very difficult to obtain information on the Partnership at country level. Several relevant

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<sup>51</sup> See section 3.3.

<sup>52</sup> Interview with P. Carlevaro, Eli Lilly, 24 August 2004.

<sup>53</sup> Interview with G. Elzinga, RIVM, 1 September 2004.

<sup>54</sup> Interview with G. Elzinga, RIVM, 1 September 2004; interview with J. Broekmans, KNCV, 23 August 2004.

<sup>55</sup> Interview with J. Broekmans, KNCV, 23 August 2004.

<sup>56</sup> Interview with P. Carlevaro, Eli Lilly, 24 August 2004.

documents are not available in the public domain. Knowledge of the Partnership turned out to be very limited among healthcare workers in South Africa and it was not clear to them what the Stop TB Partnership is. Common misunderstandings include that the Partnership is a funding agency like the GFATM, an organization that directly implements TB programmes, or simply the WHO by another name.<sup>57</sup>

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<sup>57</sup> A. Padarath, L. Sait & D. Barr (2004). *The stop tb partnership in South Africa: a review*. Health Systems Trust.

## 3 Governance of Stop TB

### 3.1 Partnership and governance structure

Stop TB is hosted by the WHO and does not have a separate legal status. Since the establishment of Stop TB in 1998, the initiative has rapidly grown. Stop TB operations, the number of and target countries and the Stop TB membership base have all expanded. This required changes in governance.<sup>58</sup> After an external evaluation of the Global Stop TB Partnership in 2003, there have been a number of organizational changes. The partnership is considered to have a ‘light’ structure, not involving a large bureaucracy. Nonetheless, the role and control of the Coordinating Board is increasing due to meet the requirements of the expanding partnership.<sup>59</sup>

The structure of the Stop TB Partnership comprises the following.<sup>60</sup>

- **Stop TB Partners’ Forum.** The Forum consists of an assembly of Stop TB partners and met in 2001 and 2004. It is the main coordinating body of the partnership. The Forum oversees the activities of the Coordinating Board and is responsible for generating commitment of partners and political support.
- **Stop TB Coordinating Board.** The Board decides on the strategies and priorities of Stop TB, taking into account recommendations from the forum and the WHO. It is responsible for the mobilization of resources, reviewing the implementation of the partnership and regular reporting to all partners and the general public. The Board provides oversight and guidance on the work of the Partnership Secretariat and coordinates the activities of the Working Groups. The Board was recently enlarged to 31 members and represents a broad range of partners and the Working Groups. In addition, an Executive Committee has recently been established, replacing a Working Committee. The Executive Committee consists of 7 Board members and has delegated authority to make decisions that do not require the consideration of the full Board.
- **Stop TB Partnership Secretariat.** The Secretariat supports the work of Stop TB partners and the Working Groups and is accountable to the Board. Its functions include internal and external communication, resource mobilization and preparing annual work plans and budgets. The Secretariat is hosted by the WHO and its staff

<sup>58</sup> Interview with J. Broekmans, KNCV, 23 August 2004.

<sup>59</sup> Interview with J. Broekmans, KNCV, 23 August 2004.

<sup>60</sup> Stop TB website, <http://www.stoptb.org/stop.tb.initiative/default.asp#Governance> and <http://www.stoptb.org/gdf/>, accessed in September 2004; Basic framework for the Global Partnership to Stop TB, see [http://www.stoptb.org/stop.tb.initiative/Basic\\_Framework.pdf](http://www.stoptb.org/stop.tb.initiative/Basic_Framework.pdf).



partly consists of secondments from other Stop TB partners. The Executive Secretary reports to the WHO.<sup>61</sup>

- **Working groups.** The Working Groups concentrate on different aspects of the work of Stop TB and carry out the primary coordination of the activities decided upon by the Board. They have their own independent governance mechanisms, but their work is coordinated and reviewed by the Stop TB Partnership.<sup>62</sup> There are currently six Working Groups:
  1. DOTS Expansion
  2. TB/HIV
  3. DOTS-Plus for multi-drug resistant TB (MDR-TB)
  4. New TB drugs R&D
  5. New TB Diagnostics R&D
  6. TB Vaccine R&D

The **Green Light Committee (GLC)** is a sub-group of the DOTS-Plus Working Group. This committee decides on applications of DOTS-Plus projects for preferentially priced second-line drugs. The Global Alliance for TB Drug Development (TB Alliance), an independent public-private partnership, is part of the Working Group on new drugs. These Working Groups will be described in more detail later in this chapter.

- **Global Drug Facility (GDF).** The GDF is a mechanism to expand access to high-quality TB drugs. It centrally procures TB drugs from pre-qualified suppliers, ensures their uninterrupted supply and provides technical support at country level to ensure the correct use of the drugs. GDF is hosted by WHO and managed by the Stop TB secretariat.
- **WHO Strategy & Technical Advisory Group (STAG).** The STAG provides strong policy guidance to the Board and Secretariat of Stop TB.
- **Task forces.** There are task forces on Advocacy & Communication, Financing, and Resource Mobilization.<sup>63</sup> The task forces are overseen by the Secretariat.

Regional partnerships are led by the WHO regional offices. The same countries and partners meet the regional level too. Coordination at the regional level is independent from the Coordinating Board. The regional partnerships operate largely independent from the Global Stop TB Partnership and are not accountable to it. There is a clear distinction of tasks between the global and regional levels: the former deals with global policy

<sup>61</sup> Interview with G. Elzinga, RIVM, 1 September 2004.

<sup>62</sup> Stop TB website, [http://www.stoptb.org/Working\\_Groups/default.asp](http://www.stoptb.org/Working_Groups/default.asp), accessed in September 2004.

<sup>63</sup> The establishment of a Resource Mobilization Task Force was approved in March 2004. See Board Meeting 22-23 March 2004: *Summary of decisions and actions*; and *Resource Mobilisation efforts of the Stop TB Partnership Secretariat: Update*.

development and global coordination, whereas the latter deals with specific countries and implementation bottlenecks.<sup>64</sup>

### 3.2 Coordinating Board

The role of the Board is to provide guidance and oversight to the partnership, but not to control it. The Board can signal certain developments and make recommendations to partners, but not enforce them. The structure of the partnership is not intended for this purpose and there is no legal foundation to enforce decisions of the Board.<sup>65</sup> Decisions of the Board should be made by consensus whenever possible.<sup>66</sup>

In March 2004, the composition of the Stop TB Coordinating Board was changed in response to the outcomes of the independent evaluation of the partnership. The number of international agency seats was reduced from 3 to 2, and new seats were created to provide for the representation of additional groups. The total number of seats was expanded from 27 to 32. The new the composition of the Coordinating Board will be as follows:<sup>67</sup>

- 6 Working Group chairpersons
- 6 Regional representatives (Africa, the Americas, Eastern Mediterranean, Europe, Southeast Asia, Western Pacific)
- 4 High-burden country representatives
- 4 Donor countries
- 3 Multilateral agencies (including the WHO and World Bank)
- 3 NGOs and technical agencies (including the CDC and IUATLD)
- 1 Foundation (Soros Foundation)
- 1 Representative of communities with TB or TB/HIV
- 1 Representative of the corporate business sector
- 1 Representative for advocacy and communication
- 1 Representative form the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM)
- 1 Chair of the WHO STAG

Donor governments coordinate their input in board meetings. For instance, the UK was in the Board of Stop TB and also represented The Netherlands, and now The Netherlands is a

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<sup>64</sup> Interview with J. Broekmans, KNCV, 23 August 2004.

<sup>65</sup> Interview with H. Schooten, 27 May 2004.

<sup>66</sup> Stop TB website. <http://www.stoptb.org/stop.tb.initiative/default.asp#Governance>, accessed in September 2004.

<sup>67</sup> Board Meeting 22-23 March 2004: *Summary of decisions and actions, and Proposal on Board Function and Structure, Delegation of Authority by the Coordinating Board, and Working Group Processes; Stop TB Coordinating Board - Terms of Office and staggering members*; see <http://www.stoptb.org/coordinatingboard>.

board member and represents the UK too.<sup>68</sup> The chair of the Coordinating Board, which is the chair of the Executive Committee as well, is currently from the Canadian government.

It is not clear to all Board members what the contribution of the industry representative to the governance of Stop TB will consist of.<sup>69</sup> The Secretariat comments that he or she *'is expected to share with other board members the constituent's view and interest, and bring skills, experience or access to resources relevant to the operation of the Stop TB Partnership'*.<sup>70</sup> Some believe that a main reason for including an business representative in the Board is to gain more support for TB drug development.<sup>71</sup> However, more frequently it is understood that a business representative should strengthen the link with large corporations and influential actors that participate in the World Economic Forum (WEF).<sup>72</sup> This representative could be from any business sector, not necessarily from the pharmaceutical industry.

Pharmaceutical companies are not directly involved in the governance of the Stop TB Partnership. Eli Lilly believes the private sector in general should be more represented and acknowledges that this requires full transparency, because a suggestion of conflicts of interest may be present. However, Eli Lilly perceives that pharmaceutical companies are not in a position to influence the course of the whole initiatives anyway. It is therefore *'sad that others are afraid of the private sector'*.<sup>73</sup>

As far as industry partners are concerned, it is generally perceived that potential conflicts of interests are sufficiently addressed in Stop TB. The TB Alliance has a transparent and careful approach to deal with conflicts of interests around the development of new TB drugs, including the exclusion of partners from discussion when necessary. In other Working Groups, such conflicts are less of a problem because the present drugs against TB are over 30 years old and do not involve large business interests.<sup>74</sup>

However, several sources point out that conflicts of interest occur for donor governments as well. Their influence in the Board perceived to be quite large because of the funds they control. Some bilateral donors are suspected of using Stop TB to serve their own agendas. For example, donors try to prioritize specific target countries according to their own political and economic interests.

### 3.3 Working Groups

#### *DOTS-Plus*

<sup>68</sup> Interview with H. Schooten, 27 May 2004.

<sup>69</sup> Interview with H. Schooten, 27 May 2004.

<sup>70</sup> Correspondence with M. Hayakawa, Stop TB Secretariat, on 25 August 2004.

<sup>71</sup> Interview with H. Schooten, 27 May 2004.

<sup>72</sup> Interview with J. Broekmans, KNCV, 23 August 2004.

<sup>73</sup> IPPPH website, <http://www.ippph.org>, accessed in September 2004.

<sup>74</sup> Interview with G. Elzinga, RIVM, 1 September 2004.

The aim of the Working Groups on DOTS-Plus is to develop policy guidelines for the management of MDR-TB on the basis of pilot projects. The Working Group provides the expensive second-line anti-TB drugs, required for the treatment of MDR-TB, at preferential prices to DOTS-Plus pilot projects in low- and middle-income countries.

Drug-susceptible TB can be cured in 6-8 months using first-line anti-TB drugs. MDR-TB is a form of the disease that is resistant to at least isoniazid and rifampicin, the most powerful first-line drugs. Therefore treatment of MDR-TB with first-line drugs is usually not effective. It requires chemotherapy with second-line anti-TB drugs of up to two years that is much more expensive and more toxic to patients.

The DOTS-Plus strategy for MDR-TB builds on the DOTS strategy and takes into account the use of second-line anti-TB drugs. Apart from the appropriate management of MDR-TB cases, it minimizes the further development of MDR-TB. Therefore second-line anti-TB drugs should only be used in approved DOTS-Plus pilot projects. A Scientific Panel of the Working Group has set the standards for these projects.<sup>75</sup> Projects applications are reviewed by the Green Light Committee (GLC), a sub-group of the Working Group established in March 2000 for this purpose. As of October 2003, there were 16 GLC-approved DOTS-Plus pilot projects with a combined total of over 4,000 patients, and 11 more projects were under review.<sup>76</sup>

Pilot projects that have been found in compliance with the guidelines and validated by the GLC, benefit from preferential pricing arrangements for second-line anti-TB drugs negotiated by the Working Group. Preferential prices are much lower than market prices. The cost of MDR-TB treatment ranges from US\$10,000 to \$20,000 in high-income countries and \$2,000-\$8,000 in low-income countries, whereas the cost of a preferentially priced treatment regime was \$500-\$1,500 in 2000.<sup>77</sup> The GLC claims it has reduced the cost of second-line TB drugs by more than 95 percent through negotiations with the pharmaceutical industry.<sup>78</sup> Some pharmaceutical companies also refuse to sell second-line anti-TB drugs to projects not been validated by the GLC.<sup>79</sup>

The Green Light Committee is an independent body of technical experts. The WHO is a permanent member of the GLC, houses it, and is responsible for coordinating GLC activities. As of 2003, other members were the CDC, KNCV, IUATLD, NTP-Estonia, and

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<sup>75</sup> See *Guidelines for the Establishment of DOTS-Plus Pilot Projects for the Management of MDR-TB*, WHO/CDS/TB/2000.279.

<sup>76</sup> WHO (2004). *Fourth annual meeting of the Stop TB Working Group on DOTS-Plus for MDR-TB*. Paris, France, 27-28 October 2003. WHO/HTM/TB/2004.341.

<sup>77</sup> Treatment costs depend on the type of drug resistance. *MDR-TB Treatment Regimen Costs*, available at WHO website, <http://www.who.int/gtb/policyrd/images/drug-prices-&-pilot-proje.gif>.

<sup>78</sup> Stop TB website, [http://www.stoptb.org/world.tb.day/WTBD\\_2003/News/Press\\_Release\\_Partnership.htm](http://www.stoptb.org/world.tb.day/WTBD_2003/News/Press_Release_Partnership.htm), accessed in August 2004

<sup>79</sup> WHO (2000). *DOTS-Plus & the Green Light Committee*. WHO/CDS/TB/2000.283.

Harvard University.<sup>80</sup> GLC Members serve for a period of at least two years and receive no financial benefits for participation.<sup>81</sup> The independence of the GLC has been arranged within the WTO and involves complicated measures.<sup>82</sup> Institutional members and consultants are required to adhere to rules of conflict of interest and confidentiality, and are excluded from the discussion of applications from sites at which they have (had) a direct relationship. The review of applications may involve a site visit. Decisions in the GLC are taken by consensus.<sup>83</sup> A representative of Eli Lilly stresses that the private sector should not be involved with the GLC.<sup>84</sup>

The choice of second-line drugs for an MDR-TB programme depends on the local drug resistance pattern and also on individual patients. Each programme has its own protocol for treatment with cocktails of 5 to 8 different drugs. The programmes are designed by the government, with assistance from the WHO and other relevant organizations. According to Eli Lilly, pharmaceutical companies themselves are not involved in the choice of drugs.<sup>85</sup>

All second-line anti-TB drugs are off patent and available from generic producers, except for the antibiotic Levaquin (levofloxacin). This product remains under patent until 2010 and is available only from Ortho-McNeil Pharmaceutical, a wholly owned subsidiary of Johnson & Johnson.<sup>86</sup>

### **New drugs**

The Working Group on new drugs acts as a global forum to coordinate R&D activities for new TB drugs. Its lead agency is the Global Alliance for TB Drug Development (TB Alliance), an independent public-private partnership. The TB Alliance is a US-based non-profit organization with its own governance structure, Board of Directors and Chief Executive Officer (CEO). The Stop TB Partnership, as a whole, is a major partner of the TB Alliance.<sup>87</sup>

<sup>80</sup> E. Jaramillo, Presentation at the *Meeting of National Managers of the Tuberculosis Control Programmes in the Eastern Mediterranean Region Damascus*, Syrian Arab Republic, 15-17 September 2002.

<sup>81</sup> Call for nominations, [www.uictmr.org/upload/home\\_news/2004\\_call\\_for\\_nominations\\_to\\_glc\\_jprevr\\_fr\\_61.doc](http://www.uictmr.org/upload/home_news/2004_call_for_nominations_to_glc_jprevr_fr_61.doc), accessed in September 2004.

<sup>82</sup> Interview with J. Broekmans, KNCV, 23 August 2004.

<sup>83</sup> Call for nominations, [www.uictmr.org/upload/home\\_news/2004\\_call\\_for\\_nominations\\_to\\_glc\\_jprevr\\_fr\\_61.doc](http://www.uictmr.org/upload/home_news/2004_call_for_nominations_to_glc_jprevr_fr_61.doc), accessed in September 2004.

<sup>84</sup> Interview with P. Carlevaro, Eli Lilly, 24 August 2004.

<sup>85</sup> Interview with P. Carlevaro, Eli Lilly, 24 August 2004.

<sup>86</sup> Ortho-McNeil holds New Drug Applications (NDAs) for Levaquin, while the Japanese Daiichi Pharmaceuticals Co. owns the patent on the drug and has licensed it to Ortho-McNeil through Johnson & Johnson. See Ortho-McNeil website, <http://www.ortho-mcneil.com/about/aboutjnj.html>; IPD Analytics, <http://www.ipdanalytics.com/Services.htm>; Electronic Orange Book, [http://www.accessdata.fda.gov/scripts/cder/ob/docs/tempnodet.cfm?Appl\\_No=020635&TABLE1=RX](http://www.accessdata.fda.gov/scripts/cder/ob/docs/tempnodet.cfm?Appl_No=020635&TABLE1=RX); all accessed in August 2004.

<sup>87</sup> TB Alliance website, <http://www.tballiance.org>, accessed in September 2004.

The CEO of the TB Alliance is the chair of the Working Group on new drugs and a member of the Stop TB Coordinating Board.

### 3.4 Funding of the partnership and financial structure

In 2003, funding of the Stop TB Partnership came from the following sources:

- Donor governments: Canada, The Netherlands, the US (USAID), the UK, and Norway
- Multilateral organizations: the World Bank and WHO
- Foundations and others: Harvard University, Open Society Institute (OSI)
- In kind contributions: Management Sciences for Health, IUATLD, University of California

Most Stop TB funds are used for the procurement of (relatively cheap, off-patent) first-line TB drugs through the GDF. Table 1 provides a break-up of Stop TB funding and shows that over 70% of funds went to the GDF. The GDF has approved 61 country applications comprising a total of over 2.5 million treatments. In addition, over 470,000 patients are receiving their drugs via GDF's direct procurement mechanism to date.<sup>88</sup> Prices of drugs procured by the GDF have fallen by 30% compared to previous international tenders, to less than US\$10 for a full 6-8 month course of treatment.<sup>89</sup>

The GDF is actively seeking new donors to ensure that the resources required for grants up to 2006 are acquired. Furthermore, it is exploring relationships with large donors and lenders, such as the GFATM and World Bank, to use the direct procurement mechanism. A Memorandum of understanding between Stop TB and the GFATM is currently being concluded, in order to improve structured collaboration.<sup>90</sup> Drug donations to the GDF, like the donation by Novartis, are being considered as a mechanism to diversify funding sources.<sup>91</sup>

**Table 1: Funding of Stop TB.**

Category	GDF	Secretariat	Unspecified	Total
Donor governments <sup>92</sup>	14,911	2,507	2,066	19,484
Multilateral organizations	-	-	1,029	1,029
Foundations and others <sup>93</sup>	342	736	-	1,078
<b>Total</b>	<b>15,253</b>	<b>3,243</b>	<b>3,095</b>	<b>21,591</b>

Source: Stop TB Partnership Secretariat, Financial Report 2003.

<sup>88</sup> Stop TB website, [http://www.stoptb.org/gdf/whatis/facts\\_and\\_figures.html](http://www.stoptb.org/gdf/whatis/facts_and_figures.html), accessed in September 2004.

<sup>89</sup> Stop TB website, [http://www.stoptb.org/world.tb.day/WTBD\\_2003/News/Press\\_Release\\_Partnership.htm](http://www.stoptb.org/world.tb.day/WTBD_2003/News/Press_Release_Partnership.htm), accessed in September 2004.

<sup>90</sup> Board Meeting 22-23 Macrh 2004: *Summary of decisions and actions*.

<sup>91</sup> Stop TB website, [http://www.stoptb.org/gdf/whatis/facts\\_and\\_figures.html](http://www.stoptb.org/gdf/whatis/facts_and_figures.html), accessed in September 2004.

<sup>92</sup> Including in-kind contributions for the GDF of US\$ 213,000.

<sup>93</sup> Including in-kind contributions for the GDF of US\$ 188,000 and for the Partnership Secretariat of US\$ 274,000.

In 2003 a new arrangement with the WHO was adopted by the Board of Stop TB, which should increase transparency of the partnership's finances. Stop TB now has a completely separated trust fund within the WHO accounting system. Funds are held by a trust fund at the World Bank until they are used.<sup>94</sup>

The Stop TB Partnership itself is only a coordination body and has a tiny budget compared to the total operations it coordinates. The Coordinating Board makes recommendations and guidelines for Stop TB Partners, but does not have authority over partners' allocation of funds for the Global Plan to Stop TB.<sup>95</sup>

For the five-year period 2001-2005, the total estimated costs of the Global Plan to Stop TB are US\$ 9.1 billion. Roughly half of these costs, US\$ 4.5 billion, is for DOTS expansion in high-burden countries. The majority of the costs of DOTS expansion are borne by the countries themselves. In 2003, the governments of high-burden countries (HBCs) financed 58% of the National TB Control Programmes (NTPs) themselves, and they typically fund all the general healthcare staff and facilities required for the treatment of TB patients.<sup>96</sup>

During the first three years covered by the Global Plan, approximately US\$ 680 million had been available from external sources. Hence, direct contributions to National TB Programmes, DOTS improvement and R&D efforts were much higher than contributions to or through the Stop TB Partnership.<sup>97</sup>

The GFATM has become a major external donor for TB control. It has approved over US\$ 1 billion of grants for TB and TB/HIV control for a period of five years. Disbursements of these grants started in 2003 and have reached US\$ 120 million so far.<sup>98</sup> During its first two years to TB control programmes, the GFATM supported 16 of the 22 high burden countries.<sup>99</sup>

The resources for implementing the Global Plan to Stop TB have been falling short and competition for donor funds for public health is increasing. The Partnership therefore established a Resource Mobilization Task Force to increase contributions from donors, including companies.<sup>100</sup>

<sup>94</sup> Board Meeting 22-23 Macrh 2004: *Summary of decisions and actions*.

<sup>95</sup> Interview with H. Schooten, 27 May 2004.

<sup>96</sup> WHO (2004). *Global Tuberculosis Control: Surveillance, Planning, Financing*, p 38-9.

<sup>97</sup> WHO (2004). *Progress Report on the Global Plan to Stop Tuberculosis*. WHO/HTM/STB/2004.29.

<sup>98</sup> [http://www.theglobalfund.org/en/funds\\_raised/reports](http://www.theglobalfund.org/en/funds_raised/reports), customized report generated on 5 August 2004; WHO (2004). *Global Tuberculosis Control: Surveillance, Planning, Financing*, p 41.

<sup>99</sup> Stop TB website, [http://www.stoptb.org/world.tb.day/WTBD\\_2003/News/Press\\_Release\\_Partnership.htm](http://www.stoptb.org/world.tb.day/WTBD_2003/News/Press_Release_Partnership.htm), accessed in September 2004.

<sup>100</sup> Board Meeting 22-23 Macrh 2004: *Summary of decisions and actions*; and *Resource Mobilisation efforts of the Stop TB Partnership Secretariat: Update*.

### 3.5 Monitoring and evaluation

There has been a thorough external evaluation of the Stop TB Partnership in 2003, which led to improvements in the partnership structure. The progress of the Global Plan to Stop TB is monitored by the Stop TB Partnership.

### 3.6 Transparency

In general, transparency about partnership governance is high. Publicly available documents posted on the Stop TB website include the following:

- Reports of Board meetings
- Background documents for Board meetings, including financial reports
- Reports of Board teleconferences
- Reports of Working Committee teleconferences (until September 2003)
- The Stop TB Partnership Framework, describing the partnership structure
- The report of the independent evaluation of the Stop TB Partnership in 2003

Only about financial decisions, relatively little information was found.



## 4 Controversial issues

There exist concerns that many GPPIs follow a 'vertical approach', failing to integrate with existing national health systems or paying no attention to the strengthening of healthcare infrastructure. As a consequence, GPPIs could impose an additional burden on already weak systems and draw scarce resources away from other healthcare programmes. However, Stop TB seems to be an example of a GPPI where integration has been relatively successful. In Stop TB, strategy design and monitoring systems follow a vertical approach. These are managed at the global level. Implementation of Stop TB is largely embedded in national healthcare systems, with local reference centres that deal with other diseases as well. Because of this approach, Stop TB could have more favourable impact on national health systems than some other GPPIs.<sup>101</sup>

Integration is stimulated by the nature of the disease. DOTS expansion would not be possible without integration into local health systems. In each village, there may be only a few people with TB, so to reach them all integration is a necessity. This is not a point of discussion. A good TB programme will strengthen the health care system. Inversely, it may be necessary to improve health systems to increase the coverage of TB programmes. As the treatment of TB requires daily supervision of a healthcare worker that medications are taken correctly for a period of 6-8 months, DOTS programmes can put a considerable strain on already understaffed healthcare systems. There are no problems about donor funding for TB programmes that is used for the strengthening local health systems to address this issue.<sup>102</sup>

Integration of Stop TB with other GPPIs is on the agenda, but there are still few examples of it in practice. First, successful pilot programmes are required to demonstrate that integration is effective. This can take place on the national level, for example with TB-HIV programmes. Such programmes have already been established and evaluations are being completed. After that, the programmes can be scaled up. In the case of TB-HIV, this has now begun.<sup>103</sup> However, it is pointed out that special attention for TB emerged only recently. This might explain why integration between different programmes, although desirable, is still at the beginning.<sup>104</sup> It is also perceived that there are still too little funds available for such integrated approaches.<sup>105</sup>

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<sup>101</sup> Interview with G. Elzinga, RIVM, 1 September 2004.

<sup>102</sup> Interview with J. Broekmans, KNCV, 23 August 2004.

<sup>103</sup> WHO (2004). *Progress Report on the Global Plan to Stop Tuberculosis*. WHO/HTM/STB/2004.29.

<sup>104</sup> Interview with J. Broekmans, KNCV, 23 August 2004.

<sup>105</sup> Interview with G. Elzinga, RIVM, 1 September 2004.

## 5 Analysis and conclusions

The partnership policy of Stop TB is a little strange. On the one hand, the continuous expansion of membership may be helpful to build a broad alliance and generate more political support. Yet on the other hand, being a Stop TB partner does not entail any specific responsibilities or obligations. The term 'partnership' therefore becomes rather meaningless. Apparently, being a partner is in itself also of little value for company image. In contrast to other GPPIs, including those related to Stop TB, companies do not mention that they are a Stop TB partner in public communications.

The added value of the Stop TB Partnership is clear and mainly based on coordination. This seems to be functioning well. Companies do not have an important role in this. The only contributions of pharmaceutical companies to the Stop TB Partnership itself consist of drug donations to the GDF.

The research did not cover related partnerships such as the TB Alliance or Eli Lilly MDR-TB Partnership in detail. Company contributions to these partnerships are much larger. Probably the most important commitment of pharmaceutical companies to Stop TB is to engage in R&D for new drugs, which has been neglected for a long time. Although several new treatments are now being developed, current first-line TB drugs are over 30 years old and resistance is increasing. In terms of funding for the implementation of the Global Plan to Stop TB, pharmaceutical industry contributions are relatively small.

Ethical considerations are generally perceived to be the main motivation for pharmaceutical companies to get involved with Stop TB. However, it is remarkable that some companies are much more supportive to Stop TB than others. Johnson & Johnson stands out as a company that refuses to offer its second-line TB drugs at discounted prices, in contrast to other pharmaceutical companies.

The governance structure of Stop TB has been well designed and evaluated. It seems that potential conflicts of interests are currently more of an issue for donor governments than for pharmaceutical companies. Transparency about the governance of Stop TB and is high. However, it is more difficult to get a clear picture of some of the separate agreements and partnerships linked to Stop TB in which pharmaceutical companies are involved, e.g. for drug donations (Novartis) and technology transfer (Eli Lilly). As a general rule, these agreements are not disclosed, which prevents a full external assessment of the conditions of cooperation.



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