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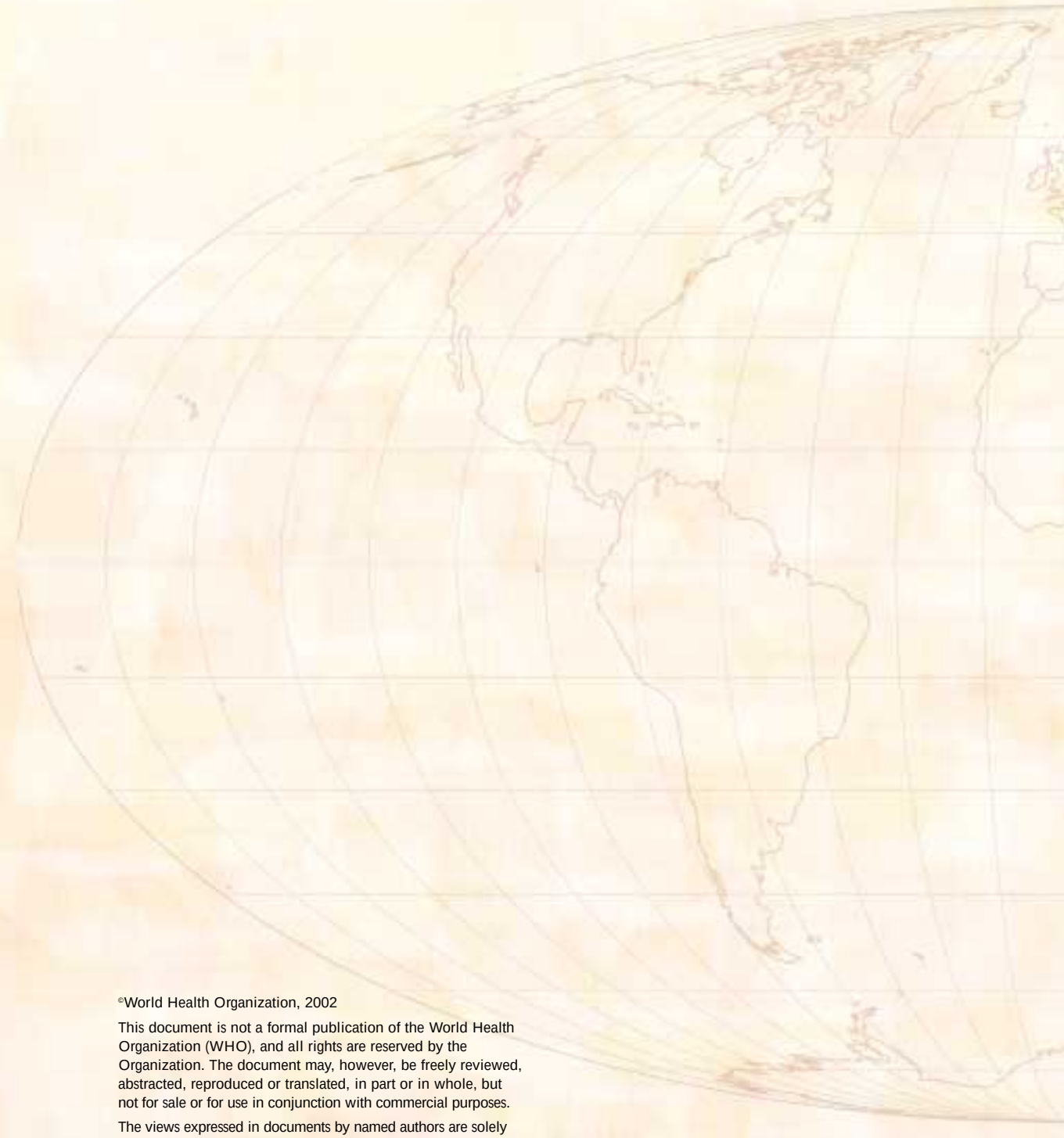
STOP TB

ANNUAL REPORT 2001

World Health Organization

The Stop TB Partnership



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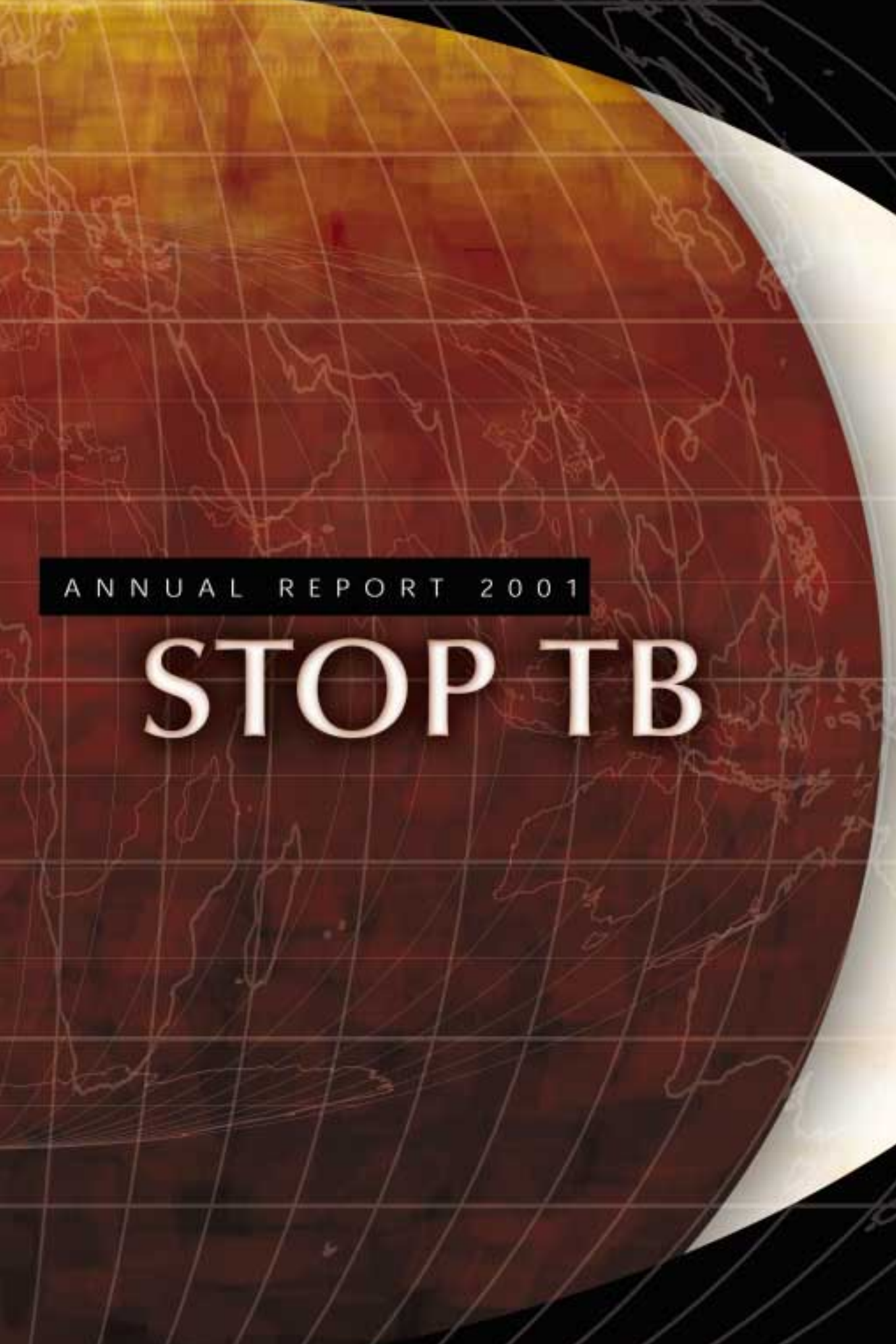

ANNUAL REPORT 2001
STOP TB

PREFACE

Since 1993 when the World Health Organization (WHO) declared tuberculosis (TB) to be a global health emergency, the international community has struggled to find the means to control the growing pandemic. Meanwhile, TB has continued to exact its remorseless toll, killing nearly 2 million people every year and developing into active disease in 6 million others. At the same time, the rising incidence of both multidrug-resistant TB (MDR-TB) and of TB/HIV coinfection posed serious new challenges to the response effort.

That's the bad news. The good news is that, with the Amsterdam Declaration in 2000 and the Washington Commitment in 2001, we have finally secured the political commitment and operational mechanisms needed to control TB and are poised to make rapid progress against the disease.

The DOTS strategy is now in use in 148 countries, compared to a mere 10 in 1991. Although only 27 per cent of TB patients worldwide were being treated in DOTS programmes by end-2001, China and India – which together account for more than a third of all TB cases – have shown that rapid DOTS expansion with high cure rates is possible even in areas with inadequate public health infrastructure and technology. Given sufficient investment, the DOTS strategy can be rapidly scaled up in other high-TB burden countries with similar outcomes.

The Stop TB Partnership has also registered rapid expansion, growing from 75 members in 2000 to 210 currently. One of its major tangible achievements in 2001 was creation of the Global Drug Facility (GDF), an innovative mechanism that helps to ensure universal access to high quality TB drugs. In just its first year, the GDF has already spent US$ 7.8 million on drugs for poorer countries with limited resources, and its Technical Review Committee (TRC) has recommended a total of 16 countries for support. As important, the international competitive bidding initiated by GDF caused drug prices to fall by roughly 30 per cent to less than US$ 10 for a full course of treatment.

All of this means that reaching the global targets for 2005 of 70 per cent case detection and 85 per cent cure of detected cases is indeed possible – but only if we ourselves believe it to be so. This is the essential condition for success. We will only do it if we believe we can, and I am firmly among the believers. Yes, current trends indicate the targets will not be reached until 2013, but they can be accelerated with innovation and improvisation of the kind demonstrated by GDF. Our donor base is strong and will be further strengthened by the new Global Fund to Fight AIDS, Tuberculosis and Malaria. We have the commitment, the tools and the resources that we need. The time is now. We can do the job, and meet the targets. Believe it.

Dr Jacob Kumaresan
Executive Secretary
Stop TB Partnership Secretariat

TB GLOBAL BURDEN UPDATE

TB kills

One third of the world's population is infected with TB. Every day more than 23 000 people develop active tuberculosis and close to 5 000 die from the disease. Each year there are 8.7 million new cases of TB and an estimated 1.7 million deaths. If current control efforts are not massively expanded, TB will kill more than 40 million people over the next 25 years. The HIV/AIDS epidemic is accelerating the death toll from TB. In areas where the WHO-recommended DOTS strategy is not yet being implemented, there is an increased prevalence of multidrug-resistant, which is over 100 times more expensive to treat.

TB and poverty

TB is a disease of poverty that disproportionately affects the poorest people in the world's poorest countries. Over 90 per cent of TB cases and deaths occur in low and lower-middle income countries, with an estimated economic cost to poor households of more than US$ 12 billion per year. TB often kills the main wage-earner in a household, pushing the entire family into long-term debt and destitution. Those TB patients who survive lose on average 20 to 30 per cent of their annual income owing to lost productivity from the disease. Thus does a vicious cycle of poverty and TB prevail: poverty increases the risk of TB, and TB impoverishes its victims.

Global TB targets

If global TB control efforts continue at the current rate, global targets approved by the World Health Assembly for 2005 will not be met until 2013. These targets are to identify 70 per cent of all infectious TB cases and to cure 85 per cent of all cases identified. Stop TB aims to achieve these targets by the year 2005 through acceleration of efforts at country and global levels.

The burden of TB can be halved by 2010 if these targets are reached by 2005, and effective TB control is subsequently maintained. By 2020, the world will have averted 25 million deaths from TB, prevented 50 million new TB cases, and halted the spread of drug-resistant strains. In addition, poorer countries will be freed from the "economic brakes" imposed by poorly controlled TB. In India, for example, the economic benefits of good TB control are estimated to be on the order of 2 per cent of India's gross national product.

Global progress in TB control via DOTS expansion

Despite many challenges, TB control has made significant progress in the past year. Since 1999 the DOTS strategy has been adopted by an additional 20 countries and is now in use in 148 countries. The proportion of all TB patients who were treated in DOTS programmes increased from 23 per cent in 1999 to 27 per cent in 2000.

The DOTS strategy focuses not just on inputs but on measurable and documented outcomes. In huge countries like China and India, DOTS was rapidly expanded during the 1990s to cover nearly half their populations, with cure rates of 90 per cent in China and over 80 per cent in India. Given sufficient investment, the DOTS strategy in other high-TB burden

countries can be scaled up relatively rapidly as well and with similar outcomes.

Opportunities to eliminate TB

The most exciting opportunity for action against TB that emerged in 2001 was the development of the Global Fund to Fight AIDS, TB and Malaria (GFATM). The GFATM was the brainchild of UN Secretary-General Kofi Annan, who has so far succeeded in gathering financial commitments totalling over US$ 1.7 billion from governments, voluntary organisations and private donors. It is vital that Stop TB benefit from this additional funding to implement the Global Plan to Stop TB, which was launched this year at the first Stop TB Partners' Forum.

TB and HIV

HIV fuels the TB epidemic in populations where people are infected with both. In high-HIV prevalence populations, many people infected with HIV develop TB, and many TB patients are coinfected with HIV. As of 31 December 2000, an estimated 36.1 million adults and children worldwide were living with HIV or AIDS. Of these, 25.3 million (70 per cent) adults and children were estimated to be living in sub-Saharan Africa, and 5.8 million (16 per cent) in South and South-East Asia. In 2000, about 12 million HIV-infected people worldwide were also coinfected with *M. tuberculosis*. About 70 per cent of coinfected people live in sub-Saharan Africa, 20 per cent in Asia and 8 per cent in Latin America and the Caribbean.

Untreated HIV infection leads to progressive immunodeficiency and increased susceptibility to infections, including TB. Moreoever, HIV is driving the TB epidemic in many countries, especially in sub-Saharan Africa and, increasingly, in Asia and South America. TB and HIV/AIDS programmes therefore share mutual concerns: prevention of HIV should be a priority for TB control, and TB care and prevention should be priority concerns of HIV/AIDS programmes. Previously, TB and HIV/AIDS programmes have largely pursued separate courses, but a new approach to TB control in high-HIV prevalence populations requires collaboration between them.

HIGHLIGHTS FROM THE PARTNERSHIP SECRETARIAT 2001

2001 will be remembered for the successful implementation of several major initiatives by Stop TB. Most notably, this year saw the first Stop TB Partners' Forum in Washington, the launch of the Global Plan to Stop TB and the launch of the Global Drug Facility. In addition, the expansion of the Stop TB Partnership, from 75 members in 2000 to 210 in 2001, reflected growing interest and commitment to global TB control.

Other highlights included the meeting of the interim Coordinating Board, held in February in Bellagio, Italy; the celebration of World TB Day 2001 on 24 March and the increase from one to three Stop TB global events on that day; the establishment of six Stop TB Working Groups and realization of their first meetings; and the inclusion of TB and malaria alongside AIDS in the remit of the Global Fund to Fight AIDS, TB and Malaria. More details on each of these new developments will be given in the relevant sections of this report.

The Global Drug Facility

A major tangible achievement of the Partnership in 2001 was the establishment and activation of the Global Drug Facility. This is an innovative scheme to help ensure universal access to TB drugs, developed in response to a call made by countries at the March 2000 Ministerial Conference in Amsterdam for new international approaches.

The GDF was initiated in 2000, developed in collaboration with partners and launched on World TB Day, 24 March 2001. Initial funding came from the Canadian International Development Agency (CIDA), and subsequent support has been provided by the government of the Netherlands and USAID.

The competitive bidding initiated by the Global Drug Facility has reduced drug prices by 30 per cent to less than US$ 10 for a full treatment course.

The GDF aims to treat up to 11.6 million patients over the next five years. So far its Technical Review Committee has recommended 16 countries for GDF support from a total of 25 applicants, totalling enough drugs to treat around 550 000 patients Since the first supply of drugs to Moldova in October 2001, shipments have also been made to the Democratic People's Republic of Korea, Myanmar and Congo Brazzaville. The GDF has already spent US$ 7.8 million on TB drugs for these countries and for others that will receive drugs in early 2002.

As important, the international competitive bidding initiated by GDF has caused TB drug prices to fall by roughly 30 per cent. A full course of treatment now costs less than US$ 10, including regimens using four-drug fixed-dose combination tablets.

THE GLOBAL PARTNERSHIP TO STOP TB

2001 also saw the first Stop TB Partners' Forum, an assembly of representatives of the organizations that make up the Partnership. The Forum convened for the first time in Washington D.C. from 22-23 October 2001. Nearly 200 participants attended from 18 high-burden countries, 9 developed countries, 9 multilateral partners, and 60 organizations. The Forum's mandate is to meet every two years in order to:

1. Consolidate partners' commitment to TB control and the Partnership's objectives;
2. Reinforce high-level political commitment to stopping TB;
3. Exchange information and identify new challenges in TB control;
4. Create and exploit opportunities for advocacy and communications activities and for social and resource mobilization; and
5. Review the progress made in the preceding two years.

The two main outcomes of the first Partners' Forum were the endorsement of the Washington Commitment and launch of the Global Plan to Stop TB.

The Washington Commitment

The Washington Commitment is a declaration endorsed by all Forum participants. It initiated a countdown to targets for the following 50 days, 50 weeks and 50 months (see box) So far the Washington Commitment has received more than 60 endorsements from governments and partner organizations.

The Global Plan to Stop TB

The second major outcome of the Forum in 2001 was the launch of the *Global Plan to Stop TB*, which the Stop TB Partnership Secretariat and Partners in Health developed with support from the Open Society Institute. The Global Plan sets out the strategy, priorities and resources needed to stop TB. Its investment section is a business plan which demonstrates to private and public sector donors that TB control is a sound investment.

The stated targets of the Global Plan are:

- By 2005, to detect 70 per cent of estimated new active TB cases and cure 85 per cent of all cases detected;
- By 2010, to reduce the global burden of TB (deaths and prevalence) by 50 per cent from year 2000 levels.

The Global Plan's strategic objectives are:

- To expand DOTS in order that all people with TB receive accurate diagnosis and treatment;
- To adapt this strategy to meet the emerging challenges of TB/HIV coinfection and drug resistance;

- To improve existing tools by developing new diagnostics, drugs and vaccines; and
- To strengthen the Stop TB Partnership so that proven TB control strategies are developed and effectively applied.

These require building a strong partnership upholding principles of inclusiveness, transparency and responsiveness among all partners, with a particular focus on TB-endemic nations. The Global Plan's mandate also involves moving beyond purely medical TB control and emphasizes the necessity of contributing to poverty reduction and health sector strengthening. To those ends, resource mobilization remains a vital objective in the fight to Stop TB.

Partnership Governance: the Coordinating Board

One hundred and forty partners involved in the consensus-building process during 1999-2000 have endorsed the governance mechanisms of the Stop TB Partnership. This framework, including the Stop TB Partnership structure, the functions and composition of the Partners' Forum and Coordinating Board, and the Stop TB Partnership Secretariat, was endorsed at the Partners' Forum.

The Coordinating Board represents and acts on behalf of the Partnership and consists of representatives selected from among different groups of stakeholders. In its composition, the Board reflects the diversity of the partnership –

COUNTDOWN TO 2005

50 Days

All high-burden countries to finalize national DOTS expansion plans

50 Weeks

Achievement of a global DOTS case detection rate of at least 35%

Establishment of interagency coordinating committees in all high-burden countries

GDF provision of TB drugs to at least 1 million additional patients

50 Months

Achievement of a global DOTS case detection rate of at least 70%

Achievement of a DOTS treatment success rate of at least 85%

Development and scale-up of effective responses to TB/HIV and MDR-TB

Development of the Global Plan to Stop TB for the years 2006-2010

scientists, policy-makers, financial donors, field/country level programme managers, the private sector, civil society and those concerned with advocacy and communications. The Coordinating Board meets two to three times a year and guides the work of the Stop TB Partnership.

Expansion of the Partnership

In 2000, Stop TB had 75 partners. Today that number has increased to 210 individuals and organisations. Among the new organizational members are ActionAid, Merlin UK, the Royal Tropical Institute and Refugee Trust International. Many of these new partners attended the first Stop TB Partners' Forum in October and provided support for the development of the Global Plan to Stop TB.

Working Groups update

Stop TB has established six Working Groups to ensure that TB control initiatives are implemented in a coordinated and efficient manner. The six Working Groups focus on the following areas of activity:

- DOTS Expansion
- TB/HIV
- DOTS-Plus for MDR-TB
- New TB Diagnostics
- New TB Vaccines
- TB Drug Development

DOTS Expansion Working Group

The essential services needed to control TB, based on diagnosis and treatment of infectious cases and incorporating essential management tools, were developed by the International Union Against Tuberculosis and Lung Disease (IUATLD) in a few developing countries in the 1980s. These services were subsequently packaged by WHO as the DOTS strategy (box below) and promoted as a global strategy in the mid-1990s.

Widespread application of DOTS has witnessed some remarkable results. Transmission has sharply declined in several countries: in Peru, the drop in incidence has been approximately 6.5 per cent per year over the past decade. Mortality has fallen: in China, a total of 30 000 deaths have been averted each year in districts implementing DOTS. Drug resistance has decreased: in New York in the 1990s, the prevalence of TB drug resistance fell by 75 per cent following aggressive interventions to improve patient management.

THE FIVE COMPONENTS OF THE DOTS STRATEGY

1. Government commitment to sustained TB control activities.

2. Case-detection by sputum smear microscopy among symptomatic patients self-reporting to health services.

3. Standardized regimens of six to eight months' treatment for, at a minimum, all confirmed sputum smear positive cases, under proper case management conditions, including directly observed therapy (DOT) at least for the initial two months.

4. A regular uninterrupted supply of all essential TB drugs.

5. A standardized recording and reporting system that allows assessment of treatment results for each patient and of the overall performance of the TB control programme.

Unfortunately, DOTS expansion is not proceeding at a rate rapid enough to achieve the global targets for 2005, and at the current rate of expansion these targets will not be reached before 2013 (see below). Millions of TB sufferers worldwide are being denied effective treatment because DOTS is not available in their area. A massive scaling up of current efforts and innovative ways of motivating all possible contributors to the fight against TB are necessary in order to meet the 2005 targets.

The Global DOTS Expansion Plan

On 16 May 2001 WHO released The Global Dots Expansion Plan, Progress in TB Control in high-burden countries, 2001. The GDEP is a strategic planning document that describes how countries and their partners can work together to expand DOTS.

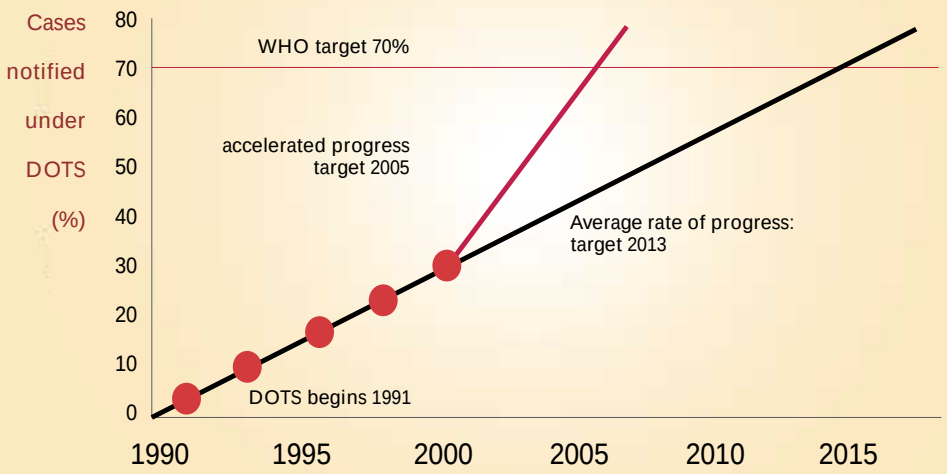
This document provides a framework whereby regions and countries may expand coverage by, first, developing well thought-out regional strategic plans, and second, by facilitating the development, monitoring, and implementation of country-specific medium-term plans. The GDEP also calls for the establishment of interagency coordinating committees (ICCs) which bring together all partners, both technical and financial, to implement the agreed upon plan under the stewardship of the country's government.

Recent analysis for the GDEP has provided estimates of the resources required to achieve the global TB control targets. The analysis suggests that an average of about US$ 1 billion per year is needed for the 22 countries with the highest number of estimated cases of TB, otherwise known as the "high-burden countries" or HBCs. Provisional work indicates that an additional US$ 200 million per year is needed in low and lower-middle income countries beyond the 22 HBCs.

At present about 70 per cent of required funding is available from HBC governments and 5 per cent from donors. The funding gap for

PROJECTED CASE DETECTION UNDER DOTS

Without accelerated expansion, World Health Assembly targets will be reached in 2013



the 22 HBCs and low and lower-middle income countries is up to US$ 300 million per year.

Although funding for combined DOTS expansion activities is currently at only 50 per cent of budget, great steps forward were made in DOTS expansion during 2001. At the end of 2000 only 12 of the 22 HBCs had even begun to develop sound country plans. By the end of 2001, 16 HBCs had produced comprehensive DOTS expansion plans while the remaining six had plans but which were either not yet translated or under development.

According to the 2001 Global DOTS Expansion Report, progress in TB control has remained slow in most of the 22 high-burden countries. There were however some notable exceptions. Peru and Viet Nam both achieved WHO targets for case detection and treatment success in 2001, and as a result Peru was officially removed from the list of HBCs. With 23 per cent of the world's active TB cases, India is also making astounding progress against the disease, having expanded DOTS coverage from 9 per cent in 1998 to 40 per cent in 2001. It is now treating more patients with DOTS than any other country in the world and is achieving cure rates in excess of 80 per cent.

2001 was a year for the preparation of plans and identification of resource gaps. The emphasis in 2002 will be on implementing these plans for DOTS expansion. The Working Group's activities will encompass four main objectives: technical assistance, support and coordination, monitoring and reporting, and advocacy.

Technical assistance activities include capacity building and human resource development, direct National TB Programme (NTP) assistance, advisors, missions and tools. The milestones in these areas are:

- International training courses, including the training of consultants
- Coordination of training and materials
- In-service training
- Medium-term plans, including budget
- DOTS coverage

Support and coordination activities include setting out regional action plans for 50 per cent of TB endemic countries, regional advisory groups and interagency committees on regional and national levels, as well as updating action plans, needs analyses and budgets for agencies supporting DOTS expansion.

The DOTS Expansion Working Group will hold its 2002 meeting in Canada and will publish DOTS Expansion Report No 3.

Working Group on TB/HIV

The goal of the Global Working Group to control TB/HIV is to reduce the burden of TB in HIV high prevalence populations. The Working Group, coordinated by WHO, is one of six established under the auspices of the Global Stop TB Partnership. The first meeting of this Working Group in April 2001 was a crucial step in harnessing and coordinating global efforts to more effectively decrease the burden of TB/HIV.

Working Group partners are currently putting into operation a new Group-endorsed strategic framework for decreasing the burden of TB/HIV. They are promoting collaborative activities between TB and HIV/AIDS programmes in key countries, building on field experiences such as the ProTEST Initiative. This Initiative is examining the feasibility and cost-effectiveness of linking voluntary counselling and testing for HIV with interventions for TB and HIV/AIDS prevention and care.

Partners are also collaborating in the development of field guidelines for phased implementation of collaborative TB and HIV programme activities. In 2002 they will be focusing on a series of proposal development workshops for four African countries that will be organized by WHO in collaboration with USAID and the Centers for Disease Control and Prevention (CDC).

Other targeted activities for 2002 include publication of *A Strategic Framework to Decrease the Burden of TB/HIV* and *Guidelines for Phased Implementation of Collaborative TB/HIV Programme Activities*, initiation of joint TB/HIV activities in four countries (with four more targeted for 2003), modelling of intervention impacts, and analysis of TB and HIV epidemiology worldwide.

Working Group on DOTS-Plus for MDR-TB

Initiated in 1999, the Working Group on DOTS-Plus for MDR-TB conducts and oversees pilot projects based on the Guidelines for Establishing DOTS-Plus Pilot Projects for the Management of MDR-TB prepared by the Scientific Panel of the same working group. The DOTS-Plus Working Group aims to improve access to second-line TB drugs for DOTS-Plus pilot projects, primarily through the Green Light Committee (GLC).

The Working Group is collaborating with the pharmaceutical industry to combat MDR-TB. As part of this collaboration, members of the pharmaceutical industry have agreed to provide preferential prices to DOTS-Plus pilot projects. The Green Light Committee, as a subgroup of the Working Group, reviews project applications and determines whether projects can benefit from the preferential prices. To date, it has reviewed twelve potential DOTS-Plus projects for participation in the pooled procurement of concessionally priced second-line TB drugs.

The GLC has approved eight applications including those of Estonia, Latvia, and the Tomsk, Kemerovo and Orel Oblasts (Russian Federation) for access to concessionally priced second-line drugs. Applications from Mexico, Nigeria and India are currently under review.

The Working Group has also published two guidelines: *Guidelines for Drug Susceptibility Testing to Second-line Drugs for DOTS-Plus*, and *Guidelines for Establishing DOTS-Plus Pilot Projects for the Management of MDR-TB*. Group members have also established a short and long-term pooled procurement process for second-line drugs.

Other achievements include negotiating for price decreases of up to 94 per cent in treatment regimens for MDR-TB; the implementation of training sessions for 10 countries applying for access to preferentially priced drugs; and the provision of technical assistance to the Philippines, Latvia, Estonia, Peru, Costa Rica and the Russian Federation. In addition, the group is building capacity for DOTS-Plus through site monitoring visits to pilot projects in the Philippines, Estonia, Latvia, Tomsk, and Peru. To date, approved DOTS-Plus projects serving over 2 000 patients are already operational and benefiting from substantial drug price reductions.

Working Group on TB Drug Research and Development

The Global Alliance for TB Drug Development (GATB) acts as the Working Group on TB Drug Research and Development. It operates as a not-for-profit, public-private partnership organization with offices in Brussels, Cape Town, and New York. Launched in October 2000, the Alliance offers a unique approach designed to accelerate the discovery and development of new drugs to fight TB.

On the eve of World TB Day 2001, the GATB presented research data and stressed the urgent need for new drugs in the fight against the global tuberculosis epidemic. The data highlighted some alarming trends – particularly the rate at which people are becoming infected with both HIV and latent TB infection (LTBI), showing that the number of people with TB/HIV coinfection (10.7 million in 1997) is rising rapidly and thereby increasing the number of active TB cases. The report stressed the need for research into shorter treatment regimens for both latent and active TB, and identified neglected areas within TB drug research and development. The GATB will seek to address these issues by forming partnerships with the pharmaceutical industry and public research organisations.

GATB members also announced preliminary research findings demonstrating that a TB drug that significantly reduces the period of treatment could be highly profitable. This announcement

was the result of two comprehensive studies undertaken by the Global Alliance: *The Scientific Blueprint for TB Drug Development* published in April 2001, and The Pharmocoeconomics of TB Drug Development. The latter report provided the data required to make informed decisions regarding TB drug development investment on the part of industry, philanthropic foundations, and global financial and health organizations.

GATB and stakeholder organizations also organized dozens of scientific events focusing on TB drug development worldwide. These included a meeting in Cape Town in February 2001, the Inaugural Gordon Conference in the USA in June 2001, and a symposium at the IUATLD annual conference in Paris in October 2001. The Working Group's goals for 2002 are to:

- Have three candidates in preclinical trials
- Expand capacity for experimental animal studies
- Initiate regulatory standardization and establish surrogate marker strategy
- Strengthen clinical trial capacity in developing countries

By 2003-2004, the Working Group's aim is to establish further partnerships with industry, stimulate research for new TB drug targets, improve screening capacity for compound libraries and increase the preclinical pipelines. It is their further aim to have at least five candidates through preclinical trials by 2005.

Working Group on New TB Diagnostics

More than 100 years after its inception, the microscopic examination of sputum is still the only widely available diagnostic tool for TB in most developing countries. This technique has several pitfalls, not least of which is an inability to diagnose non-infectious TB cases, coupled with the difficulty of maintaining well-equipped laboratories in developing country settings. The upshot is that only a small fraction of TB patients are quickly and accurately diagnosed, leading to increased morbidity, impediments to DOTS expansion, the erosion of faith in public health care services and most importantly, continued transmission of infectious TB.

Progress is being made, albeit slowly. There are now more than 50 private sector enterprises involved in developing TB diagnostics. Like GATB, the Working Group on diagnostics functions as a "virtual shop," exchanging information and keeping abreast of new developments through the Internet and by email. The Working Group is aiming at the following global targets:

- Development of an evidence base for best use of TB diagnostics (timing and target populations) for improved disease control by 2004
- Identification and evaluation of at least 5 diagnostic candidates Phase I/II trials by 2005

THE PHARMACOECONOMICS OF TB DRUG DEVELOPMENT

Released in May 2001, *The Pharmacoeconomics of TB Drug Development* demonstrates that a TB drug that reduces the period of treatment to two months could capture much of the total annual worldwide market for TB drugs, currently worth up to US$ 470 million. This estimate, however, could be considered conservative. According to the Alliance, a drug that not only reduces treatment to two months but is also effective against MDR-TB and dramatically shortens the treatment for latent TB infection (particularly in patients who are HIV-positive) would capture a substantially larger market. The Alliance's goal is to have a new drug registered by 2010 and available in developing countries by 2012.

- Completion of Phase III trials of at least 1 case-detection tool and at least 3 new drug susceptibility testing methods by 2005
- Utilization of an international system for evaluation of TB diagnostics by 2005
- Publication of guidelines for use of new TB tests by 2007

The Group's targets for 2002 are to have:

- Completed head-to-head trial of serologics
- Initiated DST Phase III and Phase IV evaluation
- Established *M. tuberculosis* strain bank
- Initiated global diagnostic market analysis
- Completed mathematical model of diagnostic delay and dropout

Working Group on New TB Vaccines

For years health experts have recognized the necessity of improving on the current BCG vaccine. While it is effective in the prevention of several serious forms of TB in children, BCG does not fully protect against pulmonary TB in adults.

A series of new developments in microbiology, genetics and biotechnology, however, have substantially contributed to our knowledge of *M. tuberculosis*. For the first time since the advent of BCG, researchers now believe that a new and effective TB vaccine can be developed by 2020. So far, the TB Vaccines Working Group has met once, on 9 June 2001 in Geneva. This date was selected to coincide with the WHO Global Forum on TB Vaccines Research and Development. The purpose of the Working Group meeting was to recommend the next steps and determine a framework for the development, clinical study and introduction of improved TB vaccines for the global community. The Working Group, which also functions as the TB Vaccine Initiative Advisory Committee for WHO (TBVIAC), then met to establish its agenda and formulate a five-year plan for activities to promote and facilitate TB vaccine development.

The Working Group's activities for 2002 include: ad hoc meetings of the preclinical and clinical task forces, establishment of a primate TB vaccine testing network, beginning development of clinical Phase III testing sites, development of "vaccino-economic" analysis and cost-effectiveness modelling, building of international consensus on standardized reference reagents and supporting their development and distribution, and development of a comprehensive advocacy and information strategy for new TB vaccines.

It is important to note that of a total of eight projected milestones associated with the above-listed activities, six will be partially or wholly unattainable unless additional funding of US$ 800 000 is secured, including development of primate facilities and testing sites, appointment of a consultant on vaccino-economic analysis, commissioning production of standard reagents, and development of a beta-version TB vaccine website.

THE GLOBAL DRUG FACILITY (GDF)

Development of GDF

A Core Technical Group was created in November 1999 to finalize the GDF prospectus and to develop recommendations on the scope, principles, objectives and governance of the GDF. The prospectus was presented at the Stop TB Coordinating Board meeting in Bellagio in February 2001. The scope and principles of the GDF were endorsed and interim operations were approved with funds made available by CIDA. It was agreed that the GDF would be managed by the Stop TB Partnership Secretariat in WHO for an initial period of two years, to be followed by an external evaluation. Since then further funding has been provided by the government of the Netherlands and USAID.

The benefits

It is estimated that at least 10 million TB patients will benefit during the first five years of the facility's operation, with an additional 45 million served after 10 years. By 2020, 25 million TB deaths will have been averted and 50 million TB cases prevented; TB prevalence will have been reduced by 75 per cent and its incidence by 50 per cent. A beneficial by-product will be the strengthening of medical infrastructures as a whole – including the addition of large numbers of trained staff, improved diagnostic capacity, treatment and practice, sustainable monitoring systems and rationalized procurement systems, ensuring a ready supply of affordable drugs.

How it works

As a body with a limited life span of 10-15 years, the GDF is designed to meet short-term needs for TB drugs to support DOTS expansion and thereby give countries time to develop and strengthen local drug procurement capacity. Countries were invited to apply for GDF support in early 2001, and a technical review committee comprising 12 independent experts in TB control was formed.

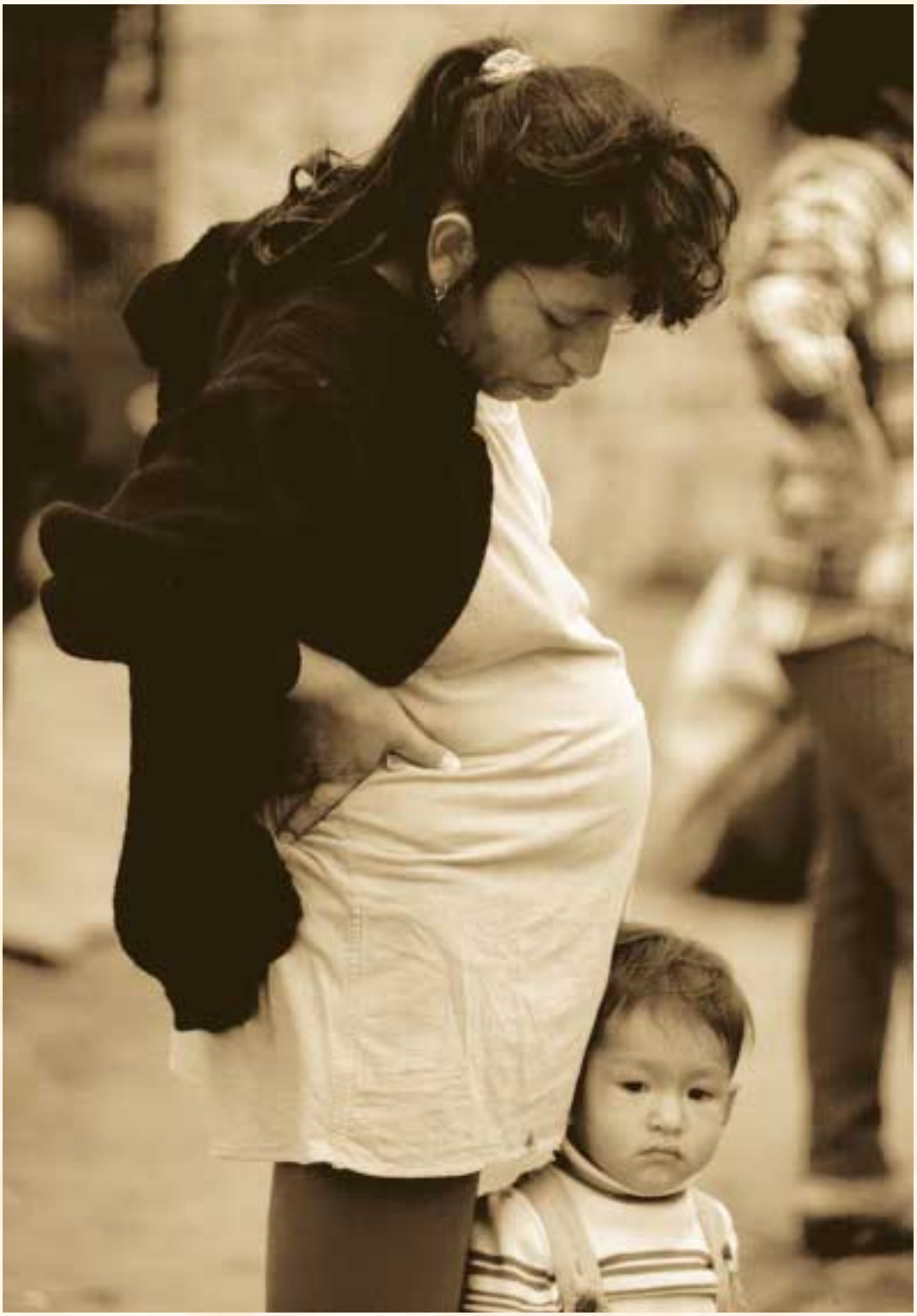
The GDF held two rounds of applications and the TRC appraised application forms from 25 countries. To date, 16 applications have been accepted for support, with two awaiting a final decision. In 2001 only national governments were eligible to apply for GDF support, but it was agreed in late 2001 that NGOs would be able to apply as well. A direct procurement mechanism was also established to enable countries and organizations to buy drugs with their own funds through GDF mechanisms and at GDF prices.

Drug procurement and quality assurance

The GDF purchases drugs to be supplied as grants-in-kind through limited international competitive bidding from pharmaceutical manufacturers who meet pre-qualification standards of experience, quality and capacity. In 2001, the contract was awarded to MEG/Svizera. In the first year of operations the GDF has relied on the pre-qualification process of Stop TB partners involved in international procurement of TB drugs. The GDF is now developing a long-term and more robust approach to pre-qualification, with the aim of publishing a white list of approved manufacturers and products.

Following a competitive bidding process, the GDF contracted with UNDP/IAPSO for procurement services. IAPSO has been responsible for tender management, procurement, pre-shipment inspections, laboratory analysis, shipping, insurance and communications with recipients, and has also developed a web-based ordering and tracking system (www.stoptb.unwebbuy.org) to enable GDF recipients to follow their order on the Internet.

Quality is a key concern for the GDF, and it has contracted with SGS for pre-shipment inspection and independent laboratory analysis of each batch of drugs before dispatch to recipient countries.



THE ROLE OF ADVOCACY AND COMMUNICATIONS IN STOP TB

Stop TB's global advocacy is focused on mobilizing political will and financial and human resources, and on increasing the involvement of a broad range of multi-sectoral partners that include the UN, bilateral agencies, NGOs, foundations, and industry and research institutions.

Media activities are centred on raising public awareness of TB as a major killer and the necessity of its control. Press and media events exploit new media and are generally organized in tandem with the publication of new available data and other TB control events and initiatives. In 2001, other advocacy activities focused on linking TB to various policy areas such as HIV/AIDS, human rights, and sustainable development. Thus communication remains a key instrument driving the global movement to Stop TB.

During the 2000-2001 biennium, Stop TB established a sound communications infrastructure, including a monthly electronic communiqué, weekly web alerts, quarterly Stop TB newsletters and the Stop TB website, which is updated daily. The website had over 50 000 hits in the second half of 2001.

The Stop TB quarterly newsletters focused on the following themes in 2001:

- June: World TB Day, sent to over 5 000 interested parties;
- September: TB/HIV, sent to the Stop TB Partners and to UNAIDS network;
- December: DOTS Expansion, sent to Stop TB partners and national and local level organizations working in TB control.

Communications activities in 2001 – highlights of events and meetings

During the World Health Assembly in May 2001, Stop TB Partners launched the Global DOTS Expansion Plan with Peruvian Minister of Health Dr E Pretell Zarate in attendance at the press conference.

At the first UNGASS meeting in New York in June, the International Union Against Tuberculosis and Lung Disease (IUATLD) organized TB – "The forgotten companion of HIV" in a side event aimed at informing delegates and the media of the often-overlooked link between HIV/AIDS and TB.

At the first Stop TB Partner's Forum in Washington on October 21, advocacy materials included three informational videos.

WORLD TB DAY 2001

"DOTS: TB cure for all" was the theme for World TB Day held 24 March 2001. The theme was chosen to highlight access to TB treatment and cure for all as integral to the exercise of fundamental human rights – that it is a TB patient's "right to the highest attainable standard of health" as set out in the WHO charter.

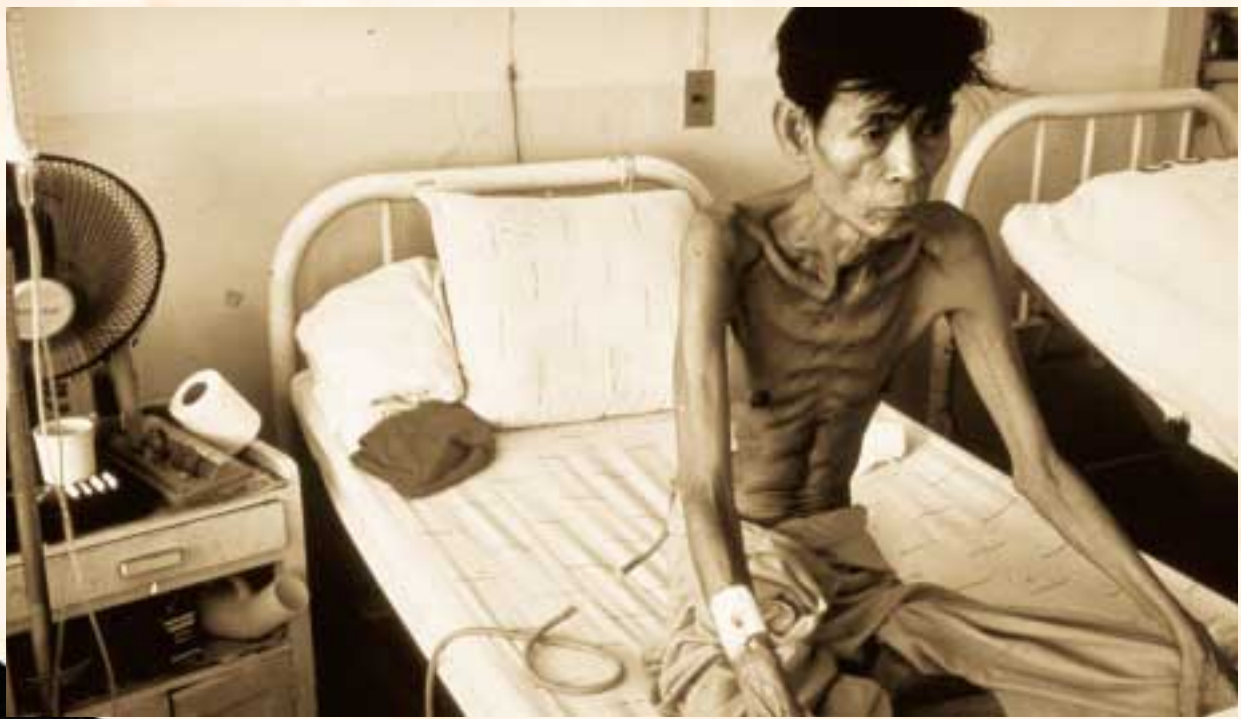
To that end, the Stop TB Partnership called for increased access to TB treatment for all and emphasized three points:

- TB treatment is a human right;
- New mechanisms are needed to increase access to treatment;
- New drugs are vital to ensure the long-term sustainability of effective treatment.

For the first time World TB Day 2001 featured a wide range of events organized by different Stop TB Partners throughout the world. Key events included:

- 16 March: His Grace Archbishop Desmond Tutu initiated World TB Day events in South Africa.
- During March 2001 the South African government, in partnership with other stakeholders, inaugurated the opening of the Tyger Trade and Training Centre (TTTC), a multi-sector initiative that aims to treat both the economic and social problems associated with TB through job skills training, media and public awareness campaigns and community mobilization.
- 20 March: Médécins Sans Frontières sponsored a panel discussion on "Defusing the Time Bomb: The World's TB Crisis" at the City University of New York.
- 21 March: In Washington DC the National Council for the Elimination of TB and Stop TB launched the Omnibus Control Act of 2001 and the Global Drug Facility (GDF) in a joint event.
- During the week preceding World TB Day 2001, the Global Alliance for TB Drug Development held a press conference in Brussels to announce the publication of the executive summary of The Economics of TB Drug Development.
- On the eve of World TB Day 2001, the Bill & Melinda Gates Foundation awarded US$ 10 million to the United Nations Development Programme/World Bank/ WHO Special Programme for Research and Development in Tropical Diseases (TDR) to facilitate the development of new tests for tuberculosis diagnosis.

Other communications efforts for World TB Day focused on the production of various materials, such as the Stop TB series on Guidelines for Social Mobilization and of World TB Day Highlights in 2000 and 2001. Also produced were background documents and a series of videos on current issues relating to TB for the Stop TB Partners' Forum.



LOOKING AHEAD – 2002

2001 saw the achievement of global coordination among the Stop TB Partners, which was reflected in the success of the Partners' Forum in Washington and the endorsement of the Washington Commitment by all participants. It also saw the production of the *Global Plan to Stop TB*, setting out the resources and actions needed to meet the targets set for 2005. This means that Stop TB goes forward into 2002 able to turn for support and expertise to a wide range of individuals and organizations, including and going beyond those who have traditionally worked against TB.

The Partnership also now knows exactly what is required in order to meet the 2005 targets. It is vital that Stop TB use our partners to the full and that the partners stand by their commitment to contribute to the fight against TB. With the Partnership Secretariat at its centre, this network of partners can scale up efforts against tuberculosis and leverage available funding in innovative ways.

The launch of the GDF is a concrete example of how new mechanisms can be implemented in a short period of time. Within eight months of its inception the facility had already delivered drugs to three countries. More such innovative responses to specific problems in TB control will be necessary if the 2005 targets are to be met, since changes in the way we tackle TB as well as an increase in the scale of current efforts are necessary to reach these goals on time.

2001 was a year in which the groundwork was laid for further implementation of very large DOTS expansion schemes, effective responses to TB/HIV and MDR-TB, and a medium-term advocacy and communications strategy for Stop TB. 2002 will see the focus firmly shifted from planning to implementation and therefore will be the first year in which we see a real acceleration towards the 2005 targets. There is still a long way to go but the 2005 targets can be met if all partners work together effectively in the ways agreed in 2001.