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DOTS EXPANSION PLAN TO STOP TB IN THE WHO EUROPEAN REGION 2002–2006

The DOTS Expansion Plan to Stop TB in the WHO European Region 2002–2006 is presented to the Regional Committee for its consideration and approval. It should be read in conjunction with document EUR/RC52/9 and draft resolution EUR/RC52/Conf.Doc./5.

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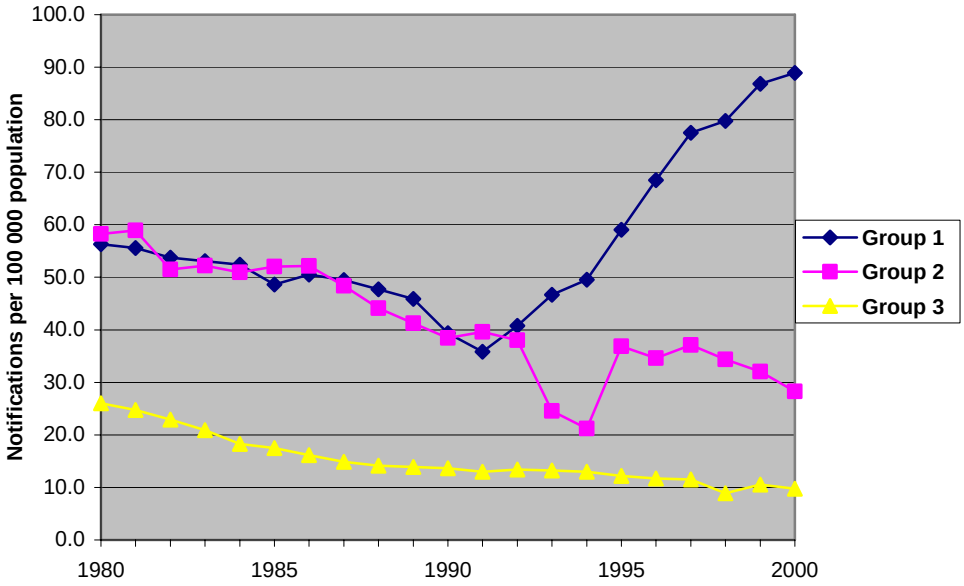
Introduction

The current tuberculosis situation in the European Region

The tuberculosis (TB) situation is critical in 16 of the 51 countries in the WHO European Region, with a resurgence of the disease and a dramatic increase in notification rates in the last 10 years (Fig. 1). Today, countries with a growing TB burden represent more than three quarters (77%) of the European TB burden, with the potential to affect other countries in the Region. TB is also a public health concern in the 35 other European countries with intermediate and low TB burdens, where the decline in TB morbidity and notification rates has levelled off as a result of war, civil conflict and insecurity, or the emergence of high-risk groups of TB among immigrants. Without additional efforts, countries with a low TB burden may take decades to enter the elimination phase (1 case per million population) and go on to eradicate the disease.

TB is the leading infectious killer of young people and adults in the European Region, despite the existence of a highly cost-effective strategy known as DOTS (directly observed treatment, short-course), which can cure the disease. The absolute number of successfully treated cases has increased significantly in the Region, in 1999 reaching 66% in non-DOTS areas and 78% in areas where DOTS had been implemented. Nevertheless, in 2000 only 15% of the population of the five countries with the highest TB burdens in the Region (the Russian Federation, Ukraine, Romania, Uzbekistan and Kazakhstan, in that order) had access to DOTS.

Fig. 1. Tuberculosis notification rates in the WHO European Region, 1980–2000



Group 1: 16 countries with a high TB burden: Armenia, Azerbaijan, Belarus, Estonia, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Republic of Moldova, Romania, Russian Federation, Tajikistan, Turkmenistan, Ukraine, Uzbekistan.
Group 2: 11 countries with an intermediate TB burden: Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Hungary, Poland, Portugal, Spain, the former Yugoslav Republic of Macedonia, Turkey, Yugoslavia.
Group 3: 24 countries with a low TB burden (and low incidence): Andorra, Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Luxembourg, Malta, Monaco, Netherlands, Norway, San Marino, Slovakia, Slovenia, Sweden, Switzerland, United Kingdom.

DOTS case detection[1] in the Region is only 10.1% (22 430 notified sputum-smear-positive TB cases in DOTS areas out of 220 813 estimated cases in 2000), which is far from the 70% global target.[2] Although most of the countries with a high TB burden have adopted the DOTS strategy within the last five years, only 20% of notified TB cases benefited from the DOTS strategy in 2000. The European Region has the lowest DOTS coverage (17.3%) and the lowest DOTS case detection rate of the six WHO regions.

From the global Stop TB Partnership to the DOTS Expansion Plan to Stop TB in the WHO European Region

Following a resurgence of TB in many parts of the world, the global Stop TB Partnership was launched in Bangkok in November 1998 and now comprises over 100 organizations worldwide committed to combating TB. The Stop TB Partnership coordinates the work of its partners through six working groups (covering, respectively, DOTS expansion, TB/HIV co-infection, multidrug-resistant TB, new diagnostics, new drugs and new vaccines) and within the Global TB Drug Facility (GDF) initiative. The draft of the Global Plan to Stop TB was launched during a meeting in Washington, DC in October 2001, the first forum of the Global Partnership to Stop TB (Annex 3). As part of the Global Plan to stop TB, the Global DOTS Expansion Plan (GDEP) is a template for mobilizing the human and financial resources necessary to expand TB control as part of the national health system, especially in the 22 countries with the highest TB burden in the world, in order to achieve the global targets for TB control.

The DOTS Expansion Working Group met in Cairo in 2000 and Paris in 2001, with the aim of providing support in planning, expanding and sustaining TB control efforts in order to reach the global target. One of its activities is to facilitate the development of regional plans.

GDF is another initiative of the global Stop TB Partnership to secure access to high-quality TB drugs. GDF was launched in May 2000 and became operational in January 2001. In June 2002, four European countries (Armenia, Republic of Moldova, Tajikistan and Uzbekistan) were approved to receive GDF support.

In 1999 the Global Partnership established the Working Group on DOTS-Plus to address multidrug-resistant TB effectively and to increase access to second-line anti-TB drugs provided at preferential prices. Within that Working Group, the Green Light Committee receives applications for and validates projects that comply with the guidelines.[3]

The Ministerial Conference on Tuberculosis and Sustainable Development, held in Amsterdam in March 2000, issued the Amsterdam Declaration to Stop TB. This called for accelerated expansion of TB control measures and for increased national and international political commitment and financial resources to reach the global targets by 2005. The Washington Commitment to stop TB issued in October 2001 (Annex 3) urges intensified efforts to implement the Amsterdam Declaration.

The Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM) is a separate mechanism, created as an independent public–private partnership to increase the global resources available to combat these three diseases, direct resources to areas in greatest need and ensure that the funds are used effectively. The idea of an international funding mechanism to fight these diseases crystallized at the Okinawa G8 Summit in July 2000. At the urging of the United Nations

[1] For a definition see Annex 1.

[2] Estimates from *WHO report 2002: Global tuberculosis control – surveillance, planning, financing.* Geneva, World Health Organization, 2002 (document WHO/CDS/TB/2002.295).

[3] *Guidelines for establishing DOTS-Plus pilot projects for the management of multidrug-resistant tuberculosis (MDR-TB).* Geneva, World Health Organization, 2000 (document WHO/CDS/TB/2000.279).

Secretary-General and national leaders, the concept was then unanimously endorsed at the United Nations General Assembly Special Session on HIV/AIDS in June 2001. The following month, G8 leaders meeting in Genoa committed US $1.3 billion to the fund. The announcement of the approved proposals on 25 April 2002 marked the end of a very swift review process.

In 1998, the forty-eighth session of the WHO Regional Committee for Europe adopted HEALTH21,[4] target 7 of which addresses communicable diseases, and urged Member States to intensify TB control as an integral part of primary health care. Moreover, in 2000 a review of health policy undertaken by the Regional Office clearly identified TB as one of its top health priorities in 21 of the 27 countries surveyed, and TB is mentioned as a first or second priority among the 16 countries with increasing rates of TB notification.

Created in response to both the epidemiological crisis in the Region and the priorities highlighted in the health policy review, the DOTS Expansion Plan to Stop TB in the WHO European Region (the European DOTS Expansion Plan) will provide a template for mobilizing the human and financial resources needed to expand TB control as part of the national health system of each country in the Region. The European DOTS Expansion Plan will contribute to the GDEP and the global working groups on TB/HIV co-infection and multidrug-resistant TB, aiming to strengthen health systems in general in the Region and allow national TB programmes to function effectively.

Principles of the European DOTS Expansion Plan

Today the major obstacles to expanding TB control are political, managerial and financial, although special challenges remain for problems such as HIV infection and multidrug-resistant TB. The European DOTS Expansion Plan aims to stimulate social and political commitment to achieving the global TB targets as part of the overall health system. The plan highlights country needs and resource gaps, emphasizing collaboration with the governments of endemic countries, national and international agencies and nongovernmental organizations (NGOs). It is expected that this coordinated approach will reinforce political commitment, mobilize national and external resources and increase efficiency.

The European DOTS Expansion Plan is based on two principles: the development of national DOTS expansion plans and partnership-building to control TB.

National DOTS expansion plans

DOTS expansion plans for the medium term must be technically sound and feasible, and take into account the characteristics of the national health system. A plan that includes a time frame for DOTS expansion and identifies the major inputs and associated budget (drugs and diagnostic supplies, strengthening of management, supervision procedures, training, staff, patient management that respects human rights, surveillance, and adapted activities to increase case detection and cure in the context of multidrug resistance) will facilitate management, guide the effective allocation of resources, and enable monitoring of implementation and progress towards targets.

Partnership-building

Partnerships are one of the keys to success in controlling TB. Control of the disease in Europe can be achieved only through collaboration with partners, both within and outside the health sector. Partnerships must be built between countries, agencies, foundations and NGOs, while respecting and reinforcing national sovereignty in the health field. Partnerships at national level

[4] *HEALTH21. The health for all policy framework for the WHO European Region.* Copenhagen, WHO Regional Office for Europe, 1999 (European Health for All Series, No. 6).

among the various departments of the health sector (clinical practice and laboratories, health centres and hospitals, academic institutions, public and private bodies, and governmental and nongovernmental institutions) are necessary for effective TB control and to ensure universal access to TB care.

The European DOTS Expansion Plan promotes an approach that begins and ends in the country.

- National programme managers/coordinators are responsible for presenting the status, plans and needs of their programmes to expand DOTS.
- Technical and financial partners who will facilitate the expansion of DOTS are identified for high-burden countries. One of the technical partner agencies is identified by the Ministry of Health or by the partners as a focal point for each country and the main coordinator of external support, information to other partners and monitoring of progress.
- National programme managers/coordinators and the technical and financial partners discuss the areas of support on the basis of the national plan.
- The regional plan builds on country plans, and partners discuss implementation and support to intercountry (regional and subregional) activities in order to strengthen national programmes.

Goal, objectives, targets and key milestones

Goal

The goal of the European DOTS Expansion Plan is to define the scope of work needed to significantly reduce morbidity and mortality from TB, and to promote accessibility and sustainability of the DOTS strategy as part of health system development.

Objectives

The objectives of the European DOTS Expansion Plan are to:

- reduce the prevalence of and mortality from TB in the Region by half in 10 years (by 2012), i.e. to the same level as in 1990;
- expand the implementation of the DOTS strategy by making it available to at least 90% of the population in each country in the Region;
- reduce primary multidrug-resistant TB at regional level to under 1% in 10 years (by 2012);
- introduce DOTS into the broader national health policy and planning; and
- adapt the DOTS strategy to changing health systems in areas such as planning, expansion, guidelines, financing, human resource capacity, drug supply, service delivery, monitoring and evaluation, advocacy, social mobilization and operational research.

Targets

The global targets (to be reached by the end of 2005) are:

- to ensure a treatment success rate of at least 85% for cases of sputum-smear-positive pulmonary TB (PTB+) (or at least 85% for definite TB cases in Group 3 countries) in the DOTS programme; and
- to ensure that at least 70% of estimated PTB+ cases (or at least 70% of definite TB cases in Group 3 countries) are enrolled in the DOTS programme, i.e. a 70% DOTS case detection rate.

The regional targets (to be reached by the end of 2006) are as follows:

DOTS expansion in a changing health system

- to adopt the DOTS strategy for the control and elimination of TB, including a central TB coordinator and a team of national experts to guide and support the professionals involved in TB control activities;
- to adapt the DOTS strategy to changes in the health system, such as those due to integration, decentralization, cost sharing, social insurance, privatization, sector-wide approaches, primary health care and patients' rights;
- to ensure TB services are provided throughout the health system at all levels, including peripheral health facilities and involvement of civil society;
- to ensure treatment outcome is assessed for at least all cases of PTB+;
- to include DOTS indicators among health system performance indicators in Group 1 countries; and
- to ensure DOTS is provided in prisons, according to the national TB programme and with close links to the civilian health services.

DOTS performance

- to enrol all detected cases of TB in the DOTS strategy; and
- to implement DOTS-Plus projects endorsed by the Green Light Committee in regions/countries where multidrug-resistant TB is a problem.

Drug supply and quality of drugs

- to sustain free treatment with high-quality anti-TB drugs for all forms of TB;
- to sustain an uninterrupted supply of high-quality anti-TB drugs through the development of local capacities to select drugs in accordance with standard guidelines, to procure and distribute according to accepted international practice, and to monitor drug consumption;
- to strengthen the national drug regulatory authority to enforce WHO standards and requirements for drug quality in at least the Group 1 countries;
- to promote access to second-line anti-TB drugs in specialized multidrug-resistant TB units endorsed by the Green Light Committee; and
- to supply anti-TB drugs through the GDF to Group 1 and Group 2 countries meeting the criteria.

Laboratory networks

- To develop a national laboratory network and a central reference laboratory in each country;
- to strengthen the national laboratory network for bacteriological diagnosis (acid-fast bacilli and culture) and quality assurance; and
- to link national laboratory networks with the supranational network of laboratories for culture and drug susceptibility tests.

Monitoring and evaluation

- to improve the surveillance system for assessing DOTS expansion and TB control performance in general;
- to monitor drug resistance among incident cases or by representative surveys or sentinel studies in all countries.
- to establish TB/HIV co-infection surveillance in Group 1 countries;
- to assess TB prevalence and mortality through a valid vital statistics registration system;
- to improve the vital statistics registration system; and
- to monitor disbursement of funds and levels of and gaps in funding related to TB activities, at least in the Group 1 countries.

Operational research

- to develop a strategic framework for HIV-related TB in the European Region;
- to provide TB patients with anti-retroviral treatment;
- to strengthen human resources for research through training and practice at country level; and
- to develop an adapted TB control strategy for special groups such as prisoners, alcoholics, the homeless, people living in remote areas and migrant workers, and to address special issues such as gender, cross-border issues, post conflict situations, etc.

Key milestones

By the end of 2002:

- a resolution on DOTS expansion in the European Region is expected to have been approved by the WHO Regional Committee for Europe;
- a European regional meeting of the Tuberculosis Interagency Coordinating Committee will have been held; and
- a consensus strategy for eliminating TB from low-burden (Group 3) countries and performance indicators will have been developed.

By the end of 2003:

- all countries will have identified a central TB coordinator and a team of national experts;
- all countries will have incorporated a TB control plan (DOTS strategy) into their national health policy;
- DOTS coverage (population and case enrolment) will have reached 30%;
- 30 countries in Groups 1, 2 and 3 will have established treatment outcome measurements through cohort analysis, as recommended by WHO;
- 10 countries in Group 1 and 5 countries in Group 2 will be producing an annual TB budget and reporting on funding gaps during annual TB meetings held at country level (World TB Day, workshops, conferences, press conferences, television broadcasts, etc.);
- anti-TB drugs of proven quality will be provided through the GDF or the national drug procurement system to most countries in Group 1 and to 5 countries in Group 2 (Albania, Bulgaria, Hungary, Poland and the former Yugoslav Republic of Macedonia);
- 30 countries will be conducting surveillance for drug resistance; and
- 3 countries (Kazakhstan, Lithuania and Romania) will have been selected to start DOTS-Plus projects (in addition to the existing DOTS-Plus projects in Estonia, Latvia and the Russian Federation).

By the end of 2005:

- DOTS coverage (population and case enrolment) will have reached 90%, at least in the Group 1 and Group 2 countries, and all countries will have established treatment outcome measurement through cohort analysis;
- requirements for the qualification TB drugs will include at least: (*a*) registration in a recognized and well functioning national drug regulatory authority (issuing licences, controlling supply channels, using quality control laboratory, etc.); (*b*) WHO-type and non-WHO-type certificates; and (*c*) a comparative rifampicin bioavailability assessment provided by the supplier (and certification that the same manufacturing process has been maintained since bioavailability testing); and
- WHO and the European Union will have reached agreement on maintaining bilateral support within the Union for new member states such as the Baltic countries.

By the end of 2006:

- DOTS coverage (population and case enrolment) will have reached 100%, at least in the Group 1 and Group 2 countries;
- At least three large countries in Group 1 will be conducting operational research on TB prevalence surveys or mortality surveys;
- all countries will be conducting surveillance for drug resistance;
- six additional countries (Bulgaria, Georgia, Kyrgyzstan, Republic of Moldova, Ukraine and Uzbekistan) will have been selected to start DOTS-Plus projects;

- all countries will be conducting surveillance of TB/HIV co-infection;
- two countries will be conducting operational research in selected areas on anti-retroviral treatment of TB patients co-infected with HIV;
- countries in Groups 1 and 2 will be producing an annual TB budget and reporting on funding gaps during annual TB meetings held at country level (World TB Day, workshops, conferences, press conferences, television broadcasts, etc.); and
- all countries will be distributing anti-TB drugs of proven quality.

Strategy of the European DOTS Expansion Plan

Overall strategy

DOTS has proved to be the most cost-effective means of controlling the TB epidemic. DOTS coverage in the Region is still expanding (only 20% of notified cases were enrolled in DOTS in 2000), although 18 countries have already achieved nationwide coverage. DOTS expansion requires national expenditure that is often unplanned. DOTS is the basic strategy of the European DOTS Expansion Plan and has the following five key components.

1. Sustained political commitment is required to expand the human and financial resources and to make TB control a nationwide activity as an integral part of the national health system.
2. High-quality sputum smear microscopy must be available for case detection among persons presenting with symptoms of TB, including prolonged coughing. Special attention should be paid to case detection among high-risk groups, including those with HIV infection and those in institutions.
3. Standardized short-course chemotherapy under proper case management conditions must be available to all TB patients, including direct observation of treatment. Proper case management conditions imply technically sound and socially supportive treatment services. DOTS is especially recommended in Group 1 countries and among patients at risk of defaulting.
4. An uninterrupted supply of high-quality drugs is essential, together with reliable systems for drug procurement, distribution and monitoring.
5. A recording and reporting system must exist for assessing outcome for each patient and overall programme performance.

The five components of the DOTS strategy represent the minimum package necessary for TB control. Implementation of the strategy requires flexibility and adaptation to a wide variety of contexts. Each country will set its own priorities and adapt the main aspects of the DOTS strategy to meet its specific challenges.

Grouping of countries

Countries are classified in three groups according to three criteria: (*a*) the epidemiological trend in TB since the 1980s; (*b*) the types and quantities of new activities that need to be implemented to expand the DOTS strategy; and (*c*) TB mortality by age group, reflecting the TB burden in the European Region. The highest priority will be given to countries in Group 1, and particularly to the five largest countries in Group 1.

Group 1 comprises 16 countries with a total population of 313 million. The group is characterized by an increase in the estimated number of TB cases during last 10 or 20 years, an increased rate of notification (except in Tajikistan) and a high TB burden. The estimated total number of cases in the group in 2002 is 433 000, or 77% of the total TB caseload in the European Region. This group represents the largest TB burden in the Region, and the success of TB control in the Region will depend mainly on the ability of Group 1 countries to reach a high (70%) DOTS case detection rate and maintain a high (85%) treatment success rate, including areas with high levels of multidrug-resistant TB. DOTS population coverage in Group 1 was only 18.5% in 2000 (with a DOTS case enrolment coverage of 16.8%). The Russian Federation is among the 22 countries in the world with the largest TB burden. Of the 16 countries in Group 1, Kazakhstan, Romania, the Russian Federation, Ukraine and Uzbekistan represent more than half the TB burden in the European Region, and therefore are the top-priority countries in the Region.

Group 2 comprises 11 countries with an intermediate TB burden, with a total population of 197 million. The estimated total number of cases in the group in 2002 is 84 000, or 15% of the total TB caseload in the European Region. DOTS population coverage was only 14.6% in 2000 (with a DOTS case enrolment coverage of 20.0%). Apart from a few countries in war or post-war situations, most countries in Group 2 are equipped with a good health infrastructure and TB notification has fallen in the last 10 years. Nevertheless, incidence of the disease is still high, and the decrease in TB burden has slowed down in recent years.

Group 3 comprises 24 countries with a low TB burden and incidence, with a total population of some 363 million. The estimated total number of cases in the group in 2002 is 42 000, or 7% of the total TB caseload in the European Region. DOTS population coverage was only 17.8% in 2000 (with a DOTS case enrolment coverage of 19.1%); this was mainly due to a lack of monitoring of treatment outcome in enrolled patients. The decline in the TB burden has levelled off in recent years, despite the healthy economic situation. In this group, the majority of TB cases and up to 80% of the caseload are among immigrants from high-prevalence countries. Other risk groups are the elderly, the homeless and HIV-infected patients. The DOTS strategy in this group is now geared towards eliminating the disease.

Countries and TB data per group are listed in Tables 1 and 2, respectively.

Table 1. Grouping of countries

Group 1	Group 2	Group 3
Top-priority countries: Russian Federation,[a] Ukraine, Romania, Uzbekistan, Kazakhstan. Other 11 countries: Armenia, Azerbaijan, Belarus, Estonia, Georgia, Kyrgyzstan, Latvia, Lithuania, Republic of Moldova, Tajikistan, Turkmenistan.	Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Hungary, Poland, Portugal, Spain, the former Yugoslav Republic of Macedonia, Turkey, Yugoslavia.	Andorra, Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Luxembourg, Malta, Monaco, Netherlands, Norway, San Marino, Slovakia, Slovenia, Sweden, Switzerland, United Kingdom.

[a] Among the 22 countries in the world with the largest TB burden.

Table 2. TB situation per group of countries in the European Region in 2000

	Population (thousands)	Estimated			Notified		DOTS coverage
		TB cases	Smear-positive TB cases	TB deaths	TB cases	Smear-positive TB cases	
Group 1	313 378	368 835	165 756	58 936	278 675	69 519	18.5%
Group 2	197 468	77 727	34 672	8 908	55 826	16 814	14.6%
Group 3	362 722	45 625	20 385	7 758	35 434	6 597	17.8%
European Region	873 568	492 187	220 813	75 601	369 935	92 927	17.3%
World	6 053 531	8 734 804	3 836 173	1 883 620	3 671 973	1 529 806	55.0%

Key aspects and activities of the DOTS strategy

Political commitment and partnership for DOTS expansion

All countries in Group 1 (except one) and Group 2 (except four) have adopted the DOTS strategy and have proved that DOTS can cure TB in both urban and (even remote) rural areas. However, the countries have unequal political, financial and technical commitments to increase the availability of DOTS countrywide. DOTS population coverage in Groups 1, 2 and 3 is still expanding (being 18.5%, 14.6% and 17.8%, respectively in 2000) and 18 countries have already achieved nationwide coverage.

In 35 countries in the European Region, the move towards countrywide DOTS coverage requires more political commitment at central, regional, provincial and district levels, together with an increase in resources for TB control for those countries in Groups 1 and 2.

Countries that have already implemented DOTS countrywide continue to face constraints in implementation. Politicians and decision-makers must be convinced that important economic returns justify long-term investment in TB control.

The support of partners to provide the necessary technical input, training and equipment is essential for the expansion of the DOTS strategy in most countries in Groups 1 and 2. External support is essential to consolidate achievements and to ensure an adequate transition towards regular national budget funding of TB control.

Many needs are not met because of lack of resources. Activities proposed for developing and strengthening political commitment and partnerships for TB control are as follows.

Country level

- Meetings should take place between national technical and policy committees and the DOTS expansion committee.
- Meetings should be organized of the national Tuberculosis Interagency Committee.
- The national DOTS expansion plan should be seen as a component of the development plan for the health sector and, beyond health, a component of country development.
- National TB guidelines should reflect the national scheme for TB control (detection, diagnosis, treatment, registration) and TB management (quality assurance, drug supplies, risk groups, training, monitoring).
- An annual statement of expenditure and a TB budget should be prepared, highlighting national contributions, external support and funding gaps. Cost analysis is proposed for budgeting of items such as drugs, laboratory supplies, training, supervision, active case finding, operational research, stationery and printing, equipment (laboratory, transport, office, building), staff (national and external) and advocacy. The minimum requirement is to assess TB drug expenditure.
- A legal framework in support of specific TB control activities that is flexible and permits rapid updating should be enacted. The elements of such a framework should include national TB guidelines, free access to diagnosis and treatment for all TB patients, staff and budget allocation, etc.
- Annual TB activity reports translated into English should be posted on the Regional Office Web site, including budgets, statements of expenditure and funding gaps.
- World TB Day celebrations in countries should be guided by the country context.

Regional level

- Meetings should be called of the Tuberculosis Interagency Coordinating Committee.
- Results of epidemiological reviews, drug resistance surveys, TB/HIV surveillance and regional budget gaps should be posted on the Regional Office Web site.
- TB patients and their families should be encouraged to become involved in TB control activities and to share their experiences.
- Indicators should be developed to measure economic impact, staff awareness and political commitment.

TB drugs for DOTS expansion

The European DOTS Expansion Plan aims to**:**

- promote free access to TB treatment with an uninterrupted supply of high-quality drugs;
- strengthen national drug regulatory authorities;
- promote access to second-line drugs for multidrug-resistant TB at specialized units approved by the Green Light Committee; and
- encourage the use of 2- and 4-drug fixed-dose combinations to avoid the use of loose rifampicin.

The key issues and rationale for reaching the objectives are as follows.

- Free access to TB treatment can ensure complete treatment of more patients and contribute to the alleviation of poverty. Easy access will also ensure that both patients and doctors adhere to appropriate regimens. Even minimal treatment costs can hinder early treatment and affect compliance, thereby increasing the spread of infection. In the case that charges are made for care, this should not jeopardize access for all to the health facilities that DOTS provides.
- Strengthening the national drug regulatory authority will make it possible to limit the use of anti-TB drugs to TB only and ensure their quality. A proactive role by the Regional Office and other partner agencies and drug manufacturers will facilitate implementation of the product quality requirements for all anti-TB drugs and their registration with the national drug regulatory authority.
- Fixed-dose combination tablets should be registered, including comparative assessment of rifampicin bioavailability and certification of the maintenance of the same manufacturing process since bioavailability testing was carried out. Registration of pharmaceutical products should ensure not only that the product itself is of good quality, but also that the pharmaceutical industry adheres to recognized good manufacturing practices and that proper quality control is in place.
- Pharmaceutical manufacturers have agreed to sell the second-line drugs at concessional prices to DOTS-Plus pilot projects endorsed by the Green Light Committee. Second-line anti-TB drugs should be used in specialized units in countries with a strong DOTS strategy and a multidrug-resistant TB problem.
- Fixed-dose combination tablets prevent monotherapy, reduce the emergence of drug-resistant TB, increase patient and doctor compliance, simplify drug management and distribution, and reduce the risk of rifampicin being prescribed for conditions other than TB.

Proposed activities

At country level, it is proposed that an overview be made of the current situation on procurement (suppliers, manufacturers, quality of drugs and source of financing) for each country, and that

DOTS-Plus project outcomes and use of second-line drugs be monitored in selected areas and in other settings (Groups 1 and 2 only).

The Regional Office should:

- provide technical support to selected countries for the procurement and distribution of anti-TB drugs and for the improvement of drug quality assessment;
- through the GDF, act as a supplier to some countries in emergency need; and
- encourage countries with a solid DOTS strategy and a multidrug-resistant TB problem to implement DOTS-Plus pilot projects in line with WHO guidelines (applications for access to second-line drugs should be submitted to the Green Light Committee).

Monitoring and surveillance

To measure the achievements of the European DOTS Expansion Plan and to monitor drug resistance and TB/HIV co-infection, the following special activities will be carried out at national and regional levels.

- An analysis of treatment outcomes for all notified sputum-smear-positive TB cases will be published in regular quarterly reports.
- A set of indicators will be developed to monitor DOTS expansion and political commitment. These will include the appointment of high-calibre TB programme leadership; the size and administrative positioning of the national TB programme within the Ministry of Health; changes in levels of TB funding; the salary levels of TB programme staff compared to those of other staff; specific changes in TB policy, legislation or regulations; implementation of TB policies, legislation or regulations; the quantity and quality of media coverage; the frequency and scope of advocacy activities by partners and coalitions; the amount of discussion in legislatures and political forums; and the number of useful and highly visible political statements by celebrities and decision-makers.
- Prevalence and mortality surveys will be conducted through operational research in the three most densely populated countries in Group 1. The Regional Office will provide technical support in establishing a reliable vital statistics registration system. Baseline data will be established in order to assess, after 10 years, whether the objective of reducing TB morbidity and mortality by half within that period has been achieved.
- Accelerating DOTS expansion in the Region and the introduction of DOTS-Plus in the countries most affected by drug resistance are expected to reduce the current high level of multidrug-resistant TB. Drug resistance surveys should become more systematic in order to monitor trends.
- Drug resistance surveillance for second-line TB drugs should be established in countries with a problem of multidrug-resistant TB, beginning with Estonia, Latvia and the Russian Federation.
- TB/HIV co-infection will be monitored by sentinel groups among TB patients in countries with a high prevalence of HIV. The worsening HIV epidemic will cause an increased TB caseload, and a new challenge to the implementation of DOTS. Surveillance of TB/HIV co-infection in countries or areas with a high prevalence of HIV/AIDS will be reinforced. AIDS counselling in TB wards, TB treatment and AIDS care will also be developed in close collaboration with these countries.
- Projections of TB epidemiology in the Region will be updated.

Sustainable TB control and the changing health sector

Health sector reform poses challenging opportunities for the success of TB control in the Region.

Health sector reform is a unique opportunity for integrating TB facilities into the general primary health care services, with the potential for expanding the DOTS network and bringing treatment facilities closer to the patients. Moreover, the sustainability of effective TB control programmes may also be enhanced when the overall financing of the health system is improved through the adoption of better mechanisms (social insurance, sector-wide financing and cost sharing).

Health sector reform challenges the integrity of the management system inherent in the DOTS strategy. Staff reductions, integrated drug procurement, integrated reporting systems, privatization and cost-sharing schemes that often accompany health system reform may hinder some of the key components of DOTS, such as the skill of health workers to detect and treat patients, uninterrupted drug supply, free drugs and services and specific monitoring of treatment results.

Participation of national TB programmes in the planning of health sector reform and in the transition period can ensure that the fundamentals of TB control are maintained and are strengthened rather than threatened in the process. The indicators of a successful TB programme, such as a high cure rate of new and retreated TB patients, can become indicators of successful health system development.

A specific activity at country level is the development of a national TB plan in line with the general health policy.

The Regional Office will provide technical support on TB activities and health sector reform to selected countries in Group 1, especially those with separate TB services (Armenia, Kyrgyzstan, the Republic of Moldova, Romania, the Russian Federation and Ukraine).

Capacity-building for DOTS management

Capacity for effective management of the DOTS strategy needs to be strengthened, including bacteriological confirmation of diagnosis (by sputum smear microscopy and culture). Skilled human resources are still needed at provincial and district levels, both where DOTS has not been implemented and in DOTS areas with a high turnover of staff. Refresher courses should be periodically organized. In addition, health sector reform often calls for additional training and on-the-job training of multipurpose staff. Training of both postgraduate and undergraduate students needs to be covered, by adjusting the traditional curricula in schools for medical, nursing and laboratory personnel to accommodate the DOTS strategy.

The following activities need to be organized at country level:

- assessment of training needs and identification of trainers;
- training workshops for managerial teams at central and peripheral levels, general practitioners, clinicians, nurses, primary health care staff, laboratory technicians, pharmacists, and community volunteers in the public and private sectors;
- training workshops on specific issues, such as drug management, drug quality, programme review, data analysis, human rights and vulnerable groups;
- development of curricula, including the DOTS strategy, in schools for medical, nursing and laboratory staff;
- annual peer meetings at central, regional and/or provincial levels; and
- an annual national conference.

The following activities will be organized at the regional level:

- a WHO international training workshop for national and regional TB managers (in Poland);
- a WHO international training course on TB epidemiology (in Poland);
- an international training course on TB control (in Tartu, Estonia) organized by the Finnish Lung Health Association (FILHA) and the International Union Against Tuberculosis and Lung Disease (IUATLD);
- a WHO international training course on TB laboratory management (in Poland);
- an international course for TB consultants at the WHO collaborating centre for tuberculosis and lung diseases in Italy;
- meetings of the Tuberculosis Interagency Coordinating Committee and of managers of national TB programmes; and
- a IUATLD regional conference.

Laboratory services

A quality assurance system for laboratories needs to be put in place in order to improve the reliability, efficiency and use of laboratory services. The quality assurance system comprises (*a*) quality control as an internal process performed by all laboratory workers, (*b*) quality improvement based on problem-solving during on-site supervisory visits and (*c*) proficiency testing (or external quality control) through the cross-checking (re-reading) of sputum smear microscopy slides, culture and drug susceptibility tests. The reference laboratory will organize the cross-checking, and can also send slides or strains to laboratory technicians for testing. In addition to having their own national quality assurance systems, countries should be included in the WHO/IUATLD supranational reference laboratory network for the surveillance of anti-TB drug resistance. This permits the accuracy of the drug susceptibility method used to be ascertained, and allows for global comparability of drug resistance data gathered in countries.

At country level, the following activities need to be organized:

- revision of the role and number of TB laboratory service networks;
- establishment and assessment of quality assurance systems in countries in Groups 1 and 2;
- establishment and assessment of quality assurance for culture and drug susceptibility tests in all countries;
- annual meetings and training of laboratory technicians at central, regional and provincial levels;
- annual assessment of laboratory quality assurance; and
- linking of national reference laboratories with the supranational network of laboratories for quality assurance of drug susceptibility testing.

In addition, the Regional Office will support capacities for culture and drug susceptibility testing in countries with a multidrug resistance problem.

Human and patients' rights

The DOTS strategy respects and protects human rights and promotes the dignity of the individual. On the other hand, inappropriate health resource allocation and limited DOTS expansion can lead to discrimination that may not be overt.

DOTS should protect the supremacy of individual rights in the community. Respect for individual rights, such as a patient's right to privacy and non-discriminatory treatment, is provided for in the DOTS strategy as long as staff are dedicated to a flexible patient-centred way

of working. Directly observed therapy or inpatient treatment should be considered as a support and a service that respects patients' rights, rather than an obligation.

Although it is impossible to assume compliance among "unreliable" patients such as chronic alcoholics, former prison inmates or the mentally incompetent, it may be counterproductive to apply coercion if due care is not taken.

DOTS expansion actively promotes social rights and equality of treatment, provides protection for the most vulnerable groups in society, and represents the vast majority of TB cases managed in the public sector.

The following activities will be carried out, either at national level or through the Regional Office, in order to expand DOTS and to respect human rights and promote patients' rights:

- national training sessions on the attitudes of TB health staff towards patients' rights;
- regional meetings on human/patients' rights and on vulnerable groups; and
- encouragement of cured TB patients and their families to form associations and to participate in decision-making and implementation at all levels.

Social support and social insurance

Most countries in the European Region have a lot of experience of social support for TB patients as part of a social welfare scheme. Social support contributes to the alleviation of poverty, improved case detection and success rates among "unreliable" patients, and the provision of a free service to TB patients.

Social support may consist of free food for TB patients, payment of their salaries during treatment, free treatment and services, free transport, etc. Social support may, in rare cases, be a disincentive to being cured if it is not managed as an integral part of the TB services. Social welfare and social support are the best ways of ensuring sustained TB control, and should be managed according to the DOTS strategy.

Specific aspects of the DOTS strategy for each group

Group 1 countries

All key aspects and activities of the DOTS strategy are to be implemented in Group 1 countries. Some more specific aspects are as follows.

Multidrug-resistant TB and DOTS expansion

Multidrug-resistant TB poses a serious threat to the maintenance of an effective TB control strategy in Estonia, Latvia and the Russian Federation. The true magnitude of the problem is not well known in most countries, especially those in Group 1 where the burden of multidrug-resistant TB has not been evaluated. Multidrug resistance is a great constraint for TB control because its diagnosis is difficult or impossible, especially in some Group 1 countries. Being undiagnosed, such patients remain the source of drug-resistant strains of *Mycobacterium tuberculosis* for a long time, and transmission of multidrug-resistant TB in the community is inevitable. On the other hand, treatment of multidrug-resistant TB is much more expensive, and the treatment success is much lower than TB caused by drug-sensitive strains of *M. tuberculosis.*

One of the main causes of multidrug-resistant TB is a poor management of patients, particularly with regard to the choice of chemotherapy regimen and follow-up. Inadequate treatment leads to the selection of resistant mutants that are naturally present in a mycobacterial population. By spreading into the community, these lead to new cases of TB with primary resistance to drugs.

Since the most important cause of clinically significant drug resistance is a failure of medical practice (inappropriate prescription of drugs, failure to observe swallowing, unreliable drug supply), the first priority for TB control is prevention of multidrug resistance through early detection of new cases and their treatment according to the DOTS strategy.

Accelerating DOTS expansion in the Region will help to maintain multidrug-resistant TB at its current low level, prevent its development in some countries, pave the way for the DOTS-Plus strategy in settings with a high prevalence of multidrug-resistance, and hopefully reverse the upward trend. DOTS-Plus is not effective in controlling multidrug-resistant TB if the DOTS strategy itself is not already in place in most parts of the country. DOTS implementation is a prerequisite for sound TB control and the prevention of multidrug-resistant TB. Inappropriate detection and treatment of new TB cases leads to the creation of further cases of multidrug-resistant TB. This, in turn, makes the management of multidrug-resistant TB more expensive for the country and threatens global TB control efforts. Thus DOTS and DOTS-Plus should be considered as two phases of a sound TB control programme.

The following activities will be conducted at country level.

- DOTS will become countrywide in all Member States, including those with a high level of drug resistance, as a first step in controlling multidrug-resistant TB.
- Surveillance of drug resistance will be carried out in all countries. It needs to become more systematic in order to monitor the threat of increasing levels of multidrug-resistant TB.
- Surveillance of resistance to second-line TB drugs should be established in selected countries (Estonia, Latvia and the Russian Federation).
- Measures will be taken to ensure that second-line drugs for multidrug-resistant TB are used only in highly qualified centres.
- Applications will be submitted to the Green Light Committee for the establishment of DOTS-Plus projects in countries where the DOTS strategy has been carried out and where there is a high rate of multidrug-resistant TB.

The following activities will be conducted at regional level.

- In areas with a high rate of multidrug-resistant TB, and where the DOTS strategy has been implemented, external partners will provide technical support to the DOTS-Plus strategy.
- The Regional Office will coordinate DOTS-Plus projects and identify key partners for each project.

TB control and HIV/AIDS

The worsening HIV epidemic will lead to an increased TB caseload in a few countries in the Region (Belarus, Estonia, Latvia, Lithuania, the Russian Federation and Ukraine) and is a new challenge to the implementation of DOTS.

The principles of the DOTS strategy are the same for HIV-positive and HIV-negative TB patients. Nevertheless, the health services will have to cope with a rising number of TB patients, which will require the following responses.

- A strategic framework will be developed, in collaboration with WHO headquarters, for HIV-related TB in the European Region that can be adapted and implemented in the most affected countries.
- Surveillance of TB/HIV co-infection in high-prevalence countries or areas will be reinforced.

- TB staff will be trained to enable them to carry out anonymous and voluntary counselling and testing for HIV/AIDS in TB wards.
- Anti-retroviral treatment of TB patients with HIV/AIDS will be begun on an operational research basis in selected areas.
- Diagnostic criteria will be developed for pulmonary and extrapulmonary TB in areas with high HIV/AIDS prevalence.
- Mechanisms will be developed for coordinating with services providing support and care for HIV/AIDS patients. Such patients should not come unnecessarily in contact with TB patients to avoid TB transmission. Services should be developed for HIV/AIDS patients in their own homes.
- TB preventive therapy among HIV-positive patients (ProTest) could be developed on an operational research basis.

TB control in prisons

The civil and prison TB control services should be integrated to ensure that the same strategies are used in both. Continuity of treatment and access to culture and drug susceptibility testing, especially in countries with multidrug-resistant TB, cannot be sustained in isolated systems.

Overcrowding and malnutrition in some prisons, together with growing prison populations, pose another threat to DOTS expansion and might contribute to an increase in multidrug resistance. DOTS in prisons should be carried out in close coordination with the district health service where the prison is located, so as to establish a rational strategy for both civilians and prisoners. Care should be taken to avoid the DOTS strategy becoming an incentive for inmates to catch TB or remain infectious. Care must also be taken to avoid discrepancies, such as where the DOTS strategy in a prison is supported by external organizations while the public TB services in the local community lack anti-TB drugs or appropriate staffing.

Prisoners, prison staff, inmates' families and the civilian population living around the prison should all benefit from DOTS, which should be made available to all these populations at the same time and with the same treatment regimens. The DOTS strategy could be adapted in prisons to include active screening of prisoners and prison staff. The DOTS-Plus strategy can be adopted inside the prison once it has been implemented among the civilian population around the prison. This will ensure continuity of treatment with second-line drugs for regimens that last longer than the prisoner's sentence, and will benefit from civilian laboratory capacity not available inside the prison. This situation will need to be carefully assessed by national and international review teams.

Monitoring and surveillance

- In addition to the monitoring of DOTS expansion, Group 1 countries will specifically monitor DOTS expansion in areas with high levels of multidrug resistance, in prisons, in areas with high HIV prevalence and among special groups.
- The baseline monitoring and surveillance system in Group 1 countries comprises outcome of TB treatment, HIV surveillance among TB patients and drug resistance surveillance.
- An assessment of the vital statistics registration system will be conducted in three countries with a large TB burden to assess the first objective of the regional plan (to reduce by half the prevalence of and mortality from TB in the Region in 10 years).
- Regular evaluations and national and international reviews of TB control activities will be conducted.
- Political commitment will be monitored in Group 1 countries.

Group 2 countries

The five key components of the DOTS strategy remain the framework for this group. Nevertheless, some countries in the group will focus only on some elements of the strategy in order to address specific issues.

Monitoring and surveillance

- Treatment outcome reporting should be introduced in Spain and Turkey, which represent more than half the TB burden in Group 2. Additional elements of the DOTS strategy should be established in Turkey.
- A baseline TB mortality study will be conducted through the vital statistics registration system to assess the first objective of the regional plan (to reduce by half the prevalence of and mortality from TB in the Region in 10 years).
- High-risk groups and TB distribution patterns will be identified.
- Recording/reporting systems should be introduce into the private sector through, for example, legal processes or insurance channels.

Active case finding among contacts and in high-risk groups

Regular screening of high-risk groups, contact tracing, outbreak management and preventive chemotherapy should be established to attain a lower incidence of TB in Group 2 countries that have access to free TB treatment.

Active case finding should be undertaken among the close household contacts of a TB patient, followed by adequate treatment and monitoring of treatment for active cases and six months of preventive chemotherapy for those found to be infected.

Vulnerable persons (such as the homeless, chronic alcoholics, HIV/AIDS patients, displaced persons, refugees and those in post-conflict situations) and those living in institutional settings (such as prisons, hospitals, military wards, nursing homes/long term residential homes for the elderly, and shelters for the homeless and migrants) have a higher prevalence of latent TB infection and TB disease. Regular active screening among these groups, based on an evaluation of cost–effectiveness, could begin in some countries in Group 2 (Albania and Poland). These activities need to be combined with appropriate diagnosis, registration, effective treatment and monitoring of treatment.

Links with the private sector

Group 3 countries

This group of countries can allocate more human, technical and financial resources to health care than countries in the other groups, and are equipped with a good health infrastructure.

The five components of the DOTS strategy remain the framework for this group. A more aggressive approach is proposed towards the goal of elimination.

Monitoring and surveillance

- Systematic recording/reporting systems adapted to national conditions, including monitoring of treatment outcomes, will be introduced.
- Recording/reporting systems will be introduced in the private sector through strategies such as legal processes, insurance schemes, recommendations of professional associations and cross-checking of notifications.

- A baseline TB mortality study will be conducted through the vital statistics registration system.

Adapted DOTS strategy

- Government and private-sector commitment to TB control, and its eventual elimination, will be promoted through the following steps:

  - national technical leadership and a national policy committee;
  - national TB guidelines, reflecting the national scheme for TB control and elimination activities (detection, diagnosis, registration, treatment and reporting of treatment outcomes) and TB management (quality assurance, risk-group management, screening, contact tracing, training in preventive therapy and monitoring); and
  - a legal framework (laws, orders, circulars, official acts) in support of specific TB control and elimination activities.

- Regular active case finding will be developed in identified high-risk groups (immigrants from high-prevalence countries, the homeless and HIV-infected patients).
- Cases will be detected among symptomatic patients in the general population and systematic contact tracing will be carried out in households.
- Cases will be confirmed through routine culture and drug susceptibility tests will be performed, especially in groups where the risk of drug resistance is high.
- Outbreaks will be managed by active case identification and contact tracing.
- DOTS will be applied selectively in patients in high-risk groups and where the success rate is low.
- Anti-retroviral treatment and TB preventive therapy will be provided for persons newly infected with HIV.
- Specialized treatment, including the use of second-line drugs, will be provided for multidrug-resistant TB.
- Steps will be taken to ensure that second-line drugs for multidrug-resistant TB are used only in highly qualified centres.
- Surveillance will be based on a recommended and uniform reporting system capable of providing case notification and treatment outcomes. Sputum smear examination or/and culture will be included for complete assessment of treatment outcomes. Quality assurance of data should be part of the process.

Attention should be paid to surveillance and appropriate interventions in high-risk groups, such as HIV-infected patients and immigrants from high-prevalence countries. Regular screening in high-risk groups, contact tracing, outbreak management and preventive chemotherapy should be continued to maintain the low incidence of TB in this group of countries.

Research and development

Research and development in the areas of treatment delivery, the place of TB control in the health sector, and monitoring and evaluation will be promoted in collaboration with WHO headquarters and partners. Progress in improving the tools for the epidemiology, diagnosis, treatment and prevention of TB has been very slow. Research into the epidemiological model that is applicable and affordable in the Region, and especially in the countries in Group 1, will be encouraged.

The European DOTS Expansion Plan provides numerous opportunities to build capacities in operational research at national level, under the following headings.

Monitoring and evaluation

- notification and cross-notification systems in the private sector;
- cost–effectiveness of screening and preventive treatment in high-risk groups;
- surveillance of multidrug resistance and HIV/TB co-infection;
- estimates of TB prevalence and TB mortality surveys through vital statistics registration systems;
- guidelines for TB mortality surveys (vital statistics registration systems).
- analysis of obstacles in access to treatment;
- analysis of reasons for high levels of non-compliance with treatment (in the countries of the former Soviet Union); and
- political commitment.

Increase in case detection and health system reform

- public/private DOTS model in several countries in Groups 1, 2 and 3;
- decentralized and integrated TB treatment services;
- legal framework for DOTS strategy in each group;
- framework for DOTS implementation; and
- patients' rights and the participation of patients in decision-making and implementation.

Multidrug resistance

- DOTS-plus in areas with multidrug-resistant TB (individualized vs. standardized strategy); and
- drug resistance surveillance for second-line TB drugs.

HIV/AIDS

- anti-retroviral treatment of TB patients, and TB preventive therapy in HIV-infected individuals (ProTest)

Drugs and new diagnostic tools

- testing of new drugs and the length of the multidrug-resistant TB regimen;
- the impact of fixed-dose combinations on multidrug-resistant TB;
- the testing of four fixed-dose combinations under programme conditions; and
- the testing of new diagnostic tools (rapid detection of drug resistance) in countries affected by multidrug resistance.

Socioeconomic impact

- assessment of the impact of DOTS on poverty alleviation and its socioeconomic effects (schooling, education, employment).

The Regional Office and other partners could assist countries to establish their own research agenda and to identify financial sources for research. There is a need to hold workshops on strengthening the research capacity of the staff of national TB programmes who do not work in research institutions, in collaboration with WHO headquarters.

Planning and coordination

Country level

Country plan of action

Most of the countries in Group 1 are preparing a plan of action for TB control to adapt the DOTS strategy to the national context. These plans need to be updated in close collaboration with WHO and participating multilateral and bilateral agencies, and need to be approved by the national authorities. Ideally, the country plans should be based on the framework of activities included in the regional strategy. The involvement of all agencies and organizations at the time of preparation will encourage their active participation. Plans should be targeted towards achieving the national and regional goals for 2006, and should include a section on all available resources, human resources, funds and other requirements to achieve the goals. Plans should identify and prioritize the additional resources and input required from WHO and other partners.

National interagency committees

In every Group 1 country, a Tuberculosis Interagency Committee should be established at national level, gathering together influential and interested persons, technical agencies supporting the national TB programme, aid agencies, national and international NGOs, associations and representatives of civil society to form a coalition against TB. Events and activities should be arranged every year to contribute to the national DOTS expansion plan and the achievement of its goals.

WHO collaboration

WHO will maintain its technical collaboration by placing country advisers in the Russian Federation and Ukraine, and intercountry advisers in the central Asian republics and the Balkans (Annex 6).

In 1990, the Royal Netherlands Tuberculosis Association (KNCV) organized the first Wolfheze Workshop as a platform for managers of national TB control programmes in low-prevalence countries of western Europe. It had been recognized that low-prevalence countries were moving towards the elimination of TB as a public health problem, but were still confronted with common problems such as “micro-epidemics”, reappearance of the disease in socioeconomically deprived populations and high-risk groups, and imported cases of multidrug-resistant TB. The Workshop was organized to discuss common solutions to these problems.

The changed political situation in Europe after 1989 offered the possibility of including programme managers from central and eastern Europe. The Workshop therefore changed its focus from TB control in low-prevalence countries to TB control in general in Europe. The objective of the Workshop is to allow programme managers to develop adequate intervention strategies adapted to the epidemiological needs of countries, to stimulate implementation, to evaluate implemented strategies, to monitor epidemiological changes and to signal new developments.

The annual Wolfheze Workshop (4–5 days) is an initiative of the World Health Organization (headquarters and the Regional Office for Europe), the European branch of IUATLD, KNCV, and the WHO collaborating centre for tuberculosis surveillance in Europe (EuroTB).

Estimated funding requirements

Cost estimates and shortfalls for DOTS expansion are presented in Annexes 7 and 8.

Regional level

WHO collaborating centres

WHO has five collaborating centres on TB in the European Region:

- EuroTB at the Institut de Veille sanitaire, Paris, France, for the surveillance of TB in Europe;
- the WHO collaborating centre for tuberculosis at the National Tuberculosis and Lung Diseases Research Institute, Warsaw, Poland, for international TB training workshops;
- the WHO collaborating centre for tuberculosis at the Central Tuberculosis Research Institute, Russian Academy of Medical Sciences, Moscow, Russian Federation, for human resource development and technical assistance for DOTS expansion in the Russian Federation;
- the WHO collaborating centre for tuberculosis at the Finnish Lung Health Association, Helsinki, Finland, for human resource development and DOTS implementation in the Baltic countries and the Russian Federation; and
- the WHO collaborating centre for tuberculosis and lung diseases at the Fondazione Salvatore Maugeri, Tradate, Italy, for training of TB consultants and technical assistants from selected Group 1 and 2 countries and for DOTS expansion in Italy.

Major donors and partners

The major donors and partners in TB control in the European Region, and their area(s) of operation, are as follows:

Aga Khan Foundation	Tajikistan
Austrian Government	Russian Federation
Caritas	Republic of Moldova
Centers for Disease Control and Prevention	Central Asia, Estonia, Latvia, Russian Federation
Council of Europe	Russian Federation
Danish Government	Baltic countries, northwest Russian Federation
Danish Lung Health Association	Baltic countries
Department for International Development, United Kingdom	Russian Federation
Deutsche Gesellschaft für Technische Zusammenarbeit	Georgia, Russian Federation
Doctors of the World	Kosovo
European Community Humanitarian Office (ECHO)	Albania, the former Yugoslav Republic of Macedonia
European Union	Ukraine, surveillance
FILHA:	Estonia, Russian Federation, training activities
Finnish Government	Baltic countries, northwest Russian Federation
French Government	Republic of Moldova, Romania, Tajikistan
Gates Foundation	Russian Federation
Gorgas/University of Alabama:	Russian Federation
International Committee of the Red Cross	Caucasus

International Federation of Red Cross and Red Crescent Societies	Belarus, Republic of Moldova, Russian Federation, Tajikistan, Ukraine
Institut de Vieille Sanitaire	Surveillance
Irish Government	Central Asia
IUATLD	Technical assistance and training
Johanniter International	Russian Federation
Kreditanstalt für Wiederaufbau	Kyrgyzstan
KNCV	Technical assistance and training
Norwegian Heart and Lung Association	Russian Federation
Medical Emergency Relief International	Russian Federation
Médecins sans Frontières	Caucasus, central Asia, Russian Federation
Management Sciences for Health	Central Asia, Republic of Moldova, Romania, Russian Federation
Netherlands Government	Republic of Moldova
Norwegian Government	Baltic countries, northwest Russian Federation
Open Society Institute	Georgia, Romania, Russian Federation, human resource development
Partners in Health	Russian Federation
Public Health Research Institute, Moscow	Russian Federation
Project HOPE	Central Asia
Schweizerisch–Bulgarische Gesellschaft	Bulgaria
East Europe Committee of the Swedish Health Care Community	Russian Federation
Swedish Government/ Swedish International Development Cooperation Agency (SIDA)	Baltic countries, Belarus, Kosovo, Republic of Moldova, northwest Russian Federation
Task Force on Communicable Disease Control/Baltic Sea Region	Baltic countries, northwest Russian Federation
US Agency for International Development	Baltic countries, central Asia, Republic of Moldova, Romania, Russian Federation, Ukraine

WHO technical support

WHO provides the overall technical and strategic direction of the European DOTS Expansion Plan. The Regional Office for Europe will coordinate all the activities related to the European DOTS Expansion Plan in the Region. WHO will provide technical cooperation to the countries in all areas of TB control, if required. WHO staff distribution at the Regional Office and in the countries is presented in Annex 6.

The European DOTS Expansion Plan task force

A task force will be formed at the Regional Office to coordinate activities and to call on other expertise within WHO, as required. The task force will ensure a wider approach to TB control and close coordination with WHO activities in areas such as health sector development, vulnerable groups, economic analysis, surveillance of HIV/AIDS, drug quality and management, and social mobilization. The task force will also be responsible for coordinating with other WHO Regions.

Partnership

The Tuberculosis Interagency Coordination Committee

To ensure the coordination of input from international agencies at country and regional levels, a Tuberculosis Interagency Coordinating Committee has been formed. The Committee will meet as frequently as required to review progress and the need for input from partners. At its first meeting the Committee reviewed the European DOTS Expansion Plan and identified the type of assistance that each of the agencies could provide for TB control. The Regional Office task force will serve as the secretariat to the Committee. The functions, composition and operation of the Committee are given in Annex 9.

National interagency committees

If it does not already exist, a Tuberculosis Interagency Committee will need to be formed at country level to monitor progress in implementing the national DOTS expansion plan, to ensure optimal coordination, and to review the budget, expenditure and funding. The committee will be composed of representatives of all agencies working in the field of TB or that are interested in TB control, as well as selected ministries and NGOs interested in TB control.

Resources required

Accurate estimates of the financial investments required to achieve global targets on a country-by-country basis are essential, both for resource allocation at country level and to allow donors to mobilize aid funds. As pointed out above, financial monitoring at country level will be routinely updated to estimate expenditure, resource needs, funding sources and gaps.

Costs will focus on TB programme expenditure, both directly and for the use of general health service facilities and staff. The proportion of expenditure on non-TB-specific activities or the utilization of general health services (integrated drugs distribution, transport, X-rays, microscopes, health facilities, etc.) will be calculated by standard methods. National plans detailing funding requirements will need to take account of:

- first- and second-line TB drugs;
- other supplies (laboratory, printing, office supplies);
- equipment (laboratory, diagnosis, transport);
- operational costs for personnel (training, supervision, monitoring and surveillance, screening surveys, transport, maintenance);
- advocacy, social mobilization and meetings;
- salaries for national and technical support (external staff);
- diagnostic and treatment facilities;
- non-TB-specific requirements (buildings and rehabilitation, drug distribution, transport, etc.).

In the last 10 years national and international resources to develop and expand the DOTS strategy have been limited, and this has hampered expansion of the initiative, especially in countries in Group 1 (Table 3).

Table 3: Estimated budget and shortfall for TB control in Group 1 countries, 2002–2006 (million US$)

		2002	2003	2004	2005	2006	2002–2006
TB drugs	required	14–27	15–30	17–33	18–36	20–40	83–167
	shortfall						
Others	required	41–68	45–75	50–83	55–91	60–100	250–417
	shortfall						
Total	required	55–95	60–105	67–116	73–127	80–140	333–577
	shortfall						

The overall requirements for 100% DOTS implementation in the Group 1 countries in the Region is around US $55–140 million per year, including the cost of second-line drugs. The current status of each country in Group 1 is still being assessed as to the amount available and expected shortfall each year. Standard methods will be used to provide a breakdown of the costs of TB drugs, including second-line drugs, and for operational costs to implement DOTS.

These estimates will vary as drug and other prices change, and will need to be refined as national plans and budgets are prepared or revised. WHO and the Tuberculosis Interagency Coordinating Committee will coordinate with all partner agencies to obtain adequate funding. Contingency funds will also be required to fill unforeseen needs.

ANNEX 1. Glossary of terms

Definite TB case
A patient with a positive culture for the *Mycobacterium tuberculosis* complex. In countries where culture is not routinely available, a patient with two sputum smears positive for acid-fast bacilli is also considered a definite case).

DOTS
The WHO/IUATLD recommended strategy for TB control. It comprises:

- political commitment to ensuring sustained, comprehensive TB control activities;
- case detection by sputum smear microscopy among symptomatic patients self-reporting to health services;
- standardized short-course chemotherapy using regimens of 6–8 months, for at least all confirmed sputum-smear-positive cases; good case management includes directly observed therapy (DOT) during the intensive phase for all new sputum-smear-positive cases, the continuation phase of rifampicin-containing regimens and the entire re-treatment regimen;
- a regular, uninterrupted supply of all essential anti-TB drugs; and
- a standardized recording and reporting system that allows assessment of case-finding and treatment results for each patient and of the performance of the TB control programme overall.

DOTS area
An area where treatment outcome is monitored for all notified cases (as opposed to non-DOTS areas, where treatment outcome is monitored for some or none of the notified cases).

DOTS case detection
New cases of sputum-smear-positive pulmonary TB (PTB+) notified in DOTS areas divided by the estimated PTB+ in the same area. To reach a 70% DOTS case detection rate, it is necessary to detect 70% of the estimated PTB+ and to enrol all detected cases of PTB+ in the DOTS strategy.

DOTS coverage
The percentage of the country's population living in geographical areas served by DOTS.

Extrapulmonary TB
TB of organs other than the lungs, such as the pleura, lymph nodes, abdomen, genitourinary tract, skin, joints, bones, meninges, etc.

Global TB control targets
To treat successfully 85% of new sputum-smear-positive tuberculosis cases detected[5] and to detect 70% of the estimated new sputum-smear-positive tuberculosis cases.[6]

[5] The number of new sputum-smear-positive cases cured or with treatment completed 12 months or more after enrolment *divided by* the number of new sputum-smear-positive cases enrolled 12 months or more earlier in the same period.
[6] The number of new sputum-smear-positive cases diagnosed during a period of time in a define geographical area *divided by* the number of estimated new sputum-smear-positive cases during same period of time in the same area.

High-TB-risk groups
Groups of the population at increased risk of exposure to TB infection. Some countries arbitrarily consider these as groups with rates of more than 100 cases per 100 000 population, while others prefer relative risk.

Low-TB-incidence countries
Countries with crude case notification below 20 (all cases) per 100 000 inhabitants and declining.

Pulmonary TB, sputum smear-negative (PTB-)
A case of pulmonary TB that does not meet the definition for smear-positive TB given below.

Pulmonary TB, sputum-smear-positive (PTB+)
Two or more initial sputum smear examinations positive for acid-fast bacilli; **or** one sputum smear examination positive for acid-fast bacilli plus radiographic abnormalities consistent with active pulmonary TB as determined by a clinician; **or** one sputum smear positive for acid-fast bacilli plus sputum culture positive for *M. tuberculosis*.

TB burden
Estimates of the TB burden combine the burden due to premature mortality with the burden due to illness. The TB burden is customarily measured by considering the incident cases and the resulting deaths in a population over a period of a year. The units of measurement are years of life lost (YLL) due to premature mortality and years lived with disability (YLD), which are added together to produce disability-adjusted life years (DALYs) lost. In this document, the TB burden is calculated by the estimated number of TB cases of all forms in 2001.

TB case
A patient in whom TB has been bacteriologically confirmed, or has been diagnosed by a clinician.

Tuberculosis Interagency Committee (TB-IC)
A committee established at national level to review financial resource requirements, coordinate the input of partner agencies and devise strategies for meeting funding shortfalls. TB-ICs also monitor progress in the expansion of DOTS coverage and the global DOTS targets (70% case detection rate and 85% success rate) and facilitate feedback to national decision-makers.

Tuberculosis Interagency Coordinating Committee (TB-ICC)
A committee established at regional level to review the financial requirements for, achievements of and technical constraints to the objectives of the European DOTS Expansion Plan, to coordinate the input of partner agencies and to devise strategies for meeting the funding shortfalls of the entire Region. The TB-ICC also monitors progress towards the expansion of DOTS coverage and the global DOTS targets (70% case detection rate and 85% success rate) and facilitates feedback to national decision-makers.

ANNEX 2. Resolution WHA53.1 of the Fifty-third World Health Assembly – Stop Tuberculosis Initiative

The Fifty-third World Health Assembly,

Concerned that the global burden of tuberculosis is a major impediment to socioeconomic development and a significant cause of premature death and human suffering;

Being mindful of the fact that most countries with the greatest burden of disease will not meet global targets for tuberculosis control for 2000 set by resolutions WHA44.8 and WHA46.36;

Welcoming the establishment, in response to resolution WHA51.13, of a special Stop Tuberculosis Initiative to accelerate action against the disease and to coordinate activities across WHO,

1. ENCOURAGES all Member States:

   (1) to endorse the Amsterdam Declaration To Stop Tuberculosis, as an outcome of the Ministerial Conference on Tuberculosis and Sustainable Development (Amsterdam, March 2000), and to note and apply as appropriate the recommendations from that meeting, paving the way for creation of broad and long-lasting high-level political support to tackle tuberculosis within the broader context of health, social and economic development;

   (2) to accelerate tuberculosis control by implementing and expanding the strategy of directly observed treatment, short course (DOTS) and to commit themselves politically and financially to achieving or to exceeding as soon as possible the global targets set by resolutions WHA44.8 and WHA46.36;

   (3) to ensure that sufficient domestic resources are available, especially in developing countries, to enable them to meet the challenges of stopping tuberculosis, and that the capacity to apply them exists;

   (4) to give high priority to intensifying tuberculosis control as an integral part of primary health care;

2. RECOMMENDS that Member States should:

   (1) participate with WHO in the global partnership to stop tuberculosis, and establish and sustain country-level partnerships for:

      (a) study of antituberculosis drug resistance and means of its containment;

      (b) improvement of diagnostic laboratories;

      (c) access to antituberculosis drugs for the poorest populations;

      (d) education and monitoring of patients to ensure better compliance with the treatment regimen;

(e) training of health workers in the DOTS strategy;

(f) integration of tuberculosis control into primary health care institutions and activities at the central and peripheral level;

(2) include case detection and treatment success rates – the basic outcome measures for tuberculosis – among performance indicators for overall health sector development;

(3) continue to assess the magnitude of the impact of the AIDS epidemic on the tuberculosis epidemic and develop strategies to better address tuberculosis in persons with AIDS and in HIV-infected populations, to speed up coordination between prevention and treatment programmes for the two epidemics so as to foster an integrated approach at all levels of the health system, and to the maximum extent possible, to monitor for multidrug-resistant tuberculosis and address issues leading to its containment;

3. CALLS ON the international community, organizations and bodies of the United Nations system, donors, nongovernmental organizations and foundations:

(1) to support and to participate in the global partnership to stop tuberculosis by which all parties coordinate activities and are united by common goals, technical strategies, and agreed-upon principles of action;

(2) to increase organizational and financial commitment towards combating tuberculosis within the context of overall health sector development;

4. REQUESTS the Director-General to provide support to Member States, particularly those with the highest tuberculosis burden, by:

(1) applying, as appropriate, the recommendations of the Ministerial Conference in Amsterdam;

(2) exploring partnerships and options for enhancing access to safe, high-quality curative drugs;

(3) promoting international investment in research, development and distribution of new diagnostics to speed up case detection and strengthen epidemiological surveillance, including support to Member States for community-based prevalence surveys or among high-risk subpopulations, the poor and those who are vulnerable to infections, new drug formulations to shorten duration of treatment, and new vaccines and other public health measures to prevent disease, reduce suffering and save millions from premature death;

(4) sustaining an active and participatory partnership with external organizations throughout the development and implementation of the Stop Tuberculosis Initiative and its activities;

(5) supporting regional programmes intended to coordinate tuberculosis control programmes.

ANNEX 3
Washington Commitment to Stop TB

22–23 October 2001, Washington D.C.,USA

The first Stop TB Partners' Forum,

Involving ministerial representatives from high-burden countries comprising 80% of the global TB burden,
heads of agencies and representatives of Stop TB partners, meeting in Washington D.C. at the World Bank,
recognizing tuberculosis as a critical factor contributing to persistent entrapment by poverty,
and as such being an impediment to economic development,
herewith expresses its commitment to further operationalize the Amsterdam Declaration to Stop TB[7] by:
undertaking urgent and accelerated action against tuberculosis over the next 50 months;
intensifying efforts to reach the global targets for tuberculosis control by 2005;
detecting 70% of people with infectious tuberculosis, and
successfully treating 85% of those detected; and
mobilizing additional resources through increasingly coordinated efforts.

The Partners' Forum participants Hereby issue the Following Statement:

I. We are encouraged by the progress made in implementing the Amsterdam declaration:

- Tuberculosis (TB) is now increasingly recognized internationally as a social and economic – as well as a health – issue;
- The number of countries adopting DOTS has increased substantially;
- Several TB high-burden countries have rapidly expanded DOTS coverage;
- A growing number of TB high-burden countries have established national coordination mechanisms as partnerships to optimize support for control programmes; some have also initiated partnerships with the private sector;
- The Global Partnership to Stop TB is continually expanding and developing operational mechanisms to accelerate action;
- A Global Plan to Stop TB, comprehensively describing the actions, resources and partnerships that will accelerate progress towards TB elimination, has been developed;
- National and international resources invested in TB control and research have increased substantially;
- The Global Fund to Fight AIDS, TB and Malaria is being developed to channel additional resources to countries;
- A Global DOTS Expansion Plan, identifying the actions and resources needed to meet the global targets for TB control in the 22 high-burden countries, has been developed by countries and partners.

[7] At the Ministerial Conference on *Tuberculosis and Sustainable Development*, held in Amsterdam, March 2000.

- The Global TB Drug Facility (GDF) has been launched and is already delivering tuberculosis drugs to countries in Africa, Asia and Eastern Europe, at considerably reduced prices;
- The Global Alliance for Tuberculosis Drug Development has been established and is funding research into new drugs;
- The Global Working Group on TB/HIV is promoting implementation of the range of interventions available to decrease the burden of TB/HIV.
- TB vaccines development has received renewed attention and reinforced support through coordination and resources;
- The TB Diagnostics Initiative has expanded to involve more partners.

II. Despite this welcome progress, there is no room for complacency. We note with grave concern that:

The level of public awareness, as well as the degree of political and financial commitment, remains inadequate. As a result, the global TB epidemic continues to worsen, undermining the development of families, communities and thus national economies. It traps the world's poorest, stigmatizing individuals, marginalized and vulnerable groups (including prisoners, refugees, migrants and the homeless) in a vicious cycle of disease and poverty;

- Only one in four people with tuberculosis is treated with DOTS. The current rate of DOTS expansion is still far too slow to reach the global targets by 2005. Failure to reach these targets will condemn millions of people to disease and death;
- The TB epidemic continues to grow, and more people now die from tuberculosis than ever before—nearly two million every year;
- The tuberculosis epidemic increases ten per cent per year in Africa—largely due to HIV/AIDS. Thirteen million people around the world are dually infected with TB and HIV, the majority in Africa and Asia;
- Similar increases in rates of TB have been observed in the former Soviet Union, as a result of the severe socio-economic difficulties of the last decade;
- Two of every three people stricken with tuberculosis are young adults in their most productive years—many also suffering from AIDS—who are cut down in the prime of their lives;
- Hundreds of thousands of people, many of whom are socially disadvantaged and have no access to effective treatment, have drug-resistant tuberculosis;
- The magnitude of suffering and death caused by the global tuberculosis pandemic is both alarming and unacceptable. Far more than just a health concern, this human tragedy demands urgent action on a global scale to address both the TB and HIV/AIDS epidemics and their repercussions on global development;
- Many countries continue to face serious constraints to TB control, with insufficient human and financial resources, and an inadequate health care infrastructure.

III. As partners, including representatives of the national governments of 18 of the highest TB burden countries, we recognize that urgent and specific action is needed over the next 50 months to accelerate progress against tuberculosis and to achieve the global targets, which are to detect 70% of infectious cases, and cure 85% of those detected. We commit to:

- **Ensuring that all people with TB have access to effective care by:**

    1. Developing and implementing strategies for development of sufficient, sustainable, human and financial resources to meet the challenge of stopping tuberculosis;

2. Expanding tuberculosis prevention and care programmes based on the DOTS strategy in all public health services, in line with internationally accepted standards and practices;
3. Developing sustainable systems capacity to plan, implement, manage and evaluate TB programmes
4. Monitoring and evaluating national tuberculosis programmes to confront the disease and prevent the emergence of drug-resistant strains and effectively manage people with drug resistant tuberculosis;
5. Working in close public-private sector collaboration with other health service providers in the private sector , nongovernmental organizations (NGOS) and social security agencies;
6. Raising awareness and mobilizing society to undertake tuberculosis prevention and care;
7. Promoting the development of national and sub-national partnerships with all stakeholders in society, including government departments and organizations, private health sector partners, industry, NGOs, social security agencies and the community.

- **Addressing the urgent issue of the tuberculosis and HIV/AIDS co-epidemic by:**

1. Massively expanding DOTS coverage, to ensure that people with tuberculosis, irrespective of their HIV status, have access to effective care and support;
2. Enhancing effective collaboration between tuberculosis and HIV/AIDS prevention and care programmes, promoting increased use of all appropriate interventions, including voluntary counseling and testing, and community-based initiatives in education, care and support;
3. Building on lessons learnt from successful DOTS programmes in providing appropriate treatment, care and support for people with HIV/AIDS.

- **Co-ordinating effective action by:**

1. Collaborating within the health sector. The care of adults and children with tuberculosis is an integral part of primary health care and a major contributor to the overall development of national health systems;
2. Collaborating across sectors. Confronting tuberculosis requires collaboration across government sectors and action across the entire spectrum of society. It is a complex socio-economic problem that impedes human development, and cannot be controlled by the health sector acting alone;
3. Collaborating across borders. Recognizing that TB respects no borders, and that other countries not represented in this Forum face many or all of the same problems, we call upon our colleagues around the world to join us and actively participate in building momentum *against* tuberculosis and *for* better health for all. TB control is a global public good and requires global action. The epidemic will continue to worsen unless we share resources, best practices and tools within and across borders.

IV. As partners, including high tb burden countries, committed to achieving the global targets to stop tb within the next 50 months, we affirm our support to these efforts.

While recognizing that it is first and foremost the responsibility of affected countries to initiate and sustain action against tuberculosis, we call attention to the fact that the problem is often greatest in the very countries which can least afford to take action. Because it is in the interest of the global community to support tuberculosis control worldwide:

- **We commit to sharing our resources by:**

1. Providing technical assistance to support global, regional and national stop TB programmes and activities;
2. Mobilizing increased financial resources for countries and partners in support of the Global Plan to Stop TB, using existing mechanisms and new initiatives, such as the Global Fund to Fight AIDS, TB and Malaria.
3. Establish a mechanism for direct financing of the Stop TB Partnership

- **We commit to working in partnership by:**

  1. Endorsing the Framework of the Global Partnership to Stop TB;
  2. Collaborating through Stop TB Working Groups and other operational structures established by the partnership to achieve the objectives of the Global Plan to Stop TB;
  3. Promoting and supporting the development of interagency coordinating committees, or similar mechanisms, at the national and regional level;
  4. Supporting the further development of the Global TB Drug Facility and other initiatives of the Global Partnership to Stop TB.

V. Together, as national governments and other Stop TB partners, We commit to monitoring our progress, and undertaking the following specific actions:

- ***Within the next** 50 days – by the end of 2001:*
  - All high-burden countries will finalize national plans to achieve the global targets for TB control;
  - All partners represented in this meeting will affirm their commitment to the Global Plan to Stop TB;
  - All partners support the launch of the Global Fund to Fight AIDS, TB and Malaria.
- ***Within the next** 50 weeks - by the end of 2002:*
  - We will achieve a DOTS case detection rate of at least 35%;
  - All high-burden countries will establish interagency coordinating committees, or similar mechanisms, that will include tuberculosis control within the scope of their mandates;
  - The Global TB Drug Facility will provide drugs to treat at least one million additional patients.
- ***Within the next** 50 months - by the end of 2005:*
  - We will achieve a DOTS case detection rate of at least 70%, whilst maintaining a treatment success rate of at least 85%;
  - We will develop and scale up effective responses to TB-HIV and to multidrug-resistant TB (MDR-TB);
  - We will develop the Global Plan to Stop TB for the period 2006–2010.
- ***Within the next** 50 years - by 2050:*
  - We will eliminate tuberculosis as a global public health problem.

We mandate the Stop TB Partnership Secretariat to report annually to the Forum on progress in achieving these objectives.

ANNEX 4. Targets and expected results for 2006 and milestones in 2002 and 2003

Targets	2002	2003	2006
Regional Committee resolution on DOTS expansion	X		
First meeting of the TB-ICC	X		
DOTS strategy for TB elimination in low-TB-burden countries	X		
Performance indicators in low-TB-burden countries	X		
Central TB coordinator and a team of national experts		All countries	All countries
DOTS coverage (population and case enrolment)		At least 37%	90%
Treatment outcome measurement (DOTS)		30 countries	46 countries
DOTS case detection			70%
Yearly statement of expenditure and TB budget highlighting national budget, external support and funding gaps		10 countries in Group 1 5 countries in Group 2	All countries in Groups 1 and 2
Quality TB drugs distributed		15 countries	At least all countries in Groups 1 and 2
TB drug resistance surveillance		30 countries	All countries
Second-line TB drug resistance surveillance			3 countries
DOTS-Plus project		3 countries (i.e. total of 6)	6 countries (i.e. total of 12)
TB/HIV co-infection surveillance		20 countries	All countries
Anti-retroviral treatment in selected areas		1	3
TB mortality survey (research)		1 country	3 countries
TB plan (DOTS strategy) in national health policy		35 countries	46 countries
DOTS adapted to health system reform (integration, decentralization, cost sharing, social insurance, privatization, sector-wide approach, primary health care, patients' rights)	1 country	6 countries in Groups 1 and 2	46 countries
Active case finding among contacts of cases and in high-risk groups		1 country in Group 2	5 countries in Group 2

ANNEX 5. DOTS expansion by country (percentage of the population covered)

Group 1 – High TB burden

Country	1999	2002	2004	2006
Armenia	80%	100%	100%	100%
Azerbaijan	12%	100%	100%	100%
Belarus	0%	10%	30%	100%
Estonia	0%	100%	100%	100%
Georgia	96%	100%	100%	100%
Kazakhstan	100%	100%	100%	100%
Kyrgyzstan	100%	100%	100%	100%
Latvia	100%	100%	100%	100%
Lithuania	3%	50%	100%	100%
Republic of Moldova	0%	83%	100%	100%
Romania	4%	50%	100%	100%
Russian Federation	5%	25/25% *	35/60% *	45/90% *
Tajikistan	3%	50%	100%	100%
Turkmenistan	0%	20%	50%	100%
Ukraine	0%	4%	17%	40%
Uzbekistan	2%	40%	60%	100%

* Coverage with/without federal commitment.

Group 2 – Intermediate TB burden

Country	1999	2002	2004	2006
Albania	0%	50%	100%	100%
Bosnia and Herzegovina	100%	100%	100%	100%
Bulgaria	0%	50%	100%	100%
Croatia	0%	10%	30%	100%
Hungary	100%	100%	100%	100%
Poland	11%	30%	100%	100%
Portugal	100%	100%	100%	100%
Spain	0%	10%	30%	100%
The former Yugoslav Republic of Macedonia	0%	50%	100%	100%
Turkey	0%	10%	30%	100%
Yugoslavia	0%	30%	60%	80%

ANNEX 6. Distribution of WHO TB staff in the European Region

Location	No. of staff/posts required	Current No. of staff/posts	Current or possible funding
Regional Office (Copenhagen)	4	3	WHO (2) USAID (1)
Russian Federation	4	2	USAID
Central Asia (Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan, Uzbekistan)	2	1	USAID
Ukraine	1	1	USAID
Balkan area	1	1	EU
Total	12	7	

ANNEX 7. Regional Office budget for TB control, 2000/2001

Source of funds	Funds (US $)	
WHO budget	992 110	
Voluntary donations	6 574 166	• 61% USAID • 23% ECHO • 6% DFID • 5% Finnish Government Remaining 5% from: • Austrian Government • French Government • Irish Government • Norwegian Government • SIDA • World Bank
Total	7 566 276	

ANNEX 8. Estimated budget and additional needs for TB control in the WHO European Region, 2002–2006 (US $)

Source of funds	2002	2003	2004	2005	2006
Planned costs	4 500 000	4 500 000	4 500 000	4 500 000	4 500 000
WHO budget	530 000	530 000	N/A	N/A	N/A
Voluntary donations	3 000 000	3 000 000	N/A	N/A	N/A
Funding gap	970 000	970 000	N/A	N/A	N/A

ANNEX 9. Terms of Reference of the Tuberculosis Interagency Coordinating Committee

A. Functions, Composition and Operation

The Tuberculosis Interagency Coordinating Committee (TB-ICC) shall represent the interests and responsibilities of the partners collaborating with WHO in its DOTS Expansion Plan to Stop TB in the WHO European Region. It acts as a coordinating body of the DOTS Expansion Plan to Stop TB in the WHO European Region.

1. Functions

The TB-ICC shall have the following functions:

(a) to review the annual report of the DOTS Expansion Plan to Stop TB in the WHO European Region;

(b) to review the budget, any shortfall and the financial statements of the DOTS Expansion Plan to Stop TB in the WHO European Region and make appropriate recommendations to the Regional Director for improving coordination between international partners and national TB control;

(c) to review the technical assistance, technical achievements and constraints towards the objectives of the DOTS Expansion Plan to Stop TB in the WHO European Region and submit its findings to the Regional Director;

(d) to review the regional and national plans of action of the DOTS Expansion Plan to Stop TB in the WHO European Region and make recommendations to the Regional Director; and

(e) to review from a scientific and technical standpoint the content, scope and dimensions of the operational research activities of the Programme, their relevance to national TB programmes, and approaches to be adopted.

2. Membership

The ICC shall have the following membership.

- *Representatives of financial contributors*. Government representatives of those countries that contributed to the general budget of the DOTS Expansion Plan to Stop TB in the WHO European Region in the previous year.
- *Representatives of Member States combating TB*. Government representatives of countries in which TB is a major health problem, and of countries actively engaged in TB control.
- *International organizations*. Representatives of the World Bank and the United Nations Development Programme (UNDP) and other interested organizations (WFP, UNFPA, UNICEF, UNHCR, etc.).
- *Nongovernmental organizations*. Representatives of the International Union Against Tuberculosis and Lung Disease (IUATLD), the Royal Netherlands Tuberculosis Association (KNCV and EuroTB, and of other nongovernmental organizations to be selected annually by the Regional Director from among those indicating to WHO their interest in membership.

- Experts selected by the Regional Director on the basis of scientific and technical competence (in public policy development for tuberculosis control, operational research and development) necessary to properly advise on all aspects of TB control.

On written application, observer status for the TB-ICC meetings may be granted to interested parties by the Regional Director, who may delegate this function.

3. Operation

The TB-ICC shall meet once a year. The TB-ICC may also meet more often on the proposal either of the Regional Director or of the Chairperson in agreement with the Regional Director.

The Chairperson of the TB-ICC shall be designated for two years from and by the members of the TB-ICC. The Chairperson shall preside over meetings of the TB-ICC, and undertake additional duties as appropriate with the agreement of the Regional Director. Each TB-ICC meeting shall elect a Vice-Chairperson and Rapporteur from among its members, who will ensure that the decisions reached during the meeting are formally adopted and recorded before its closure.

The TB-ICC should, whenever possible, adopt its conclusions by consensus. Observers are encouraged to take part in the discussions of the TB-ICC. The WHO task force shall be Secretariat of the TB-ICC, and shall provide appropriate support services as required.

The TB-ICC shall be informed by the Secretariat of all policy decisions and recommendations concerning TB and its related issues made by the WHO Regional Committee for Europe, the World Health Assembly and the Executive Board and of all reports and recommendations concerning the Regional Office produced by the Tuberculosis Strategic and Technical Advisory Group (STAG).

WHO shall prepare an annual report on the basis of a full review of all scientific, technical and financial aspects of the Programme, and provide any necessary support to the TB-ICC.