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## **Roadmap for the implementation of the Consolidated Action Plan to Prevent and Combat Multidrug- and Extensively Drug-Resistant Tuberculosis in the WHO European Region 2011–2015**

In response to the alarming problem of multidrug- and extensively drug-resistant tuberculosis (M/XDR-TB) in the WHO European Region, and in order to scale up a comprehensive response and to prevent and control M/XDR-TB, a consolidated action plan has been developed for 2011–2015 for all 53 Member States of the WHO Region for Europe and partners. The Plan has six strategic directions and seven areas of intervention. The strategic directions are cross-cutting and highlight the corporate priorities of the Region. The areas of intervention are aligned with the Global Plan to Stop TB 2011–2015 and include the same targets as set by the Global Plan and World Health Assembly resolution WHA62.15, to provide universal access to diagnosis and treatment of MDR-TB. The implementation of the Consolidated Action Plan would mean that the emergence of 250 000 new MDR-TB patients and 13 000 XDR-TB patients would be averted, an estimated 225 000 MDR-TB patients would be diagnosed and at least 127 000 of them would be successfully treated thus interrupting the transmission of MDR-TB; and 120 000 lives and US\$ 5 billion would be saved.

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## Target audience

This document is written primarily for those responsible for tuberculosis control in WHO European Member States' ministries of health and other government bodies responsible for health in penitentiary services, health financing, health education and social services. It also urges and supports the intensified involvement of civil society and communities affected by the disease, professional societies, partners and donors, national and international technical agencies including the WHO Regional Office for Europe and all stakeholders engaged in tuberculosis control in the Region.

## Abbreviations

ACSM	advocacy, communication and social mobilization
AIDS	acquired immunodeficiency syndrome
DOT	directly observed treatment
DOTS	first component and pillar element of the Stop TB Strategy recommended for the control of tuberculosis
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EU	European Union
EXPAND TB	Expanding Access to New Diagnostics for TB, Project
HIV	human immunodeficiency virus
MDR-TB	multidrug-resistant tuberculosis, resistant to isoniazid and rifampicin
PHC	primary health care
TB	tuberculosis
USAID	United States Agency for International Development
XDR-TB	extensively drug-resistant tuberculosis, resistant to isoniazid and rifampicin and to any one of the fluoroquinolone drugs and to at least one of the three injectable second-line drugs (amikacin, capreomycin or kanamycin)
Xpert MTB/rifampicin	A cartridge-based, automated diagnostic test that can identify <i>Mycobacterium tuberculosis</i> and resistance to rifampicin



## Executive summary

The Consolidated Action Plan to Prevent and Combat Multidrug- and Extensively Drug-Resistant Tuberculosis (M/XDR-TB) in the WHO European Region 2011–2015 has been developed to strengthen and intensify efforts to address the alarming problem of drug-resistant TB in the Region.

The Plan has been prepared in Region-wide consultation with representatives of the 53 European Member States, experts, patients and communities suffering from the disease. The participatory process of developing the Plan was led by the Regional Director's Special Project to Prevent and Control M/XDR-TB and was overseen by an independent steering group composed of representatives of key technical and bilateral agencies, Member States and civil society organizations.

In order to scale up a comprehensive response and to prevent and control M/XDR-TB, the Action Plan has been developed for the 53 Member States, the WHO Regional Office for Europe and partners. This Plan has six strategic directions and seven areas of intervention. The strategic directions are cross-cutting and are designed to safeguard the values of the Health 2020 strategy and highlight the corporate priorities of the WHO European Region. The areas of intervention are aligned with the Global Plan to Stop TB 2011–2015 and include the same targets as set by the Global Plan and World Health Assembly resolution WHA62.15, namely to provide universal access to diagnosis and treatment of MDR-TB.

Following a detailed assessment of interventions in the Region to tackle TB and MDR-TB, and considering the Member States' responses to the Regional Director's request for input and feedback at the Eighteenth Standing Committee of the Regional Committee's second session (Andorra 18–19 November 2010), the first draft of the Consolidated Action Plan was prepared. The WHO Regional Office for Europe organized a three-day workshop in Copenhagen from 6 to 8 December 2010 and finalized the second draft of the Plan with the participation of country representatives and key experts in the field. The Plan was posted on the internet between 25 February and 11 April 2011 for consultation with the public and civil society and sent on 5 May 2011 to Member States for their review and inputs. This document includes the comments and inputs received.

The Regional Office has developed a monitoring and evaluation framework and integrated it in the Consolidated Action Plan. A joint platform with partners will be established to follow up and assist in the implementation of the Plan. The Plan is built on the core principles of the Health 2020 Strategy with the vision of equitable access to health.

The Consolidated Action Plan is being submitted for endorsement by the WHO Regional Committee for Europe at its sixty-first session in Baku, Azerbaijan, in September 2011, together with a resolution. A concise version of the Plan has been developed for endorsement by the Member States.

The Regional Office has assisted Member States with high burdens of MDR-TB to develop national MDR-TB response plans based on the commitment made by ministers from the 27 countries in the world with a high M/XDR-TB burden meeting in Beijing in 2009. The Action Plan will act as a guide for Member States in the further development and integration of national MDR-TB response plans into their national TB and/or national health strategy plans.

The Plan aims to decrease by 20 percentage points the proportion of MDR-TB among previously treated patients, to diagnose at least 85% of all estimated MDR-TB patients and to treat successfully at least 75% of all patients notified as having MDR-TB by the end of 2015.

Successful implementation of the Action Plan would mean that the emergence of about 250 000 new MDR-TB patients and 13 000 XDR-TB patients would be averted; an estimated 225 000 MDR-TB patients would be diagnosed and at least 127 000 of them would be successfully treated, thus interrupting the transmission of MDR-TB; and about 120 000 lives and US\$ 5 billion would be saved.

## Introduction and background

Multidrug- and extensively drug-resistant tuberculosis (M/XDR-TB) is a man-made phenomenon that emerges as a result of inadequate treatment of tuberculosis and/or poor airborne infection control in health care facilities and congregate settings. In 2009, almost 330 000 new and relapsed cases of TB (5.6% of the global burden) and more than 46 000 deaths due to TB were reported in the WHO European Region, the majority of them in 18 countries which have made it a high priority to stop TB (1).<sup>1</sup> Although the trend in TB notification has been falling since 2005, the notification rate of new and relapsed cases of TB in the 18 countries is still eight times higher than in the rest of the Region (73 vs. 9 cases per 100 000) and double the regional average (37 per 100 000 population) (2).

Of the 440 000 (range 390 000–510 000) estimated multidrug-resistant TB (MDR-TB) cases, both primary and acquired, in the world, 81 000 (range 73 000–90 000) are estimated to be in the European Region (18.4% of the global burden). The Region also contains the top 15 countries in the world with the highest proportion of MDR-TB among newly diagnosed and previously treated cases of TB (Fig. 1,2) (3).<sup>2</sup> Of the 27 countries worldwide with a high burden of MDR-TB, 15 are in the Region (4). MDR-TB is also reported as being linked to upstream determinants of health such as low socioeconomic status, migration and urbanization, leading to downstream TB risk factors such as poor living conditions (indoor pollution, malnutrition), imprisonment, specific health behaviour (tobacco use, alcohol and drug abuse, diabetes) and HIV infection that are of great concern for most countries of the Region, irrespective of their burden of TB.

Both globally and regionally, TB and MDR-TB are observed to occur disproportionately among men, as they are more likely to be exposed to risk factors such as tobacco and alcohol consumption or imprisonment. Gender differences in TB notification rates in some eastern European countries are, however, higher than expected, suggesting that some women may be failing to seek diagnosis and care in time.

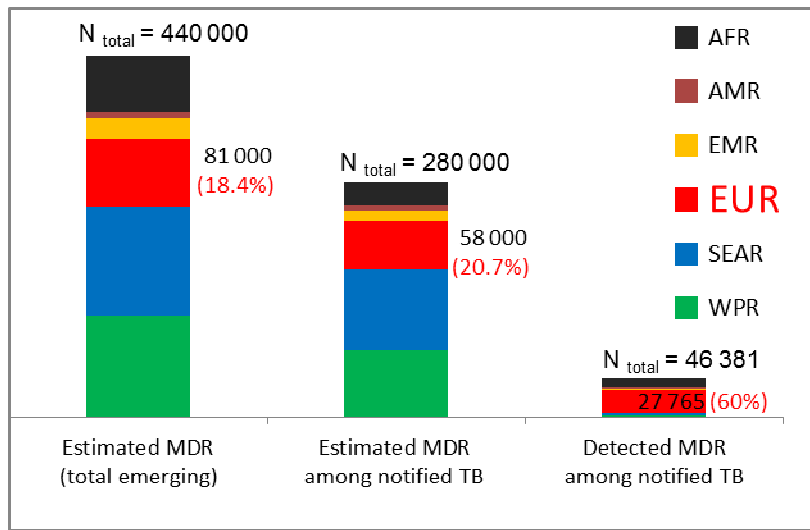
MDR-TB is the result of inadequate treatment of TB, which can then be transmitted within the community, and/or poor airborne infection control in health care facilities and communal settings. It is also the result of differential exposure to the risk factors described above and inequitable access to health and social protection systems.

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<sup>1</sup>Armenia, Azerbaijan, Belarus, Bulgaria, Estonia, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Republic of Moldova, Romania, Russian Federation, Tajikistan, Turkey, Turkmenistan, Ukraine, Uzbekistan.

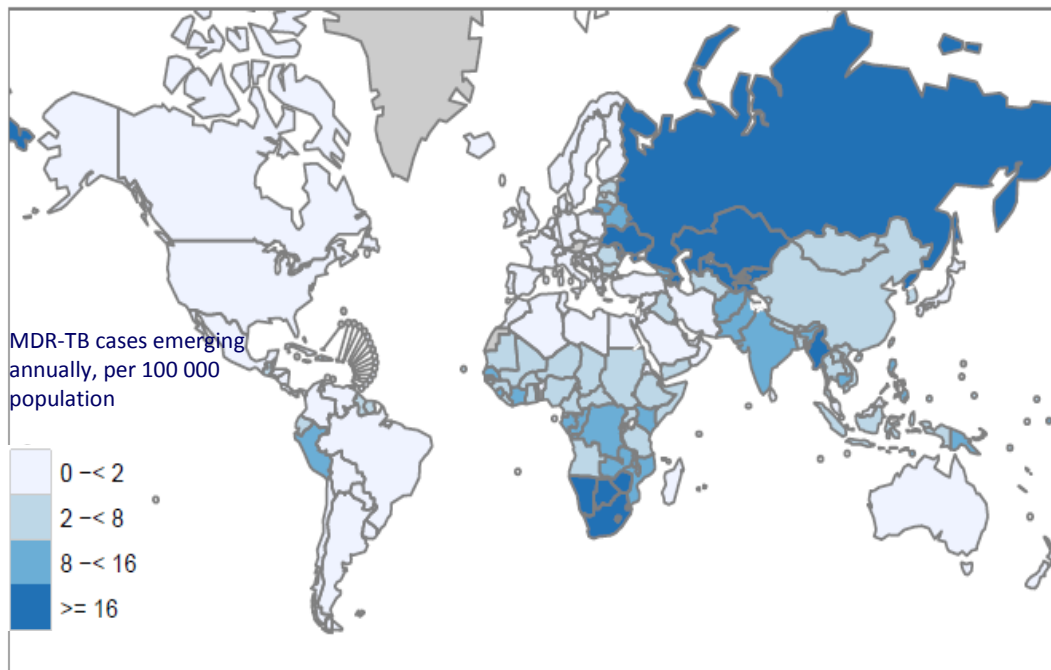
<sup>2</sup>High-burden MDR-TB countries were selected on the basis of an estimated absolute number of at least 4000 MDR-TB cases arising annually and/or at least 10% of all newly registered TB cases estimated with MDR-TB, as of 2008. The 15 countries of the WHO European Region with a high MDR-TB burden are Armenia, Azerbaijan, Belarus, Bulgaria, Estonia, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Republic of Moldova, Russian Federation, Tajikistan, Ukraine, Uzbekistan.

Fig.1. Proportion of cases of MDR-TB emerged and notified in the WHO European Region compared to other WHO regions, 2009



Source: WHO Regional Office for Europe (3).

Fig.2. Estimated global MDR-TB incidence, 2009



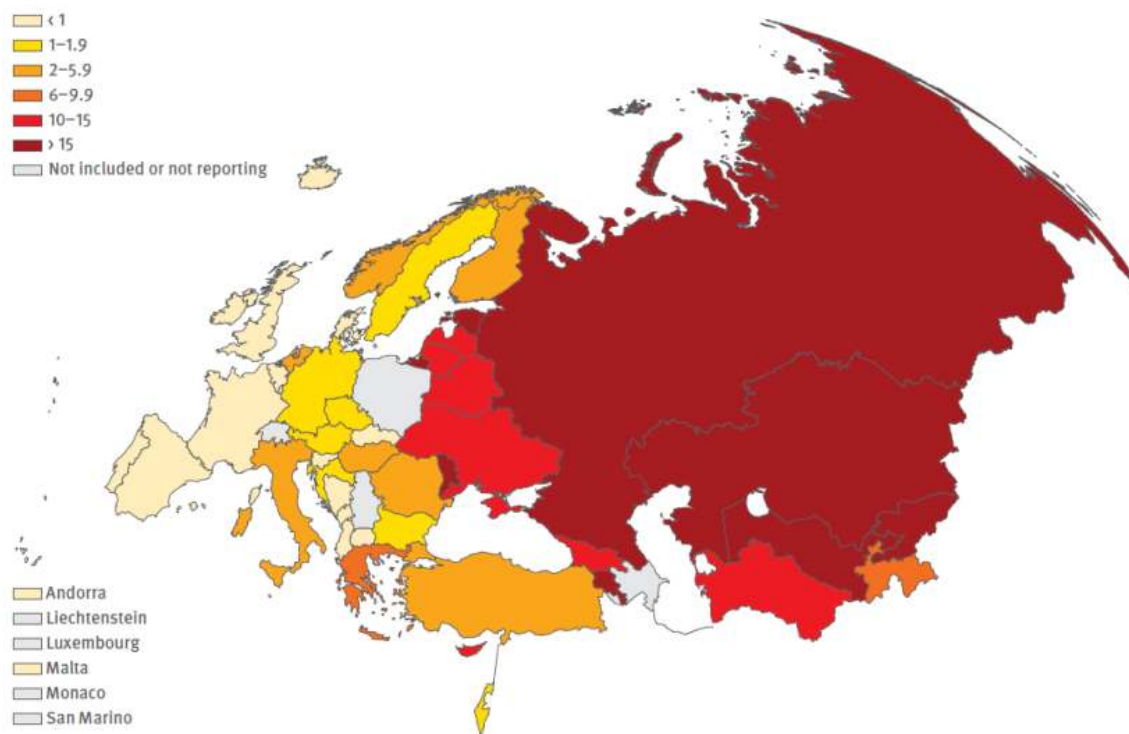
Source: WHO Regional Office for Europe (3).

In 2009, the proportions of MDR among newly diagnosed and previously treated TB patients were very alarming, at 11.7% and 36.6%, respectively (Fig. 3). Furthermore, many countries in the Region have reported extensively drug-resistant TB (XDR-TB), including those in the



European Union/European Economic Area (EU/EEA).<sup>3</sup> In spite of the still very low coverage (2.7%) of drug susceptibility testing with second-line drugs, especially in eastern Europe, the total number of patients with XDR-TB notified in the Region almost tripled from 132 in 2008 to 344 in 2009, the vast majority of them (81%) in non-EU/EEA countries. In order to diagnose XDR-TB, there is a need for second-line drug susceptibility testing, which is not readily available for all patients.

Fig. 3. Notified number of TB cases with primary multidrug resistance, Europe, 2009 (%)



Source: European Centre for Disease Prevention and Control (2).

Note. Data from Kosovo (in accordance with United Nations Security Council Resolution 1244 (1999)) are not included in the figures reported for Serbia.

In 2009, from an estimated 81 000 (range 73 000–90 000) MDR-TB patients, only 27 765 cases (34%) were notified due to limited laboratory capacity (Table 1) (2,3). Of these, only 61.8% (17 169 cases) were reported as receiving adequate treatment with quality second-line drugs.

<sup>3</sup>The 30 EU and EEA countries are: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom. The 24 countries in the rest of the European Region (non-EU/EEA) are: Albania, Andorra, Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Croatia, Georgia, Israel, Kazakhstan, Kyrgyzstan, Monaco, Montenegro, the Republic of Moldova, the Russian Federation, San Marino, Serbia, Switzerland, Tajikistan, the former Yugoslav Republic of Macedonia, Turkey, Turkmenistan, Ukraine and Uzbekistan.

Table 1. The 15 high-burden MDR-TB countries in the WHO European Region with an estimated annual incidence of over 4000 MDR-TB cases per year and/or at least 10% newly registered cases with MDR-TB

<b>Countries</b>	<b>Estimated MDR-TB annual incidence, cases (95% CI)</b>	<b>Estimated MDR-TB among new TB cases (%) (95% CI)</b>	<b>Reported cases of MDR-TB, 2009</b>
Armenia	480 (380–580)	9.4 (7.3–12.1)	156
Azerbaijan	4 000 (3300–4700)	22.3 (19.0–26.0)	–
Belarus	800 (260–1300)	12.5 (0.0–25.3)	867
Bulgaria	460 (99–810)	12.5 (0.0–25.3)	43
Estonia	94 (71–120)	15.4 (11.6–20.1)	86
Georgia	670 (550–780)	6.8 (5.2–8.7)	369
Kazakhstan	8 100 (6400–9700)	14.2 (11.0–18.2)	3644
Kyrgyzstan	1 400 (350–2400)	12.5 (0.0–25.3)	785
Latvia	170 (140–200)	12.1 (9.9–14.8)	131
Lithuania	330 (270–390)	9.0 (7.5–10.7)	322
Republic of Moldova	2 100 (1700–2400)	19.4 (16.8–22.2)	1069
Russian Federation	38 000 (30 000–45 000)	15.8 (11.9–19.7)	14 686
Tajikistan	4 000 (2900–5100)	16.5 (11.3–23.6)	319
Ukraine	8 700 (6800–11 000)	16.0 (13.8–18.3)	3482
Uzbekistan	8 700 (6500–11 000)	14.2 (10.4–18.1)	654

Source: World Health Organization (5).

The treatment of MDR-TB patients is lengthy, taking up to two years with second-line drugs and sometimes surgery, often accompanied by adverse effects, imposing a further burden on patients and their families. In 2008, the treatment success rate among MDR-TB patients in the Region receiving quality-assured second-line drugs was 57.4%, while the other one third of notified MDR-TB patients had no (or were not reported as having) access to quality treatment. Access to quality second-line drugs for treatment of M/XDR-TB is limited in many Member States. Some of these drugs are too expensive and/or not available for all the patients.

The drug supply system often fails to ensure treatment for the whole course of treatment. Hospital services have serious setbacks, which in some cases contribute to the development of M/XDR-TB, while outpatient services face serious challenges to ensure continuity of care and access by socially vulnerable groups.

Despite good progress in several countries, the TB control network has not fully included the prison system. There are still wide differences in policy and administration, including financial capacity, between ministries of health and penitentiary health authorities in many countries, leading to unequal health care services.

The WHO-recommended package of airborne infection control measures is not at present being implemented in most diagnostic and treatment facilities. The latest available data from the 15 high-burden MDR-TB countries indicate that implementation of TB infection control interventions is still limited. Infection control assessments have been carried out in 10 of these countries, but only 4 have national infection control plans while 6 are in the process of preparing them.

In response to the alarming problem of M/XDR-TB in the WHO European Region, the Regional Director has established a Special Project to Prevent and Combat M/XDR-TB in Member States. The Regional Office, in collaboration and coordination with other partners, has provided guidance and technical assistance to Member States to improve TB, MDR-TB and TB/HIV

prevention, control and care, including planning and programme management, airborne infection control, surveillance, monitoring and evaluation, development of human resources capacity, quality-assured laboratory diagnosis, guidelines and policy development, provision of quality medicines through the Global Drug Facility and Green Light Committee, advocacy, communication and social mobilization. The institutional capacity of health systems needs to be improved to ensure sustainable and effective TB and M/XDR-TB prevention and control.

Bacille Calmette-Guérin (BCG) – the only vaccine so far available against TB – was first used in 1921. It has limited efficacy for protection against the disease and cannot be administered to people living with HIV, although it can protect, to some extent, against the severe form of TB in children. The most effective medicines against TB were discovered in the 1950s; since then, other agents have been introduced with often more frequent and serious adverse events. There is an urgent need for more effective medicines and vaccines, including for children and people living with HIV. European scientific institutes can play an important role in research and development of new medicines and vaccine.

Recently, an automated rapid nucleic acid amplification test has been endorsed by WHO as a rapid method for diagnosis of TB and rifampicin resistance. However, this technology and other WHO-endorsed diagnostic methods are not yet widely available in most countries with a high MDR-TB burden in the Region and their introduction is urgently needed.

In the Berlin Declaration on Tuberculosis, endorsed in 2007, all Member States committed themselves to respond urgently to the re-emergence of TB in the Region and properly address M/XDR-TB (6). Adequate interventions addressing drug-resistant TB require proper national planning and effective implementation, comprehensive approaches in and across countries and strong support from national and international partners. They therefore depend on strong institutional capacity at national, subnational and transnational levels. Ministers from the 27 countries of the world with a high M/XDR-TB burden met in Beijing, China, from 1 to 3 April 2009 to address urgently the alarming threat of M/XDR-TB. This was reflected in a call for action on M/XDR-TB, to help strengthen health agendas and ensure that urgent and necessary commitments to action and funding are made in order to prevent this impending epidemic (7). In May 2009, the sixty-second World Health Assembly in its Resolution 62.15 urged all Member States to achieve universal access to diagnosis and treatment of M/XDR-TB as part of the transition to universal health coverage, thereby saving lives and protecting communities (8). The 15 high-burden MDR-TB countries in Europe have already developed their national M/XDR-TB response plans for 2011–2015. They now need to align their approved national TB plans with the new commitments in preventing and controlling M/XDR-TB.

The WHO Regional Director for Europe has confirmed WHO's strong commitment to fight against TB and M/XDR-TB as a regional priority and to develop an action plan to prevent and combat M/XDR TB in the Region. This position was endorsed by the Regional Committee at its sixtieth session in Moscow in September 2010.

In order to scale up a comprehensive response and to prevent and control M/XDR-TB, the Consolidated Action Plan to Prevent and Combat M/XDR-TB in the WHO European Region 2011–2015 has been developed for the 53 Member States, the WHO Regional Office for Europe and partners. This Plan has six strategic directions and seven areas of intervention. The strategic directions are cross-cutting and are designed to safeguard the values of the Health 2020 strategy and highlight the corporate priorities of the WHO European Region. The areas of intervention are aligned with the Global Plan to Stop TB 2011–2015 and include the same targets as set by the Global Plan and World Health Assembly resolution WHA62.15, namely to provide universal access to diagnosis and treatment of MDR-TB.

The Action Plan has been developed under the guidance of an independent steering group which included representatives of selected Member States, technical agencies and civil societies involved in TB control in Europe.<sup>4</sup> It is consistent with the Beijing Call for Action and the Berlin Declaration.

A task force led by the Regional Office has developed a comprehensive monitoring and evaluation framework to document progress in the implementation of the Plan (Annex 1).

## Outline of the Consolidated Action Plan

### Goal

To contain the spread of drug-resistant tuberculosis by achieving universal access<sup>5</sup> to prevention, diagnosis and treatment of M/XDR-TB in all Member States of the WHO European Region by 2015 (8).

### Targets

The Consolidated Action Plan aims:

- to decrease by 20 percentage points the proportion of MDR-TB among previously treated patients by the end of 2015;<sup>6</sup>
- to diagnose at least 85% of all estimated MDR-TB patients by the end of 2015;<sup>7</sup>
- to treat successfully at least 75% of all patients notified as having MDR-TB by the end of 2015.

### Strategic directions

The six strategic directions of the Action Plan are:

- (i) to identify and address the determinants and underlying risk factors contributing to the emergence and spread of drug-resistant TB (areas of intervention 1, 4, 6 and 7);

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<sup>4</sup>The steering group included: the European Centre for Disease Prevention and Control, the European Commission, the European Respiratory Society, the Global Fund to fight Against AIDS, TB and Malaria, the International Union Against Tuberculosis and Lung Disease, KNCV Tuberculosis Foundation (Netherlands), Partners in Health, United States Agency for International Development (USAID), WHO headquarters and the Regional Office. In October 2010, the steering group was expanded to include civil society representatives (TB Europe Coalition) and English-speaking TB focal points from Germany, the Netherlands, Romania, the Russian Federation, Slovakia and Uzbekistan.

<sup>5</sup>Universal access is defined as evidence-based practices and quality services that are available, accessible, affordable and acceptable by people irrespective of their age, sex, sexual orientation, religion, origin, nationality, socioeconomic status or geographical background.

<sup>6</sup>It would, however, be difficult within the time span of this Consolidated Action Plan – if indeed possible – to reduce primary MDR-TB significantly enough to be attributable to interventions under the Plan. Apart from the need to improve airborne infection control in health care facilities and communal settings, many primary MDR-TB patients who have been infected in the community might develop MDR-TB in the near future. The proportion of MDR-TB among previously treated patients would be a more sensitive indicator of improvement in case-holding and appropriate treatment of patients and thus preventing the further development of MDR-TB.

<sup>7</sup>In 2009, only 34.5% of estimated MDR-TB patients were notified. With universal access to diagnosis, it would be expected that most sputum culture-positive patients would be identified, notified and reported, although many culture-negative TB patients may not be detected.

- (ii) to strengthen the response of health systems in providing accessible, affordable and acceptable services with patient-centred approaches: in order to reach the most vulnerable populations, all barriers to access must be addressed and treatment must remain truly free of charge for patients; innovative mechanisms are to be introduced to remove barriers to equitable access to diagnosis and treatment of drug-resistant TB and create incentives and enablers for patients to complete their course of treatment (areas of intervention 1, 2, 3, 4, 5, 6 and 7);
- (iii) to work in national, regional and international partnerships in TB prevention, control and care (area of intervention 6);
- (iv) to foster regional and international collaboration for the development of new diagnostic tools, medicines and vaccines against TB (areas of intervention 2, 3 and 6);
- (v) to promote the rational use of existing resources, identify gaps and mobilize additional resources to fill the gaps (area of intervention 6);
- (vi) to monitor the trends of M/XDR-TB in the Region and measure the impact of interventions (area of intervention 5) (Annex 2).

### **Areas of intervention**

Based on the objectives in the Global Plan to Stop TB 2011–2015 (9)<sup>8</sup> to achieve a reduction in the burden of drug-resistant TB, the seven areas of intervention of the Consolidated Action Plan are to:

- (i) prevent the development of cases of M/XDR-TB;
- (ii) scale up access to testing for resistance to first- and second-line anti-TB drugs and to HIV testing and counselling among TB patients;
- (iii) scale up access to effective treatment for all forms of drug-resistant TB;
- (iv) scale up TB infection control;
- (v) strengthen surveillance, including recording and reporting, of drug-resistant TB and monitor treatment outcomes;
- (vi) expand countries' capacity to scale up the management of drug-resistant TB, including advocacy, partnership and policy guidance;
- (vii) address the needs of special populations.

### **Milestones**

It is anticipated that the following milestones will be achieved:

- by the middle of 2012, establishment of a regional mechanism for coordination and collaboration among partners for provision of technical assistance and scale-up of the response to M/XDR-TB;
- by the end of 2013, availability of a rapid molecular diagnosis test for MDR-TB<sup>9</sup> endorsed by WHO and in use for all eligible patients in Member States;

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<sup>8</sup>It has been decided to refer to the objectives in the Global Plan as “areas of intervention” and to define specific objectives under each of these areas, to ensure they are “smart” (specific, measurable, achievable, realistic and time-bound).

<sup>9</sup>A rapid test is defined as one which provides a diagnosis within 48 hours of the specimen being tested and can therefore influence the initial treatment on which a patient is placed.

- by the end of 2014, introduction of an electronic case-based database for notification and treatment outcome of MDR-TB patients at national level in all high-burden MDR-TB countries;
- by the end of 2013, reporting by all high-burden MDR-TB countries of more than 50% of estimated MDR-TB cases;
- by the end of 2013, completion by all 18 European high-priority TB countries of a knowledge, attitude and practice survey and undertaking of a health system assessment needs related to TB and MDR-TB;
- by the end of 2012, national M/XDR-TB action plans adopted, budgeted and embedded in the national TB strategic plans of all 18 European high TB priority countries;
- by the end of 2013, provision by all Member States of an uninterrupted supply of quality-assured first and second-line drugs for treatment of all TB and M/XDR-TB patients;
- by the end of 2013, monitoring and reporting of treatment outcomes of M/XDR-TB patients by all Member States according to internationally recommended methods;
- by the end of 2012, testing of all previously treated TB patients for resistance to first and second-line drugs;
- by the end of 2015, availability of at least one new medicine for M/XDR-TB patients with a more effective and shorter treatment regimen for use.

### **Cost of implementing the Plan**

The Regional Office has commissioned the Royal Tropical Institute in Amsterdam to develop a detailed costing tool for implementation of the Action Plan. The front-line services have been costed, including the detection and treatment of MDR-TB and XDR-TB patients. Stewardship costs include funds needed for human resource capacity-building and technical assistance. Based on the best estimates, implementation of the Plan would cost US \$5 billion. Annex 3 presents an overview of the costs and the methodology.

### **Expected achievements<sup>10</sup>**

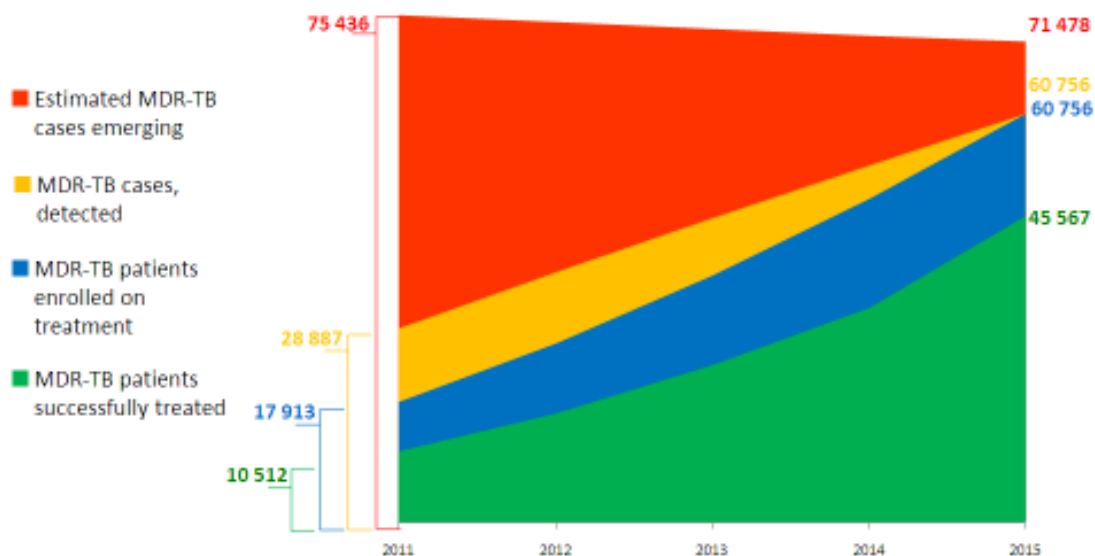
Epidemiological modelling developed by the Regional Office together with the M/XDR-TB costing tool indicate that the implementation of the Consolidated Action Plan will result in:

- 225 000 MDR-TB patients being diagnosed within three days of presenting to a health care service with TB symptoms;
- 127 000 DR-TB patients being treated successfully;
- 250 000 cases of MDR-TB being averted;
- 13 000 cases of XDR-TB being averted;
- 120 000 lives being saved;
- US\$ 5 billion being saved (Fig. 4).

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<sup>10</sup>The method to determine the expected achievements has been developed in collaboration with the Royal Tropical Institute in Amsterdam. Costs for MDR-TB case detection and treatment, as well as for stewardship, and the epidemiological data used were taken from the following sources: WHO, European Centre for Disease Prevention and Control, the Foundation for Innovative Diagnostics, UNAIDS and academic publications. When data on TB epidemiology in Europe were not available in these sources, assumptions based on expert opinions and linear progression of targets and milestones defined in the Plan were used.

Fig. 4. Expected achievements from the implementation of the Action Plan, 2011–2015



## Regional analysis of the strengths, weaknesses, opportunities and threats in relation to M/XDR-TB

The Consolidated Action Plan is based on a detailed analysis of the strengths, weaknesses, opportunities and threats in relation to M/XDR-TB in the European Region. Annex 2 provides an overview of the problems identified and how the Plan addresses them.

### Strengths

#### Governance

- Member States have evinced a strong political commitment to address the problem of TB through their endorsement of the Berlin declaration (6), the Beijing meeting of high-burden MDR-TB countries (7) and World Health Assembly resolutions (8).
- The Regional Director has established a special project to prevent and combat M/XDR-TB in the Region.
- WHO headquarters and the Regional Office have assisted high-burden MDR-TB countries to prepare national MDR-TB response plans.
- All 15 high-burden MDR-TB countries have finalized their national MDR-TB response plans.
- There is good intelligence on drug-resistant TB based on surveillance of drug resistance in countries, well-established reporting to WHO and the European Centre for Disease Prevention and Control (ECDC) and operational research exploring some social determinants of and risk factors for TB.

#### National policies

- Some countries in the Region are participating in the WHO Good Governance for Medicines programme.

### ***Partnerships***

- The Regional Office and partners have intensified their support to Member States to prevent and control TB and M/XDR-TB.
- An increasing number of national and international organizations are will ing to strengthen partnership and coordination.

### ***Implementation***

- WHO headquarters, the Regional Office and country offices and other technical agencies have been providing technical assistance to Member States.
- The Global Fund to Fight AIDS, Tuberculosis and Malaria has been instrumental in pilot implementation of MDR/TB control projects.
- Under the Green Light Committee mechanism, 19 countries in the Region have set up MDR-TB control projects.
- Two medicines quality control laboratories in non-EU countries in the Region have been pre-qualified by WHO.
- Several pharmaceutical manufacturers in non-EU countries have initiated a process for pre-qualifying their TB drug products through the WHO pre-qualification mechanism.
- Strong WHO collaborative centres and centres of excellence for MDR-TB control have been established in the Region.
- Member States have skilled health care staff involved in TB prevention and control.

### **Weaknesses**

#### ***Health systems***

- National TB control programmes are insufficiently engaged in reforms of health systems (with both national and international institutions).
- Interaction with other levels of health systems, including primary health care (PHC) services, is limited by the vertical structure of TB control programmes.
- There is only limited involvement by other sectors (including the private health sector and social services).
- Health and public health professionals and practitioners lack capacity and training in working intrasectorally and intersectorally.
- Coordination is poor between TB and other programmes for collaborative activities (such as for HIV, alcohol, drug users and tobacco and other communicable and noncommunicable diseases).
- TB care for children is not consistently integrated into HIV and primary health care and maternal and child health programmes.
- Collaboration mechanisms for a continuum of care between countries (cross-border TB control, migrant labour) are lacking or inadequate.
- Financing mechanisms provide disincentives in some settings (such as financing based on bed occupancy rather than performance of services, which results in large bed capacity and long hospitalization).



- Fragmentation in financial flows by programme, as well as inappropriate incentives, inhibits coordinated responses by health systems and causes misalignment between policies and implementation on the ground. Unclear mandates and stewardship across agencies (for example, penitentiary and civil), actors and levels of care regarding M/XDR-TB are hampering an effective response by Member States.
- Inefficient and unequal distribution of health resources (notably in human resources and pharmacies) is leading to ineffective responses from health systems.
- Weak provider networks and referral systems are undermining the capacity of health systems to ensure case detection, follow-up and continuity of treatment in PHC and other ambulatory care facilities and are likely to contribute to X/MDR-TB.
- Entrenched political power in TB hierarchies has created a strong resistance to change.
- DOTS is being poorly implemented in some countries.

### ***National policies***

- TB policy and guidelines are outdated in some countries.
- Most countries lack policies for multidisciplinary approaches to patients' problems (socioeconomic status and poverty, unemployment, psychiatric disorders, alcoholism and drug addiction).
- There is a lack of policies on preventive treatment regimens for M/XDR-TB.

### ***Case-finding and diagnosis***

- MDR-TB is being under-diagnosed in children, with a consequent risk of drug resistance spreading.
- Contact-tracing is poor in some settings.
- Limited coverage of culture and drug susceptibility testing led to only 34% of estimated MDR-TB being detected in 2009.
- Most Member States have only a limited diagnostic capacity for early detection of TB and M/XDR-TB.
- External quality assurance of culture and drug susceptibility testing has not yet covered all patients.
- External quality assurance drug susceptibility testing for second-line TB drugs (especially second-line injectables and fluorquinolones) is largely unavailable.
- Good established laboratory networks are lacking.
- There is a lack of paediatric diagnostic tools and inadequate surveillance and reporting of TB in children.

### ***Treatment***

- Medical care for M/XDR-TB is inadequate in some settings.
- Treatment regimens in some settings are inappropriate.
- There is a lack of novel medicines for shorter and more effective treatment regimens.
- National TB control programmes are either not, or only to a limited extent, involved in strengthening outpatient treatment in some settings.

- Default prevention and retrieval in most settings are weak or non-existent.
- Palliative care for patients who fail M/XDR-TB treatment is not available.
- Management of TB in children is outdated in some countries.

### ***Drug management***

- In 2009, only 61.8% of patients diagnosed with MDR-TB benefited from adequate treatment owing to Member States' difficulties in procuring quality second-line drugs.
- Quality-assured second-line drugs are in short supply in some countries.
- Pharmaceutical regulations and inspection in many non-EU countries are weak and lack enforcement mechanisms to assure universal drug quality and prevent over-the-counter sales of antimicrobials (such sales occur in some Member States).
- Weak pharmacovigilance mechanisms and a lack of unbiased drug information for prescribers and patients in most high-burden MDR-TB countries are possible contributors to irrational (improper) use of TB medicines.
- Most countries in the Region do not have a law on procurement of medicines that would define medicines as products requiring unique specifications and action to assure their quality.
- There is a lack of centralized units for procurement and distribution of second-line drugs.

### ***Information systems***

- Reporting and information-sharing among international technical agencies and bilateral donors is poor.
- Many Member States lack surveillance of M/XDR-TB.
- Treatment outcome definitions for M/XDR-TB are either absent or applied differently so that comparability of treatment success cannot be used as an important indicator of TB control quality.
- Surveillance mechanisms based on matched information coming from both laboratories and clinicians are inadequate.
- Reporting on social determinants and equity is limited, so it is difficult to establish which populations are most at risk beyond general categories (for example, prisoners and injecting drug users).

### ***Infection control***

- Airborne infection control is poor in most inpatient facilities and laboratories.
- The infrastructure of many TB inpatient and outpatient facilities is poor.
- There is a lack of policies on hospitalization, from indications for admission until preparation for discharge to ambulatory care, according to the epidemiological situation.

### ***Human resources***

- Human resources are overburdened (TB services are understaffed, at least in some settings): staff are poorly motivated, underpaid and overloaded.

- In some settings, human resources are not being organized in such a way as to guarantee that M/XDR patients receive dedicated high-quality health care.
- TB clinical expertise is getting weaker in low-prevalence countries.

### ***Community involvement***

- Civil society is only involved to a limited extent in TB prevention, control and care.
- Patient-centred approaches are not fully established in most high-burden MDR-TB countries and there is a lack of mechanisms/initiatives for community-based treatment.
- Public health education is inadequate, leading to a prevailing stigma.
- It is difficult to engage TB and MDR-TB patients in advocacy and a watch-dog role.

### ***Special populations***

- Coordination is weak between the different health authorities involved in TB control and the civilian and penitentiary services.
- Marginalized populations (homeless, migrants, etc.) and vulnerable groups (such as children and pregnant women) lack access to adequate diagnosis and treatment.
- Stigma and discrimination associated with MDR-TB worsen adherence to treatment.

### **Opportunities**

#### ***(Subregional) partnerships***

- Intercountry cooperation would address cross-border TB control and care and improve second-line drug availability.
- Cities or institutes responsible for TB control could be twinned.
- Goodwill ambassadors and private entrepreneurs could be involved in TB control.
- The involvement of civil society, patients' associations and professional societies could be increased.

#### ***Health systems***

- The private sector could be involved. Services could be purchased by health insurance funds and university health care services from ministries of health.
- The involvement of bilateral agencies, the Global Fund, UNITAID, TB REACH and other funding mechanisms could be stepped up to fill the gaps in financing.

#### ***Technical***

- A new rapid diagnostic test has been endorsed by WHO which can confirm rifampicin resistance with high positive and negative predictive values.
- WHO has started a European Review of Social Determinants and the Health Divide which will also be looking at the social determinants of TB and their distribution and how to address them in the Health 2020 Strategy.

## **Threats**

### ***Health systems***

- Social determinants, risk factors and health system factors contributing to an increase in MDR-TB still prevail.
- Health systems in transition and the global financial crisis are threatening health and health protection systems and contributing to a widening of the health divide.
- Interventions initiated under the Global Fund grant will not be taken over by national health authorities owing to shortages of funds and the financial crisis.
- Civil society organizations and patients' associations supported through the Global Fund may be obliged to reduce or end their activities if national health authorities do not take over all components of the TB programme and continue to finance them.
- Global Fund eligibility criteria can be modified and as a result some high-burden MDR-TB countries may not be eligible for grants.
- The financial crisis and budget cuts are leading to fewer resources available for TB and M/XDR-TB control.
- Funds to scale up MDR-TB prevention, diagnosis and treatment are lacking.
- Such lack of funds may slow down or even interrupt the development of new tools against TB.
- Poor quality DOTS implementation and MDR-TB management are seriously contributing to an increase in M/XDR-TB.
- The vertical structure of TB control programmes leads to limited interaction with other levels of health systems, including PHC services.
- Other sectors (such as the private health sector or social services) are only involved to a limited extent.
- Coordination is poor between TB and other programmes for collaborative activities (such as for HIV, alcohol, drug users and tobacco and other communicable and noncommunicable diseases)

### ***Technical***

- HIV infection and other co-morbidities continue to rise, particularly among vulnerable groups.
- There is only limited or no uptake of findings with regard to social determinants (particularly upstream factors such as gender) and their impact on X/MDR-TB.
- Existing pharmaceutical policies, regulations, and practices may not support the rapid introduction, adoption and implementation of new TB tools and their proper utilization.

### ***International dimensions***

- Reporting and information-sharing is poor among international technical agencies and bilateral donors.

## **Areas of intervention (adapted from the objectives of the Global Plan 2011–2015)**

### **1. Prevent the development of M/XDR-TB cases**

In order to decrease the burden of the disease, every effort should be made to prevent the development of drug-resistant TB and particularly MDR-TB.

Among the main causes for the emergence of MDR-TB is inadequate and inappropriate treatment. TB patients diagnosed should be put on appropriate treatment regimens as early as possible. They need to be counselled and supported throughout the course of treatment in order to increase their adherence to treatment. Some of the interventions related to this area are discussed under scaling up the management of drug-resistant TB (area of intervention 6) and TB infection control (area of intervention 4). In this area, two other distinctly relevant interventions are considered: improving patient adherence and preventive treatment.

#### **1.1 Identify and address social determinants related to M/XDR-TB**

Activity 1.1.1. The Regional Office and partners, in collaboration with the Member States, will conduct studies on social determinants and reasons for defaulting from treatment for M/XDR-TB by the end of 2012.

Activity 1.1.2. All Member States will include action in their national health strategies to address the social determinants of M/XDR-TB in their national budgets by the end of 2013.

Activity 1.1.3. All Member States will define measures to engage national and local governments, together with partners, in providing psychosocial support for TB and M/XDR-TB patients by the end of 2013.

#### **1.2 Improve patient adherence to treatment**

Activity 1.2.1. In collaboration with partners, the Regional Office will document the best practices for models of care and patient support (inpatient, outpatient, home/community-based models of care) in different settings and provide a compendium of models and minimum packages of interventions enabling and facilitating patients to adhere to treatment by the end of 2012.

Activity 1.2.2. In collaboration with partners, the Regional Office will provide technical assistance to Member States on aspects of health systems and patient-centred approaches on a continuous basis, notably health system stewardship/governance, financing, service delivery and resource creation and management, with particular emphasis on enabling PHC and ambulatory care services to assume the responsibility for action regarding TB and M/XDR-TB as stated in this Action Plan, including “boundary management” between the prison and civil health systems to ensure continuity of care.

Activity 1.2.3. From 2012 onwards, the Regional Office and other partners will analyse and assess every other year the options for models of care and case-holding in collaboration with national TB programme managers and health authorities.

Activity 1.2.4. All Member States will strengthen and/or establish measures to improve the prevention of treatment default and retrieval by the end of 2012. These efforts and their impacts are to be reported during the national TB programme managers meeting in 2013.

Activity 1.2.5. By the first quarter of 2014, all Member States will specify strategies and mechanisms for expanding ambulatory treatment and social support and their linkages with the national health plans, and measures to engage national and local governments in the provision of continuous quality ambulatory treatment. They will also support interventions such as incentives and social and psychosocial support for TB and M/XDR-TB patients.

### **1.3 Increase the efficiency and availability of health financing for TB control**

Activity 1.3.1. By the end of 2013, the Regional Office and partners, in collaboration with the Member States, will conduct an in-depth health financing analysis of current resources available for TB prevention and control interventions, including the organization of funding flows, in order to identify: sources of fragmentation, potentially perverse or misaligned provider payment incentives associated with different types of TB intervention, formal or informal out-of-pocket payments that hinder access to care, and other financial and non-financial barriers to access as well as the role of private and public providers and the financial incentives in place for each. They will recommend measures to improve the alignment of financing arrangements with the service delivery strategies that are defined for more effective TB prevention and control.

Activity 1.3.2. The Regional Office, in collaboration with other international donors, will conduct country-specific operational cost-effectiveness or option assessments of the advantages of different policy options and models of care focused on strengthening case-holding in the 18 high-priority TB countries by the end of 2013.

Activity 1.3.3. Member States and partners will explore the possibility of establishing financing mechanisms for MDR-TB treatment at supranational level through the development and creation of a European Fund for Treatment of MDR-TB by the end of 2013. Such a Fund could provide financial support to countries according to the number of MDR-TB cases treated.

### **1.4 Apply the full capacity of PHC services in TB prevention, control and care**

PHC services that will assume TB responsibilities must be fully operational to deliver prevention, control and care services and integrated into the TB referral system as well as diagnostics and treatment chains. Member States need urgent investment in human resources, infrastructure and technology to scale up PHC capacity and access to quality prevention, control and care.

Activity 1.4.1. The Regional Office and partners will provide technical assistance to Member States on measures to strengthen PHC involvement in TB prevention and control.

Activity 1.4.2. The Regional Office will support the development of formal collaboration agreements between regional TB and public health centres of excellence on the one hand and national TB programmes and health authorities responsible for TB policy in the Region. The collaboration agreements and twinning mechanism will form the basis for a strong partnership between these centres and national TB programmes and relevant health authorities for the development of medium- and long-term national TB strategic plans for strengthening case detection, follow-up and treatment of TB and X/MDR-TB in each of the 18 high-priority TB countries by 2012.

Activity 1.4.3. The Regional Office, in collaboration with TB and public health centres of excellence as well as cooperating national TB programmes, will prepare a guide for expanded and accelerated quality case-finding and diagnosis and treatment of TB in PHC and ambulatory facilities by 2012.

Activity 1.4.4. The Regional Office, in collaboration with TB and public health centres of excellence as well as cooperating national TB programmes, will develop a three-year plan to

strengthen the development of PHC towards more effective TB prevention, control and care for each of the 18 high-priority TB countries by 2013.

Activity 1.4.5. The Regional Office and partners will provide technical assistance to high-priority TB countries on implementation of the practical approach to lung health.

Activity 1.4.6. The Regional Office will support TB and public health centres of excellence as well as cooperating national TB programmes in the provision of technical assistance to health authorities to help accelerate the uptake of quality-assured WHO-backed best practices in TB case detection, follow-up and complete treatment through new and existing funding mechanisms, including the EXPAND-TB project and Global Funds by 2012.

Activity 1.4.7. The Regional Office will support the TB and public health centres of excellence as well as cooperating national TB programmes in (i) building human resource capacity through regular country visits to monitor the performance of national and subnational health authorities and PHC providers involved in TB prevention, control and treatment, and (ii) the provision of technical assistance both in-country and through internships of one to two months in their reference centres of excellence and twinning national TB programmes.

Activity 1.4.8. Member States will specify the strategies and mechanisms for integrating TB ambulatory treatment and patient support in PHC services by the end of 2012.

## **1.5 Consider management of M/XDR-TB contacts**

At present no preventive or prophylactic treatment is available to be given to individuals who have been recently infected with or exposed to M/XDR-TB strains.

Activity 1.5.1. The Regional Office and partners will facilitate the review of the cost-effectiveness of current practices in the management of contacts of M/XDR-TB patients by the end of 2012.

Activity 1.5.2. The Regional Office, in collaboration with other partners, will put forward a set of recommendations for management of M/XDR-TB contacts and their prophylactic/preventive treatment by mid-2013.

Activity 1.5.3. Member States will introduce the Regional Office's recommendations on contact-tracing and management of M/XDR-TB contacts by the beginning of 2014.

### **Examples of best practice**

#### *Norway*

To prevent morbidity, mortality and development of M/XDR-TB in migrants, Norway has introduced regulations to secure the right for all illegal migrants to stay in the country while possible TB disease is being investigated or until its treatment is completed. Treatment is free and includes the cost of transport. For patients not covered by national or private insurance, the hospital and/or municipality where they are treated or residing is obliged to cover the cost of treatment.

#### *Russian Federation*

The patient-centred approach used in Tomsk *oblast's* TB programme was introduced with technical support from Partners in Health and financing from the Global Fund in 2004. Various strategies to address non-adherence by TB and MDR-TB patients have resulted in an overall decrease in the default rate from almost 28% to 8.9%. These strategies include enhanced social and psychological support throughout chemotherapy, and the development and introduction of various models of community-based treatment. The experience in Tomsk has been replicated in neighbouring areas of the Russian Federation and Kazakhstan.

## **2. Scale up access to testing for resistance to first- and second-line anti-TB drugs and to HIV testing among TB patients**

Despite improvements in coverage of mycobacteriological culture and drug susceptibility testing, only 34% of estimated MDR-TB cases were notified in 2009. Member States need urgent investment in technology, infrastructure and human resources to scale up capacity and access so as to diagnose drug-resistant TB and monitor responses to treatment.

Under the guidance of WHO, the Global Laboratory Initiative has developed: (i) a guide for strengthening TB laboratories aimed at ensuring quality TB diagnostics in appropriate laboratory services in the context of national laboratory strategic plans; and (ii) a laboratory tool set to standardize laboratory methods, including standard operating procedures, equipment specifications, guidelines for procurement of laboratory equipment and supplies, training packages for microscopy and culture, and a costing/budgeting tool to facilitate supply chain management and stock control at country level (10,11).

WHO has also developed a policy framework for implementing TB diagnostics to facilitate implementation at country level.

### **2.1 Strengthen the TB laboratory network**

Activity 2.1.1. The Regional Office will support the development of formal collaboration agreements between the TB Supranational Reference Laboratories Network and national TB reference laboratories in the Region. The collaboration agreements will form the basis for a strong partnership between the Supranational Reference Laboratories Network and national TB reference laboratories for the development of medium- and long-term national TB laboratory strategic plans for strengthening laboratory capacity for the diagnosis of MDR-TB and monitoring response to therapy in each of the 18 high-priority TB countries by 2012.

Activity 2.1.2. The Regional Office, in collaboration with supranational reference laboratories, will prepare a guide for expanded and accelerated quality-assured new diagnostic technologies, including an automated rapid nucleic acid amplification test for MTB/rifampicin and a TB laboratory network for diagnosis and treatment monitoring of TB by 2012. Other rapid diagnostic tests not endorsed by WHO should only be implemented after their evaluation by the Global Laboratory Initiative or by laboratory experts in other settings.

Activity 2.1.3. The Regional Office and supranational TB reference laboratories, in collaboration with national TB reference laboratories, will develop a three-year TB laboratory development plan for each of the 18 high-priority TB countries by 2013.

Activity 2.1.4. The Regional Office will support the Supranational Reference Laboratories Network in the provision of technical assistance to national TB reference laboratories to help accelerate the uptake of quality-assured WHO diagnostic technologies through new and existing funding mechanisms, including the EXPAND-TB project and Global Funds, by 2012.

Activity 2.1.5. The Regional Office will support the Supranational TB Reference Laboratories Network in building human resource capacity through regular country visits to monitor the performance of laboratory networks and in the provision of technical assistance both in-country and through internships of one to two months in their supranational reference laboratories.

Activity 2.1.6. Member States and donors will prioritize funding for the introduction of new techniques for diagnosis of M/XDR-TB, including an automated rapid nucleic acid amplification test for MTB/rifampicin.



Activity 2.1.7. Member States will ensure that quality assurance schemes are in place for all levels of diagnostic testing in TB laboratory facilities which meet at least the minimum WHO biosafety requirements by 2013.

Activity 2.1.8. All high-priority TB countries will ensure the availability of rapid tests endorsed by WHO, such as an automated rapid nucleic acid amplification test for MTB/rifampicin (Xpert MTB/rifampicin), using national resources as well as funds from the Global Fund, UNITAID and other development and technical agencies, including the United States Agency for International Development (USAID).

## **2.2 Diagnostic counselling and testing for HIV of all TB patients and for TB of all HIV patients**

Activity 2.2.1. The Regional Office and other partners will provide technical assistance to high-priority TB countries for collaborative TB/HIV activities based on routine monitoring and assessment.

Activity 2.2.2. Member States will ensure that personnel responsible for TB and M/XDR-TB care are trained in HIV counselling and testing by the end of 2012.

Activity 2.2.3. Member States will ensure that HIV counselling and testing are offered to all TB patients on an opt-out basis by the end of 2012.

## **3. Scale up access to effective treatment for all forms of drug-resistant TB**

Currently only two thirds of the M/XDR-TB patients notified are reported to have access to appropriate treatment in the Region. The lack of appropriate treatment for MDR-TB patients leads to the spread of MDR-TB and eventual the amplification of drug resistance with the emergence of XDR-TB.

### **3.1 Ensure the uninterrupted supply and rational use of quality medicines**

Activity 3.1.1. The Regional Office will support Member States and other partners with data collection to assist in the development of reliable estimates of second-line drugs needs and trends in their increase by the end of 2013.

Activity 3.1.2. The Regional Office will introduce to countries a generic indicator-based tool for conducting a continuing drug utilization review as part of routine programme performance monitoring by the end of 2012.

Activity 3.1.3. The Regional Office and partners will promote the WHO pre-qualification programme mechanism to ensure prequalification of at least all injectables, and request Member States to ensure the speedy registration of products already pre-qualified by WHO in countries by the end of 2012.

Activity 3.1.4. The Regional Office will assist countries with the development of new legislation and procedures for the procurement of medical supplies with an emphasis on quality assurance (with specifications for TB medicines) by 2014.

Activity 3.1.5. The Regional Office and partners will conduct gap analysis of pharmaceutical legislation and regulations and facilitate their improvement by 2012.

Activity 3.1.6. The Regional Office and partners will engage countries in the WHO Good Governance for Medicines (GGM) programme (five countries by 2014) and pharmacovigilance.

Activity 3.1.7. The Regional Office and partners will facilitate and promote the development of paediatric formulations of second-line anti-TB drugs by the end of 2012.

Activity 3.1.8. Member States will adopt and expand countrywide the use of first-line fixed-dose combination drugs in treatment of drug-susceptible TB by the end of 2012.

Activity 3.1.9. Member States will ensure capacity-building in planning, procurement and supply management of anti-TB medicines at all levels of the health care system according to WHO recommendations by 2012.

Activity 3.1.10. Member States will develop European certification of all drugs to treat TB with first- and second-line drugs valid for all countries in the Region.

### **3.2 Manage adverse events**

Activity 3.2.1. The Regional Office will develop a regional generic guide for managing and recording adverse reactions and side effects by mid-2012.

Activity 3.2.2. The Regional Office together with the partners will develop regional sources of unbiased drug information for prescribers and patients by the end of 2013.

Activity 3.2.3. Member States will ensure that measures to screen and/or diagnose and prevent or treat side-effects are available for all TB patients by the end of 2011.

### **3.3 Develop new medicines**

Activity 3.3.1. The Regional Office, in collaboration with the StopTB Partnership, the Global Alliance for TB Drug Development and partners, will develop a long-term regional strategy for the development of a market in TB medicines by 2013.

Activity 3.3.2. The Regional Office and Member States will facilitate research and development of new TB medicines, including paediatric formulations, hold sound clinical trials on a continuous basis and report its progress at Regional Committee meetings from 2013 onwards.

### **3.4 Scale up access to treatment**

Activity 3.4.1. The Regional Office and partners, including WHO collaborating centres, will in close consultation with Member States, develop a joint technical assistance plan for Member States in reaching universal access to treatment (including treatment of children) by 2012.

Activity 3.4.2. The Regional Office in collaboration with the Member States and other partners will develop a set of evidence-based criteria for surgery for M/XDR-TB patients.

Activity 3.4.3. Member States will ensure that resources for universal access to treatment are available by 2012 and report on progress at Regional Committee meetings from 2012 onwards.

Activity 3.4.4. Member States will ensure that health systems have the institutional capacity to develop implement, analyse and adapt TB policy; and manage and allocate resources towards effective universal access to treatment.

Activity 3.4.5. Member States will ensure that by 2012 their TB and M/XDR-TB treatment guidelines are updated according to the latest available evidence and WHO recommendations.

Activity 3.4.6. Member States will procure and make available quality-assured medicines for TB and M/XDR-TB treatment under direct observation of treatment (DOT) by mid-2012.

Activity 3.4.7. Member States will ensure adequate training, coaching and support of health care staff for scaling up the treatment of M/XDR-TB patients by the end of 2011.

Activity 3.4.8. Member States will ensure adequate training, coaching and support of health authorities at national and subnational level for scaling up treatment of M/XDR-TB patients by 2012.

Activity 3.4.9. Member States will ensure that surgery is available for eligible M/XDR-TB patients.

### **Examples of best practice**

#### *EXPAND-TB project*

The EXPAND-TB project (EXPanding Access to New Diagnostics for TB), which was established in 2008, aims to accelerate the uptake of new TB diagnostic technologies (commercial liquid culture systems, rapid speciation and molecular-line probe assays, recently endorsed by WHO(12)) into adequate laboratory services in 27 recipient countries. Project partners include WHO, the Global Laboratory Initiative, the Foundation for Innovative New Diagnostics(13) and the Stop TB Partnership's Global Drug Facility(14), with funding provided by UNITAID and other donors. During the first 18 months of the EXPAND-TB project, a wide range of activities was initiated in 23 of the 27 recipient countries, including laboratory needs assessments and gaps analyses, upgrades and renovation of laboratory infrastructure, training of staff, diagnostic policy reform and country validation of new technologies. In the European Region, this technology transfer has commenced in eight high-priority MDR-TB countries (Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Republic of Moldova, Tajikistan and Uzbekistan). The project will support countries with the routine diagnosis of MDR-TB patients and pave the way for eventual routine surveillance of drug resistance.

#### *Georgia*

Georgia launched its MDR-TB control project in 2007 with support from the Global Fund. WHO provided technical support in the framework of the Green Light Committee mechanism. With strong commitment on the part of the authorities, full engagement of highly motivated staff in the country and continuous support from WHO, Georgia moved towards integrated programmatic management of drug-resistant TB. Within two years, the successful project was expanded nationwide and the country attained universal access for MDR-TB treatment.

The Regional Office, together with other partners, trained health care staff in MDR-TB management and provided advice and technical support between the country visits. TB and MDR-TB clinical guidelines and operation manuals were updated. A regional training centre was established.

A supportive environment was created by the leadership of the national TB control programme, who played a key role in empowering health care staff and involving them in each step of the decision making. Well-planned and implemented advocacy activities, as well as the involvement of the First Lady in TB control, made it possible to attract a high level of attention to M/XDR-TB so that it became a priority for the Ministry of Health as well as for the government as a whole. The government fully funded the construction work of a new TB hospital with state of the art infection control measures. An outreach programme was established to address the needs of special population.

With technical support from the Supranational Reference Laboratory, WHO and Emory University, Georgia was among the first high-burden MDR-TB countries in the Region to put molecular diagnosis of MDR-TB into full operation. Since 2007, 1740 DR-TB patients have

been enrolled into treatment with quality second-line drugs. In February 2011, 950 DR-TB patients were simultaneously under treatment.

#### **4. Scale up TB infection control**

The importance of TB infection control cannot be overemphasized. Several high-priority countries in the Region have not yet finalized their national TB infection control plans. Infection control in many inpatient and outpatient facilities dedicated to TB care in these countries is poor. Evidence of nosocomial transmission has been documented and the risk of developing TB among health care staff is often multiple times higher than in the general population. The risk of TB transmission in communal settings (such as penitentiary services) is even higher due to overcrowding and poor ventilation. In many Member States, health care workers are often not fully aware of airborne infection control measures.

##### **4.1 Improve administrative and managerial aspects of TB infection control**

Activity 4.1.1. The Regional Office and other partners will provide technical assistance to Member States to finalize national TB infection control action plans integrated in their national TB strategic plans or national infection control or health strategies by the end of 2012.

Activity 4.1.2. The Regional Office and other partners will develop a joint technical assistance plan for Member States to improve TB infection control by the end of 2012, including country visits, TB infection control risk assessments and staff training.

Activity 4.1.3. Member States will introduce or strengthen surveillance of TB infection and disease among health care workers by mid-2013.

Activity 4.1.4. Member States will ensure all health care facilities serving TB or suspect TB patients have a sound infection control standard operating procedure by the end of 2013.

Activity 4.1.5. Member States will develop and disseminate educational messages and materials for patients and health care workers by the end of 2012.

Activity 4.1.6. Member States will ensure contact-tracing of TB patients for early diagnosis of infection and disease by the first quarter of 2012.

Activity 4.1.7. Member States will include in-service and pre-service training of health care staff in TB infection control by the end of 2012.

##### **4.2 Strengthen environmental measures for TB infection control**

Activity 4.2.1. The Regional Office and partners will organize training of trainers in environmental measures, including engineering and facility design for airborne infection control, by the end of 2012.

Activity 4.2.2. Member States will conduct cascade training of responsible staff for environmental aspects of airborne infection control by the end of 2013.

Activity 4.2.3. Governments in high-priority TB Member States will ensure that environmental preventive measures are available in high-risk TB facilities and communal settings by the end of 2013.

##### **4.3 Ensure accessibility to personal protection measures**

Activity 4.3.1. The Regional Office will share with Member States procurement specifications for TB infection control equipment by mid-2012.

Activity 4.3.2. Member States will ensure that individual respiratory protection programmes are in place and available for TB and M/XDR-TB services by mid-2012.

### **Examples of best practice**

#### *Russian Federation*

Vladimir *oblast* in the Russian Federation can be considered a model for improving TB infection control in a high TB/MDR-TB setting. With the assistance of the US Centers for Disease Control and Prevention, a core group of staff were trained in 2002. Dispensary staff then developed an infection control programme which included administrative and engineering measures and respiratory protection. Three key administrative control measures included: the separation of patients according to smear status and drug susceptibility testing; and limiting unnecessary access of staff and visitors to high-risk zones and transfer of patients from other facilities to the TB hospital immediately upon receipt of smear-positive test results. The key engineering control measures included: updating and improving negative pressure ventilation systems to meet current Russian and international standards; installing biosafety equipment; shielding UVGI fixtures that allow for non-stop usage; and use of specially designed sputum collection booths. The respiratory protection programme included staff training and fit testing, and use of certified respirators for staff working in areas with significant risk of occupational exposure to airborne TB.

As a result of these infection control interventions, a remarkable reduction in occupationally-acquired TB was achieved in the *oblast* TB dispensary (from 1083 to 166 new cases per 100 000 during the first five years of the programme and no new cases in 2008–2010). Funds from the *oblast* budget were allocated in 2005–2006 for reconstruction of the ventilation system and purchase of respirators. Infection control measures were an important part of the regional target TB control programmes (2004–2006, 2007–2009 and 2010–2012). Although it may not be possible eliminate the risk for transmission of *M. tuberculosis* infection in all health care facilities completely, implementation of and adherence to the internationally recommended measures have dramatically reduced the risk of nosocomial transmission of TB. In October 2008, the Vladimir Centre of Excellence for Tuberculosis Infection Control was established. The Centre is a partnership including the Vladimir *oblast* administration, USAID, the US Centers for Disease Control and Prevention Division of Tuberculosis Elimination, the Central Tuberculosis Research Institute in Moscow and the WHO Country Office in Moscow, and is located at the Vladimir *oblast* tuberculosis dispensary. The Centre is involved in monitoring and implementing infection control measures and serves as a training hub for the Russian Federation and other Russian-speaking countries (15).

## **5. Strengthen surveillance, including recording and reporting of drug-resistant TB and treatment outcome monitoring**

Since 1 January 2008, the Regional Office and the ECDC have jointly coordinated the collection of TB surveillance data in Europe. Their aim is to ensure a high quality of standardized TB data covering all 53 countries in the Region. While much information has been collected in many countries, the data available for certain countries are still patchy and/or outdated.

### **5.1 Strengthen surveillance**

Activity 5.1.1. The Regional Office will prepare a monitoring framework for following up the Berlin declaration by mid-2012.

Activity 5.1.2. The Regional Office and partners will conduct training and coaching of national programme managers of high-priority countries in monitoring and evaluation and using data for improving programmes' performance by the end of 2012.

Activity 5.1.3. The Regional Office will assist high-priority countries to establish drug-resistant surveillance, including second-line drugs, by 2013.

Activity 5.1.4. The Regional Office will organize training and support for surveillance staff and programme managers in minimum MDR-TB indicators, including indicators for minimum health equity surveillance (16).

Activity 5.1.5. The Regional Office, together with partners and Member States, will develop a European profile of the social determinants (including gender) of M/XDR-TB and their distribution across European Member States to provide more specific evidence about the population groups most likely to have differential exposure and vulnerability to M/XDR-TB and examples of action that can be taken to address health equity.

Activity 5.1.6. Member States will ensure the categorization of TB cases based on drug susceptibility testing to facilitate appropriate treatment and cohort reporting by the end of 2012.

Activity 5.1.7. Member States will include measures to disaggregate and analyse M/XDR-TB data by sex, age, location (urban/rural) and other social determinants, such as level of education, socioeconomic quintiles and employment status, by the end of 2012.

## **5.2 Improve recording and reporting**

Activity 5.2.1. The Regional Office and partners will finalize and promote electronic tools for recording and reporting, including the use of modern data transmission techniques such as the web, hand-held devices and satellite) by the end of 2013.

Activity 5.2.2. The Regional Office, in collaboration with partners, will assist Member States in the development of electronic systems to enhance recording and reporting systems with database structure compatible with the Regional Office/ ECDC's electronic database (such as the use of open source solutions) by the end of 2013.

Activity 5.2.3 The Regional Office and ECDC will conduct annual meetings of TB surveillance focal points for coordination of surveillance.

### **Examples of best practice**

In recent years a sustainable effort has been undertaken to move data management from paper-based to electronic systems. Of the 18 high-priority TB countries in the Region, 13 now manage electronic data at national level using stand-alone (7), web-based (2) and mixed databases. Armenia, Ukraine and Uzbekistan are implementing a comprehensive web-based TB data management tool for surveillance, reporting and recording TB and drug-resistant TB cases and monitoring their treatment outcome, managing laboratory results, and supplying and using TB medicines. In the Republic of Moldova, electronic data collected via a web interface over five years allowed for a detailed analysis of TB patient data and identification of the determinants of transmission and acquisition of drug-resistant TB.

## **6. Expand country capacity to scale up the management of drug-resistant TB, including advocacy, partnership and policy guidance**

In order to use human and financial resources efficiently, it is essential to ensure the optimal management of TB control programmes/interventions. There are huge opportunities for improving partnerships and coordination and engaging national and international organizations, including civil society, in TB control. The care and management of patients who are not responding to any treatment has not been addressed in many settings. All high-burden MDR-TB

countries have finalized their summary MDR-TB response plans, although these plans need to be updated, endorsed and implemented by the Member States.

## **6.1 Manage programme efficiently**

Activity 6.1.1. The Regional Office will assist high-priority TB countries to update and finalize their national MDR-TB response plans by the end of 2012. The plans will include organigrams endorsed health systems and national TB programmes, with explicit roles and responsibilities (executive decrees and administrative orders), lines of authority and operational plans up to provider level. The plans will also ensure that the focus of the programmes is on all TB-relevant interventions, not merely those funded or implemented by the programmes (that is to say, including PHC, prison services, TB hospitals and general hospitals, nongovernmental organizations and private services.).

Activity 6.1.2. The Regional Office, in coordination with Member States, will formalize the twinning of cities and TB and lung diseases programmes across the Region and facilitate collaboration and coordination among Member States by the end of 2013.

Activity 6.1.3. The Regional Office will develop and share a programmatic assessment check list for health authorities in Member States and advise Member States on measures to improve the programmatic aspects of TB prevention, control and care by the end of 2012.

Activity 6.1.4. The Regional Office and WHO country offices, in cooperation with partners, will provide operational guidelines for implementing high-level political statements and measuring progress on a regular basis.

Activity 6.1.5. The Regional Office together with partners will improve programme management capacity (within and across both civilian and prison services) with modern training and coaching, particularly in the efficient use of resources, analysis and interpretation of data and application of new diagnostic and programme tools on a regular basis, and ensuring of continuity of care for patients transferred between the prison and civil systems on a regular basis.

Activity 6.1.6. The Regional Office will analyse successful models of programme management and draw up recommendations to be included as criteria in WHO's forthcoming programme certification exercise, including ISO 9001-certified project management standards, by the end of 2012.

Activity 6.1.7. The Regional Office and key partners will offer mentorship for poorly performing national TB control programmes from the end of 2012.

Activity 6.1.8. The Regional Office will build on the findings of the European Review Task Group looking at the social determinants of TB and M/XDR-TB by establishing a network among Member States to exchange promising practices in tackling the social determinants (particularly upstream determinants) of TB and M/XDR-TB, and to ensure an appropriate level of care for untreatable patients.

Activity 6.1.9. The Regional Office will create a platform to monitor the implementation of this document together with Member States and partners. A consolidated progress report will be presented annually at the national TB programme managers meeting, starting from 2012.

Activity 6.1.10. All countries will have a specific dedicated M/XDR TB patient management unit or staff (as appropriate) by the end of 2012.

Activity 6.1.11. All high-priority TB countries will develop, endorse and start implementation of their national MDR-TB response plans by the end of 2012.

Activity 6.1.12 Member States will ensure that external reviews will be undertaken of their national TB programmes/interventions every three to five years, led by the Regional Office and/or ECDC and including partners and civil society organizations for the transparent and objective assessment of gaps in their programmes, including the update of organigrams, executive decrees and administrative authorities, and operational plans.

Activity 6.1.13. Member States will ensure that representatives of patients and/or communities affected by the disease are included in programme planning and assessments of quality of services by the end of 2012.

Activity 6.1.14. Member States will use the internet and other media to increase public awareness of TB and M/XDR-TB, reduce the stigma associated with the disease and emphasize the availability of treatment from 2011.

Activity 6.1.15. Health authorities will engage the TB provider network and/or programme in health system reform initiatives on a continuous basis.

Activity 6.1.16. Member States will establish palliative care mechanisms for M/XDR-TB patients who fail treatment by the end of 2012.

## **6.2 Develop human resources**

Most Member States lack strategic plans for developing human resources for TB and M/XDR-TB control. In order to prevent and control M/XDR-TB effectively, there is a need for motivated and trained staff protected against TB infection and supported by a modern management mechanism. In some Member States, health care staff are unevenly distributed at different levels of service delivery. Most in-service training courses have not been based on practical needs or accompanied by on-the-job coaching for the acquisition of knowledge and skills and their practical application.

Activity 6.2.1. The Regional Office and partners will establish and/or improve the capacity of existing centres of excellences. WHO will establish a mechanism for the accreditation of WHO collaborating centres by the end of 2012. WHO and partners will provide technical assistance to centres of excellence and enable them to provide technical assistance to provinces and countries they are to support from the end of 2012.

Activity 6.2.2. The Regional Office will finalize the adaptation and translation of training modules developed by staff from the WHO headquarters Management of Drug-Resistant Tuberculosis, Training for MDR-TB Referral Centre by the end of 2011.

Activity 6.2.3. The Regional Office will ensure that a virtual TB library and training materials in Russian are available and updated from 2012.

Activity 6.2.4. Member States will prepare and implement strategic plans for the development of human resources for the implementation of all components of the Stop TB strategy by the end of 2013. These plans will include human resources policy, finance, education, leadership, job descriptions and workload assessment, and determine staff needs, supervision and monitoring, performance-based assessment and remuneration (both monetary and non-monetary) of the staff.



### **6.3 Give policy guidance**

Expanding country capacity to scale up the management of drug-resistant TB will require leadership and action by national and subnational health authorities in different aspects of the core functions of health systems. These interventions will depend on the core functions. Member States, the Regional Office and partners will support institutional capacity-building and strengthening of health systems to undertake these core functions and, critically, to diagnose the specific nature of the problem in each country and develop related policy guidance for the response.

Activity 6.3.1. The Regional Office, in collaboration with partners, will assist Member States in providing guidance for referral systems between different levels of TB care by the end of 2013.

Activity 6.3.2. The Regional Office, in collaboration with partners, will provide technical assistance on health systems' capacity-building to optimize the health financing for TB control interventions by the end of 2013.

Activity 6.3.3. The Regional Office, in collaboration with partners, will advise on best practice regarding the scale-up and efficient management and distribution of health resources – notably human resources – by the end of 2013.

Activity 6.3.4. The Regional Office, in collaboration with partners, will provide technical assistance to improve institutional capacity for policy analysis, development, implementation and evaluation, as well as resource management (governance/stewardship) by the end of 2013.

Activity 6.3.5. The Regional Office, in collaboration with partners, will assist Member States in adopting/adapting international TB policies by the end of 2012.

Activity 6.3.6. Member States will ensure they have adopted/adapted the latest available evidence in their national TB control policies by the end of 2012.

Activity 6.3.7. Member States will ensure that the results of operational research and other studies are included in development of TB control policies on a continuous basis.

### **6.4 Ensure partnership and coordination**

Activity 6.4.1. The Regional Office will use the successful model of the Health in Prison Project (17) to assist Member States in improving TB control in penitentiary services by the end of 2012.

Activity 6.4.2. The Regional Office will establish a mechanism for coordination and collaboration among national and international partners by the end of 2012.

Activity 6.4.3. The Regional Office and partners will advocate the further involvement of European research institutes in the development of new diagnostic tools, medicines and vaccine, research on basic mechanisms of resistance, etc.

Activity 6.4.4. The Regional Office and partners will assist Member States in establishing and strengthening their national Stop TB Partnerships by the end of 2013.

Activity 6.4.5. Member States in high-priority countries will establish national Stop TB Partnerships and other relevant mechanisms to ensure the due coordination and concerted action by, and necessary funds from, all stakeholders including civil society, patients' associations and charities by the end of 2013.

Activity 6.4.6. Member States will ensure that there are sound collaborative mechanisms for improved diagnosis and treatment of TB and M/XDR-TB patients in prison services, refugee camps or other relevant settings and a continuum of care and services in the health services by the end of 2013.

### **6.5 Involve advocacy, communication and social mobilization (ACSM)/civil society**

While the potential value of advocacy, communication and social mobilization (ACSM) is generally well understood by national TB programmes, there is frequently a lack of capacity to implement such activities. The first set of recommendations for enhancing action to confront the challenge of MDR-TB relates, therefore, to increasing the capacity of national TB programmes and their partners to implement action in these areas.

Activity 6.5.1. High-priority TB countries will develop national ACSM strategies and workplans by the end of 2012 if these do not exist, ensuring that they include particular reference to the challenges of MDR-TB. To contribute to this outcome, the steps listed in the following activities will be taken.

Activity 6.5.2. The Regional Office will facilitate the adaptation and development of ACSM materials appropriate to the Region and available in at least English and Russian by the end of 2013.

Activity 6.5.3. Knowledge, attitude and practice surveys and needs assessments with a focus on MDR will be undertaken in each country or subnational region to determine objectives for changing behaviour, target groups, advocacy needs and the foci for ACSM interventions by the end of 2013. The survey results will feed into such strategies and indicate directions for priority action.

Activity 6.5.4. All civil society organizations with an interest in TB will be identified and brought together for common planning of ACSM and MDR-TB activities by the end of 2012. This will include HIV organizations and may also mean many other agencies with social welfare and human rights aims, including professional associations of doctors, nurses, pharmacists and so on. Faith-based organizations will also be included: church- and mosque-based initiatives can provide powerful support for activities. Civil society and faith-based organizations and networks will be linked into national programmes.

Activity 6.5.5. Training workshops for civil society organizations and national TB programme ACSM staff will be organized on multidrug-resistant aspects of TB and consequent ACSM needs at national and subnational region levels.

Activity 6.5.6. High-priority TB countries will review the needs of ACSM focal staff in the national TB programme in line with the ACSM workplan.

Activity 6.5.7. Member states or partners will support the development and engagement of patient advocates and treatment supporters on a regular basis.

#### ***Advocacy***

A broad set of coordinated interventions designed to place TB high on the political and development agenda will foster political will to increase and sustain financial and other resources.

Activity 6.5.8. Member States will develop national TB advocacy plans by the end of 2012, with the aim of initiating policy changes and sustaining political and financial commitments.

### ***Communication***

All forms of the media will be used to inform, persuade and generate action among the whole population or targeted subpopulations about TB, and to generate awareness of the challenge of M/XDR-TB and thus the importance of prevention, increased and speedy detection and completion of treatment.

Activity 6.5.9. Member States will train health care staff in patient-centred care and intrapersonal communication skills on a regular basis to enable them to develop appropriate consultation skills and supportive attitudes.

Activity 6.5.10. Member States will develop communication materials such as roadside and health clinic posters, to be widely used by 2013. These will be based on gaps identified in the needs assessments to support national TB objectives.

### ***Social mobilization***

Communities and affected individuals will be actively engaged in the fight against TB and MDR-TB, and in speeding up detection and supporting patients through the long treatment periods, thus reducing the current high default rates among MDR-TB patients.

Activity 6.5.11. Member States, with the technical support of partners, will develop action plans based on the messages, target communities and areas identified by the needs assessments and knowledge, attitude, practice studies and mutual consultation by the end of 2013.

Activity 6.5.12. Member States will map the presence of relevant civil society organizations that are, or might become, interested in TB at national, subnational and local levels, and reach out to build working relations with those that appear the most active and relevant.

Activity 6.5.13. Member States will assist local civil society organizations to work with their national TB programmes in devising and implementing effective plans and ensuring that in their own activities they act in alignment with national TB programme policies and priorities for:

- engaging in planning, decision-making, implementation and monitoring and evaluation processes;
- working on the social determinants that increase vulnerability to TB, such as poor quality housing, inadequate nutrition, drug and substance misuse, discrimination and unemployment;
- increasing community awareness of, and mobilization against, TB in general and MDR-TB in particular;
- referring individuals with suspect symptoms to TB clinics for diagnosis;
- providing social support to patients through the long period (commonly two years or more for MDR patients) of treatment;
- in the context of high default rates in MDR TB treatment, providing support to civil society organizations and health staff in the development of empowered patients who understand and accept the need to take treatment for two years or more;
- collaborating closely with social support, including probation, rehabilitation and housing services and health care providers;
- improving skills throughout civil society with knowledge and information about TB, especially among organizations working in communities at risk of TB.

Activity 6.5.14. Member States will support and encourage the creation of associations of current and past patients to increase public awareness.

Activity 6.5.15 Member States, in collaboration with partners, will assist with cross-border TB care, and encourage the creation of civil society organizations in migrant communities and support for those that already exist. They can do much to help increase awareness of TB and knowledge of local health services so that symptomatic individuals refer themselves appropriately.

## **6.6 Ensure ethics and human rights**

Several opportunities have been identified where attention to human rights in TB care will also aid the scale-up of effective MDR-TB treatment.

Activity 6.6.1. The Regional Office will provide guidance to Member States in revising the frameworks for ethics and human rights for TB and other infectious diseases by the end of 2012.

Activity 6.6.2. The Regional Office will provide guidance to Member States for palliative care, including home-based models, by the end of 2013.

Activity 6.6.3. WHO and partners will conduct operational research on service models (needs of patients, cost and resources) for provision of palliative care by the end of 2012.

Activity 6.6.4. The Regional Office, in collaboration with partners, will develop indicators for patient-centred care by the end of 2012.

Activity 6.6.5. WHO will issue guidance for Member States to develop their frameworks for compassionate use of medicines by the end of 2012.

Activity 6.6.6. WHO and other partners will organize a regional conference on patient-centred care and human rights in TB and HIV by the end of 2013.

Activity 6.6.7. The Regional Office, Member States and partners will include ethics and human rights in the academic curricula for TB/MDR-TB training for all health staff by the end of 2012.

Activity 6.6.8. Member States will include clear instructions in their national TB plans and guidelines on how to organize service delivery, taking into account ethical and human right concerns and international recommendations and commitments.

Activity 6.6.9. Member States will strengthen their capacity for palliative care for eligible M/XDR-TB patients by the end of 2013.

Activity 6.6.10. Member States will involve civil society organizations in carrying out client satisfaction assessments in TB services by the end of 2013.

Activity 6.6.11. Member States will ensure that mechanisms are in place to hear complaints or to impose sanctions when corruption or unethical practices occur by the end of 2013.

## **Examples of best practice**

### *The Netherlands*

In the Netherlands, like other low TB-incidence countries, MDR-TB is mainly a disease of foreign-born patients who acquired their infection abroad. The challenge is to identify (MDR-) TB cases early and to limit transmission. Furthermore, as in other countries, adequate treatment of all TB cases is important to prevent acquired MDR-TB.

In the Netherlands, about 1% of *M. tuberculosis* strains were multidrug-resistant between 1993 and 2009. In those 17 years, 187 MDR-TB cases were notified, of which 7 had an XDR-TB strain. One out of three MDR-TB cases was identified during screening, mainly through the screening programme of immigrants entering the country. In nine cases (5%), DNA fingerprinting and epidemiological cluster investigation revealed that the disease was caused by recent transmission in the country. In five cases, MDR-TB was acquired after previous treatment for (non-MDR) TB in the Netherlands.

Emphasis is made on early identification of TB and MDR-TB disease through intensified and active case-finding. At the same time, adequate treatment, guidance and supervision is essential, to prevent development of acquired drug resistance. Continuation of treatment is guaranteed by supervision of the municipal TB nurses. Patients receive psychosocial support and models of care are adopted based on the patients' need.

### *United Kingdom*

A good example of ACSM is "Find & Treat" in the United Kingdom (18).

TB cannot be effectively controlled in urban areas unless specific provision is made to find and treat the most vulnerable and socially excluded cases. The assumption that all patients will present promptly and complete treatment lasting a minimum of six months is no longer a basis for effective TB control (18). Rates of TB continue to rise across London with one in six cases occurring among hard-to-reach groups: homeless people, problem drug and alcohol users and prisoners. These groups are at high risk of infectious drug-resistant forms of TB, delayed presentation, onward transmission and death (18).

Find & Treat was established in October 2007 by the Department of Health to implement the recommendations of the Health Protection Agency's evaluation of the mobile X-ray unit (18) and to strengthen TB control in London among hard-to-reach groups.

A small multidisciplinary health and social care team, working alongside trained recent patients with personal experience of TB and homelessness, links the 30 TB treatment centres in London with most patients.

Homelessness is recognized as an independent risk factor for MDR-TB. One third of active cases with which Find & Treat works are at least mono-resistant, and 11% of these have MDR-TB. In the last three years, Find & Treat has been asked to trace over 225 active TB cases lost to mainline services, and has managed to find 75% of them and link them back into treatment.

Find & Treat also screens almost 10 000 homeless people and drug users for TB every year, using the mobile X-ray unit van. For the past six years, the unit has consistently detected a pulmonary TB rate of 250 per 100 000, with such cases being significantly less likely to be infectious at diagnosis than comparable controls who present passively to mainline TB services. The multidisciplinary model of care that has been developed, spanning traditional administrative and geographic boundaries and working with over 200 different government and civil society units, is now an essential component of TB control in London. These achievements were only possible through strong advocacy, communication and social mobilization efforts.

## **7. Address the needs of special populations**

The Regional Office and other partners advocate universal access to M/XDR-TB diagnosis and treatment, including for the most vulnerable groups such as people living with HIV, children and pregnant women, and socially disadvantaged groups including migrants, homeless, injecting

drug users or alcoholics. Countries should include action for removing barriers to access to health care for these groups.

## **7.1 Improve collaborative TB/HIV activities**

Activity 7.1.1. The Regional Office will document best practices and experiences with effective integration and service delivery models (such as one-stop shops for TB/HIV/harm reduction services).

Activity 7.1.2. The Regional Office and other partners will support training and education for HIV and TB health care professionals on a regular basis.

Activity 7.1.3. The Regional Office and other partners will support the revision of national TB/HIV policies by the end of 2012.

Activity 7.1.4. Member States will establish a functional TB/HIV coordinating mechanism to facilitate the delivery of integrated TB and HIV (and drug use/narcology) services within the same facilities, including in prisons, by the end of 2013.

Activity 7.1.5. Member States will develop directives to deliver antiretroviral therapy in TB dispensaries and TB treatment in AIDS dispensaries (or relevant/appropriate facilities) where these are lacking by the end of 2012.

Activity 7.1.6. All authorities under the ministries of health and justice in Member States will expand access to evidence-based harm reduction services, including TB and HIV prevention, diagnosis and treatment services for people living with or at risk of HIV in the Region, in particular people who use or inject drugs.

Activity 7.1.7. Member States will scale up the provision of TB prophylactic treatment in all AIDS dispensaries as a core HIV care intervention in line with internationally recommended evidence-based policies by mid-2013.

Activity 7.1.8. The Regional Office will develop guidelines on TB preventive treatment in the Region in situations of high MDR/XDR-TB prevalence.

Activity 7.1.9. Ministries of health will ensure the availability of isoniazid in AIDS dispensaries as part of HIV care intervention by the end of 2012. A precondition is WHO guidelines for regions with high isoniazid resistance and MDR-TB prevalence.

Activity 7.1.10. Nongovernmental organizations working on TB or HIV in the Region will embrace collaborative TB/HIV activities as their core business.

Activity 7.1.11. National TB and HIV programmes and dispensaries will actively engage with civil society partners to improve access to integrated TB/HIV and, where appropriate, harm reduction services for the most at-risk and vulnerable populations.

## **7.2 Strengthen MDR-TB control in prisons**

Activity 7.2.1. Member States will ensure that early diagnosis and effective treatment of M/XDR-TB are available in all penitentiary services across the Region by the first quarter of 2013.

Activity 7.2.2. Member States will establish mechanisms for the continuum of care for released prisoners receiving TB treatment by the end of 2012.

### **7.3 Improve access for hard-to-reach and vulnerable populations**

Activity 7.3.1. The Regional Office and Member States will develop a special response for diagnosis and treatment of TB in children and accelerate the adoption of updated childhood TB guidelines.

Activity 7.3.2. Member States will improve access to TB prevention, control and care for the hard-to-reach populations, especially homeless people and migrants and alcohol and drug abusers, by developing regular outreach programmes using patient activists, civil society organizations and community health care staff, as appropriate, to link with patients in their own social contexts.

Activity 7.3.3. The Regional Office and Member States will establish a mechanism for cross-border TB control and care which enables a continuum of treatment for migrant populations by the end of 2013.

Activity 7.3.4. National TB programmes will include and prioritize childhood TB in their national TB strategic or national health plans.

#### **Examples of best practice**

##### *Azerbaijan*

The main medical department of the Ministry of Justice has been carrying out regular screenings for inmates and people under investigation, starting from trial isolators in the framework of the TB control project in the penitentiary system. The compulsory diagnostic algorithm consists of a questionnaire and X-ray investigation. Sputum samples from suspicious TB cases are taken three times for microscopy and bacterial inoculation. Rapid diagnostic sensitivity tests are run routinely based on BACTEC, GeneXpert and Hain technologies. Suspected and/or confirmed cases of TB are immediately isolated in separate rooms on the spot and within several days (not later than a week) are transferred to a specialized treatment institution under the Ministry of Justice where all forms of TB, including drug-resistant TB, are treated. In this closed medical institution, treatment is available for all inmates and people under investigation without regard to sex, age, inside regime mode and conditions of punishment.

##### *Estonia*

Estonia has the second highest per capita alcohol consumption in the Region and there is a high prevalence of alcoholism among TB treatment defaulters and MDR-TB cases. In 2011, a demonstration project started with training of staff on AUDIT (alcohol use disorders identification test) and coordination between the national TB services and the psychiatric services offering counselling and treatment for alcoholism to patients undergoing treatment for TB.

Collaborative TB/HIV activities are being implemented, such as HIV testing of TB patients and TB screening among people living with HIV, co-treatment with anti-TB drugs, antiretroviral therapy and opioid substitution therapy if indicated, information for patients and training of doctors. These have resulted in earlier detection of both TB disease and HIV infection, a decreased default rate among HIV-infected TB patients and increased TB awareness among people living with HIV (19).

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## **Annex 1. Monitoring framework for follow-up of the Consolidated Action Plan to Prevent and Combat M/XDR-TB**

The development of a monitoring framework is an essential component of any effective plan. The key to the development of successful indicators is the inclusion of measures that are broad enough to reflect all aspects of the ambitious plan set out, sufficiently specific to address the critical markers of success and adequately concise in order not to overburden national programmes. Taking these guidelines into account, an international task force was constituted under the leadership of the Regional Office, with membership across the Region and including international bodies, nongovernmental organizations and civil society representatives.

This framework, based on a detailed review of the Action Plan, provides a tool for monitoring international and national implementation. It outlines detailed elements for the assessment of specific interventions at the operational level, covering inputs, processes, outputs, outcomes and impact. All indicators identified in this framework reflect the stated goals of the Action Plan, allowing implementers, the community, donors and other stakeholders to track progress towards benchmarks and the eventual achievement of all objectives.

The indicators, while regional in scope, are designed to serve as a guide to the development or adjustment of comprehensive monitoring plans at country level.

There are 11 core indicators that allow for the monitoring of performance in the main areas and interventions in the Action Plan. The list of core measures is accompanied by a full list of indicators, which closely follows the structure of the Plan. Each group of activities is reflected in the framework by one or more indicators, assessed by the task force to represent the most accurate measure of performance of the group of activities. In addition, a baseline level for the indicator, desired target, assessment frequency, monitoring mechanism and data source are defined for each indicator/group of indicators. In most cases, the baseline levels were defined based on information provided by each country through the annual TB data collection process carried out by the Regional Office and ECDC. This annual data collection process has Region-wide coverage, is undertaken only once (thus avoiding duplication of efforts by countries and partners) and ensures a user-friendly mechanism for data collection. In a limited number of indicators among the full list, the absence of baseline information might be explained by the unavailability of these data and/or questionable reliability of the information available.

In order to assess the performance of interventions, countries will be grouped based on two main criteria: (i) a high or low burden of M/XDR-TB, and (ii) whether they are one of the 18 high-priority countries to stop TB in the European Region. Analysis by country will be carried out to assess country-specific performance in preventing and combating M/XDR-TB.

The majority of the indicators, including the core set of 11, will be monitored annually. In addition to the Regional Office/ECDC annual data collection process, a periodic desk review will be carried out to monitor the activities that are not reflected in the joint TB data collection form. Desk reviews will be performed at the beginning of the implementation of the Action Plan and at the end of the period when full implementation is expected. Furthermore, in-depth assessment of the country or external technical assistance reports will provide additional material to support the measurement of indicators. In the absence of these main sources of information, short interviews will be carried out with the managers of the national programme (or equivalent) to assess the performance of the interventions implemented as part of the Action Plan. Short-term impacts will be assessed in 2016–2018 when data on the outcomes of the MDR-TB cohorts will be available. The long-term impacts will be assessed several years later.

Only data approved by Member States will be used in monitoring the Action Plan.

Following the endorsement of this framework as a formal part of the Action Plan, Member States are not expected to develop a country-level parallel system of monitoring interventions as part of the Plan. It is recommended that this framework should form the sole basis for monitoring, and that available established mechanisms for information collection should be used and, where appropriate, strengthened in order to avoid duplication of efforts and to increase efficiency and effectiveness. The indicators outlined here should be integrated in the monitoring and evaluation framework of national TB control programmes at country level. Moreover, impact indicators from the core group, such as prevalence of MDR-TB, should be reflected in the health system assessment framework in addition to those for the overall TB control area.

The full results of the assessment of performance of the interventions delivered as a result of the Action Plan will be presented via the joint Regional Office/ECDC TB report. The report will consist of detailed analysis and interpretation of data based on the indicators as well as recommendations. Tables, graphs, maps and country profiles will also be presented. Progress in implementation of the Action Plan will be reported to the Regional Committee for Europe, and the monitoring reports will be presented during the meeting of national TB programme managers/country focal points which is open to stakeholders and civil society organizations involved in TB control in the Region.





















## Annex 2. Areas of intervention under the Consolidated Action Plan to Prevent and Combat M/XDR-TB

The areas of intervention under the Action Plan described below encompass a series of activities for which technical assistance from the Regional Office and/or partners will be available or necessary. These activities are not separately listed.

Problem	Proposed solutions	Major activities
<i>Intervention 1. Prevent the development of M/XDR TB cases</i>		
In 2009, the proportion of MDR-TB among new TB cases in the Region was 11% and among retreatment cases 36%. XDR-TB notifications tripled and have been reported in many countries.	Social determinants related to M/XDR-TB should be identified and addressed, patient adherence to treatment improved and the full capacity of PHC services applied in TB prevention, control and care.	Social determinants related to M/XDR-TB should be studied, the best models of care using a patient-centred approach documented and strategies specified for integrating ambulatory treatment in PHC services.
Existing systems of TB financing in high-priority countries fund predominantly inpatient services, leaving only a small budget for additional activities such as training and outreach services.	Health financing for TB control should be made more efficient.	The cost-effectiveness of various interventions should be studied and the best funding mechanisms defined for efficient TB prevention and control.
There is no prophylactic treatment for individuals recently infected with or exposed to M/XDR-TB strains.	Prophylactic treatment should be considered to prevent M/XDR-TB among patients' contacts.	Possible regimens for prophylactic treatment should be studied and recommendations developed.
<i>Intervention 2. Scale up access to testing for resistance to first- and second-line anti-TB drugs and HIV testing among TB patients</i>		
Laboratory capacity for drug resistance testing is inadequate for first- and second-line drugs.	Both the Supranational TB Laboratory and national TB laboratory networks should be strengthened.	Human resource capacity should be built, quality assurance schemes developed and funding prioritized for novel rapid molecular diagnosis tests for all eligible MDR-TB patients. <sup>a</sup>
Voluntary counselling and testing for diagnosing HIV co-infection is poor and mortality substantially increases among HIV co-infected TB and M/XDR-TB patients.	Diagnostic counselling and HIV testing should be assured for all TB and M/XDR-TB patients.	Voluntary counselling and testing should be increased by training all responsible staff and offered to all TB patients on a provider-initiated and opt-out basis.
<i>Intervention 3. Scale up access to effective treatment for all forms of drug-resistant TB</i>		
The unavailability of appropriate treatment contributes to the spread of MDR-TB, amplification of drug resistance and emergence of XDR-TB. In 2009, only 12% of all estimated prevalent MDR-TB cases received adequate treatment with quality second-line drugs.	An uninterrupted supply and rational use of quality medicines should be ensured, adverse events managed, new drugs developed and access to quality treatment scaled up.	All aspects of drug management should be improved, including capacity-building and legislation, and the WHO Good Governance for Medicines Programme should be expanded.  A generic guide should be developed for managing and reporting side-effects and regional unbiased medicine information centres should be introduced.

Problem	Proposed solutions	Major activities
<i>Intervention 4. Scale up TB infection control</i>		
Transmission of TB as airborne infectious disease is possible in all inpatient and outpatient settings where TB patients are present, but in many patient facilities in high-priority countries infection control is poor. The risk of infection in communal settings (such as the prison services) is even higher, due to overcrowding and poor ventilation. TB among health staff is a serious occupational risk.	Administrative and managerial aspects of TB infection control should be improved. Environmental measures of TB infection control should be strengthened, and accessibility ensured to personal protection measures.	The use of new medicines should be studied and universal access ensured to quality treatment (including for children), using DOT for all TB and M/XDR-TB patients.  National TB infection control action plans and sound infection control standard operating procedures should be developed, including educational and respiratory protection programmes.  Infection control should be included in pre- and post-graduate training curricula and cascade training carried out in environmental measures.  The availability of adequate numbers of quality respirators should be ensured and surveillance of infection and disease introduced among health care staff.
<i>Intervention 5. Strengthen surveillance, including recording and reporting of drug-resistant TB and treatment outcome monitoring</i>		
Since 2008, the Regional Office and ECDC have jointly coordinated the collection of surveillance data. Available data for certain countries are still patchy and/or outdated.	Surveillance should be strengthened and recording and reporting improved.	Data collection on programme performance and drug resistance should be improved and electronic recording and reporting systems introduced for surveillance and cohort analysis.  Country representatives' capacity should be strengthened through training, inclusion in country programme reviews and participation in meetings of surveillance focal points.
<i>Intervention 6. Expand country capacity to scale up the management of drug-resistant TB, including advocacy, partnership and policy guidance</i>		
Human and financial resources are not always used efficiently since TB control is often an isolated activity under ministries of health, and partnerships and national and international organizations, including civil society in TB control, are not fully utilized.	The efficiency of programme management should be ensured, policy guidance stimulated and effective national partnerships established.	Planning mechanisms and quality of performance should be improved in line with ISO 9001 programme management standards.  TB control should be included in health system reform initiatives and other health systems funded to undertake TB programme implementation.  The status of partnerships should be legalized and the roles of the different partners formalized, using existing successful models.



Problem	Proposed solutions	Major activities
<p>The uneven distribution of health care staff at different levels of service delivery is common in high-priority countries. Most in-service training courses are not based on practical needs, while often the pre-service training curriculum for TB and M/XDR-TB is outdated.</p>	<p>Human resources development plans should be initiated.</p>	<p>Human resources plans should be developed that include a standard set of references for quality and quantity of staff.</p> <p>Funding should be ensured for new competency-based training programmes for all aspects of M/XDR-TB, and the capacity of centres of excellence should be established and/or strengthened.</p>
<p>Regular political changes at national and subnational level hinder sustained political and financial commitment. The importance of TB prevention, early diagnosis and above all the completion of treatment is not well communicated to decision-makers or the general population.</p>	<p>Continuous advocacy is needed with politicians and decision-makers at national and subnational levels, and there should be stronger involvement of civil society and patients' associations.</p>	<p>A national ACSM strategy should be developed, based on needs assessments and knowledge, attitude and practice surveys and including sustained advocacy with decision-makers.</p> <p>All forms of the media should be used to generate awareness and action among the general public to deal with the challenge of M/XDR-TB.</p>
<p>In many high-priority countries, TB services are designed around providers rather than patients. Diagnostic procedures are often long and duplicative, the efficacy of the drugs used is uncertain, hospital stays are unnecessarily long with no infection control measures and with disruption to patients' social and working lives.</p>	<p>More attention should be given to ethics and human rights in TB control.</p>	<p>The International Standards for Tuberculosis Care and the Patient's Charter for Tuberculosis Care should be introduced.</p> <p>The capacity for palliative care for eligible M/XDR-TB patients should be strengthened.</p> <p>An ombudsman mechanism should be established to develop criteria for patient-centred care, client satisfaction assessments and hearing complaints or imposing sanctions when corruption or unethical practices occur.</p>
<p><i>Intervention 7. Address the needs of special populations</i></p>		
<p>Vulnerable groups (such as children and pregnant women) and socially disadvantaged populations experience barriers to access to health care leading to continued transmission, late diagnosis and incomplete treatment.</p>	<p>Collaborative TB/HIV interventions should be improved, universal access advocated to TB, HIV and harm reduction services and access for hard-to-reach populations improved.</p> <p>Existing tools and programmes to respond to paediatric TB should be improved.</p>	<p>Functional integrated TB, HIV (and drug use/narcology) services should be established for people living with a risk for HIV (especially injecting drug users).</p> <p>Best practices should be documented on effective service delivery models, including isoniazid prophylactic treatment, and training in TB/HIV supported for all health care providers.</p> <p>Interventions should be developed to improve access to TB control, including outreach programmes, for hard-to-reach populations and a mechanism established for cross-border TB control and care for migrants.</p>

<b>Problem</b>	<b>Proposed solutions</b>	<b>Major activities</b>
Communal settings, especially prisons, are a source for continuous transmission and development of all forms of TB. Inappropriate funding of services, insufficient training of staff and lack of collaboration with the civil health authorities have caused a major problem with TB and M/XDR-TB that extends beyond the prison walls in many high-priority countries.	M/XDR-TB control in prisons should be strengthened.	Interventions should be developed to respond to TB childhood, and TB paediatric programmes integrated into HIV and primary health care and maternal and child health programmes.  Early diagnosis (including new rapid methods) and effective treatment for M/XDR-TB should be established in all penitentiary services and a continuum of quality care provided for released prisoners.

<sup>a</sup>A rapid test is defined as one which provides diagnosis within 48 hours of processing the specimen and can therefore influence the initial treatment regimen on which the patient is placed.

### Annex 3. Costing of the implementation of the Consolidated Action Plan to Prevent and Combat M/XDR-TB

In February 2011, the Regional Office commissioned a detailed costing tool for implementation of the MDR-TB Action Plan. The tool was developed by the Royal Tropical Institute in Amsterdam in close collaboration with the Regional Office. The cost of implementing the Plan from 2011 through 2015 is US\$ 4.7 billion. The annual budget required rises from US\$ 592 million in 2011 to US\$ 1.47 billion in 2015. Around 95% of the total finances will be required for the 18 high-priority countries<sup>1</sup> (Table 1).

Table 1. Financial resources required to implement the Action Plan in the WHO European Region (all countries), 2011–2015 (US\$)

	2011	2012	2013	2014	2015	Total	%
Screening for DR/ XDR	42,494,004	54,110,763	66,973,198	81,156,683	96,737,748	341,472,396	7
HIV screening of MDR/XDR patients	635,505	842,580	1,056,298	1,276,842	1,504,396	5,315,620	<1
Treatment of MDR-TB	520,740,661	618,145,345	818,359,906	1,039,915,305	1,342,151,890	4,339,313,107	87
Treatment of XDR-TB	9,737,276	18,179,842	35,850,712	64,305,869	99,642,592	227,716,293	5
Additional costs for HIV treatment	813,082	1,132,591	1,488,069	1,881,052	2,506,303	7,821,098	<1
Stewardship expenditure	14,543,740	14,543,740	14,543,740	14,543,740	14,543,740	72,718,700	2
<b>Total</b>	<b>588,964,269</b>	<b>706,954,861</b>	<b>938,271,923</b>	<b>1,203,079,492</b>	<b>1,557,086,669</b>	<b>4,994,357,214</b>	<b>100</b>

The budget requirements were estimated separately for the 18 high-priority and 35 non-high-priority<sup>2</sup> countries so as to incorporate the vastly different costs and patient numbers between the two categories. The needs assessment used a public health system perspective for budgeting and unit cost calculation. Direct costs incurred by the public health care system were included; indirect costs incurred by patients and society were excluded. A unit-cost based approach was adapted for budgeting, and includes the unit cost of screening for MDR-TB and XDR-TB and for treating an M/XDR-TB patient. The regional epidemiological model was used as a source for the number of patients screened for M/XDR-TB and the number treated for M/XDR-TB. The costs of sub-components of MDR-TB screening and treatment were calculated based on the health care resource requirements and epidemiological data. As per standard practice, a discount rate of 0.03 was chosen to estimate the budget and unit costs.

As shown in Table 1, 75% of the finances will be required for the inpatient treatment of M/XDR-TB patients, taking the average cost of hospitalization in high-priority countries at over US\$ 76 per patient per day, and in non-high-priority countries at over US\$ 194 per day.

<sup>1</sup>Armenia, Azerbaijan, Belarus, Bulgaria, Estonia, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Republic of Moldova, Romania, Russian Federation, Tajikistan, Turkey, Turkmenistan, Ukraine, Uzbekistan.

<sup>2</sup>Albania, Andorra, Austria, Belgium, Bosnia and Herzegovina, Croatia, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Israel, Italy, Luxembourg, Malta, Monaco, Montenegro, Netherlands, Norway, Poland, Portugal, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, the Former Yugoslav Republic of Macedonia, United Kingdom.

Diagnostics is the second largest category in the resource requirements, amounting to nearly US\$ 534 million. This includes GeneXpert as the least expensive diagnostic for the screening of first-line drug resistance, drug susceptibility testing (DST) using solid culture as the least expensive diagnostic for the screening of second-line DST.

Table 2. Composition of the financial resources required for the Action Plan in 2011–2015

	2011	2012	2013	2014	2015	Total	%
Drugs	5,723,532	6,888,784	9,281,568	12,040,437	15,758,322	49,692,643	1
Diagnostics	69,455,007	86,529,705	110,401,416	137,160,149	169,658,526	573,204,803	12
Ambulatory care	49,985,543	59,924,112	80,398,816	103,888,986	135,613,296	429,810,754	9
Inpatient care	433,798,624	520,331,783	698,478,190	902,906,560	1,178,933,560	3,734,448,718	75
Patient support costs	14,644,740	17,604,145	23,680,124	30,658,568	40,072,922	126,660,499	3
Additional costs for HIV treatment	813,082	1,132,591	1,488,069	1,881,052	2,506,303	7,821,098	<1
Stewardship expenditure	14,543,740	14,543,740	14,543,740	14,543,740	14,543,740	72,718,700	2
<b>Total</b>	<b>588,964,269</b>	<b>706,954,861</b>	<b>938,271,923</b>	<b>1,203,079,492</b>	<b>1,557,086,669</b>	<b>4,994,357,214</b>	<b>100</b>

Drugs constitute only 1% of the overall resource requirements for M/XDR-TB control activities. However, they are usually reported as the largest budget line in national TB control programmes as the most of the in- and outpatient costs usually stay outside the targeted planning approach used by countries in the Region. The unit cost of MDR-TB treatment includes a regimen of 6 months of intensive treatment and 18 months of continuation treatment, on the basis of the dosage for a person of average size (60 kg). The calculation was made by estimating the average cost of the three recommended MDR-TB treatment regimens:<sup>3</sup>

- Z-Km-Lfx-Eto-Cs-PAS for the resistance patterns HRS/HRES/ HREZS;
- S-Lfx-Eto-Cs-PAS for the resistance patterns HREZ;
- Z-S-Lfx-Eto-Cs-PAS for the resistance patterns HR/HRE.

The assumption for XDR-TB treatment is that patients had been treated with the maximum number of second-line drugs (Z-Cm-Lfx-Eto-Cs-PAS).

The stewardship costs, including supervision and capacity-building costs, were included in the projections of overall resource requirements and constitute 2% of the overall resource needs.

<sup>3</sup>Abbreviations used: isoniazid (H), rifampicin (R), ethambutol (E), streptomycin (S), pyrazinamide (Z), kanamycin (Km), capreomycin (Cm), levofloxacin (Lfx), ethionamide (Eto), cycloserine (Cs), para-aminosalicylic acid (PAS).

Monitoring framework for the follow-up of the Consolidated Action Plan to Prevent and Combat M/XDR-TB

Area of intervention	Indicator	Baseline	Target	Frequency	Data source	Layers of analysis	Monitoring mechanism	Input-impact level
<b>Core indicators</b>								
3.4.5	Percentage of MDR among retreated TB cases	37%	29%	Annually	WHO Global TB database	53 Member States 18 HPC <sup>a</sup> 15 HMDRC <sup>b</sup>	Routine reporting	Impact
4.1.1	Proportion of notification of TB among health care workers to TB among general population	1.46	Decrease close to 1			18 HPC 15 HMDRC		
3.4.2	MDR-TB detection rate among notified TB cases	34.5%	85%			53 Member States 18 HPC 15 HMDRC	Routine estimation	Outcome
2.1.8	Coverage of first-line drug susceptibility testing among notified previously treated TB patients (%)	41.1%	Close to 100%					
1.2.1	Default rate among new laboratory-confirmed TB patients (%)	6.6%	5%					
3.4.8	Treatment success rate in cohort of MDR-TB patients in countries reporting at least one MDR-TB case (%)	57.4%	75%					
3.4.9	Death rate in MDR-TB patients cohort (%)	10.3%	10%					
3.4.10	Failure rate in MDR-TB patients cohort (%)	11%	10%					
3.4.11	Percentage of MDR-TB patients lost to follow-up (default, transfer out, not evaluated)	21.3%	5%					
3.4.7	Percentage of M/XDR-TB enrolled in treatment (in line with WHO recommendations) to all M/XDR-TB patients detected	61.8%	Close to 100%					
5.2.1	Number of Member States with electronic case-based data management at national level, at least for MDR-TB patients	Not available	53 Member States				Output	

Area of intervention	Indicator	Baseline	Target	Frequency	Data source	Layers of analysis	Monitoring mechanism	Input-impact level
<b>1. Prevent the development of M/XDR-TB cases</b>								
1.1 <i>Identify and address social determinants related to M/XDR-TB</i>								
1.1.1	Number of Member States with a specific action on social determinants of M/XDR-TB in their national health strategies	Not available	53 Member States	Q3–2011 Q1–2016	National TB programmes	53 Member States 18 HPC 15 HMDRC	Desk review	Output
1.2 <i>Improve patient adherence to treatment</i>								
1.2.1	Default rate among new laboratory-confirmed TB patients (%)	6.6%	5%	Annually	WHO Global TB database	53 Member States 18 HPC 15 HMDRC	Routine reporting	Outcome
1.2.2	Number of Member States providing fixed-dose drug combinations to TB patients	11	18 HPC			18 HPC 15 HMDRC		Output
1.2.3	Number of Member States with no stock-out of first-line TB drugs at any level	15						
1.3 <i>Increase efficiency of health financing for TB control</i>								
1.3.1	Number of Member States reducing the gap in financing of core elements of TB control	Not available	18 HPC	Annually	WHO Global TB database	18 HPC 15 HMDRC	Routine reporting	Output
1.4 <i>Apply full capacity of PHC services in TB prevention, control and care</i>								
1.4.1	Case detection rate of new and relapsed cases of TB (%)	78%	Increase	Annually	WHO Global TB database	53 Member States 18 HPC 15 HMDRC	Routine estimation	Outcome
1.4.2	Treatment success rate among laboratory-confirmed new TB patients (%)	70%	85%				Routine reporting	Output
1.4.3	Treatment success rate among previously treated TB patients (%)	44%	Increase					

Area of intervention	Indicator	Baseline	Target	Frequency	Data source	Layers of analysis	Monitoring mechanism	Input-impact level
1.4.4	Number of Member States with ambulatory TB care integrated into PHC system	13	18 HPC	Annually	WHO Global TB database	18 HPC 15 HMDRC	Routine reporting	Output
<b>1.5 Consider management for M/XDR-TB contacts</b>								
1.5.1	Number of Member States with a national policy for management of M/XDR-TB contacts	Not available	18 HPC	2015	National TB programmes	18 HPC 15 HMDRC	Desk review	Output
<b>2. Scale up access to testing for resistance to first- and second-line anti-TB drugs and to HIV testing among TB patients</b>								
<b>2.1 Strengthen the TB laboratory network</b>								
2.1.1	Percentage of drug susceptibility testing laboratories with external quality assurance according to international standards	61%	Close to 100%	Annually	WHO Global TB database	53 Member States 18 HPC 15 HMDRC	Routine reporting	Process
2.1.2	Percentage of drug susceptibility testing laboratories achieving at least 95% of proficiency for rifampicin and isoniazid measured through external quality assurance	96%	100%					Output
2.1.3	Number of Member States using WHO-recommended diagnostics for rapid molecular tests for routine diagnosis of drug resistance	Not available	53 Member States					Output
2.1.4	Percentage of all notified TB cases where culture was performed		Close to 100%					Output
2.1.5	Percentage of all notified TB cases confirmed by culture	47.3%	Increase					Output
2.1.6	Coverage of first-line drug susceptibility testing among all notified TB patients (%)	39.8%	Close to 100%					Outcome
2.1.7	Coverage of first-line drug susceptibility testing among notified new TB patients (%)	30.0%	Close to 100%					Outcome

Area of intervention	Indicator	Baseline	Target	Frequency	Data source	Layers of analysis	Monitoring mechanism	Input-impact level
2.1.8	Coverage of first-line drug susceptibility testing among notified previously treated TB patients (%)	41.1%	Close to 100%	Annually	WHO Global TB database	53 Member States 18 HPC 15 HMDRC	Routine reporting	Outcome
2.1.9	Coverage of second-line drug susceptibility testing among notified MDR patients (%)	36.9%	Close to 100%					
2.2	<i>Diagnostic counselling and testing for HIV of all TB patients and for TB of all HIV patients (Indicators are reflected in area of intervention 7: Address the needs of special populations)</i>							
3.	<b>Scale up access to effective treatment for all forms of drug-resistant TB</b>							
3.1	<i>Ensure the uninterrupted supply and rational use of quality medicines</i>							
3.1.1	Number of Member States with no stock-out of second-line TB drugs at any level	15	18 HPC	Annually	WHO Global TB database	18 HPC 15 HMDRC	Routine reporting	Output
3.1.2	Number of Member States with paediatric formulations of anti-TB drugs in use	23	53 Member States			53 Member States 18 HPC 15 HMDRC		
3.2	<i>Manage adverse events</i>							
3.2.1	Number of Member States with national guidelines for reporting and managing adverse drug events in line with WHO recommendations	Not available	18 HPC	Q3–2011 Q1–2016	National TB programmes	18 HPC 15 HMDRC	Desk review	Output
3.3	<i>Develop new medicines</i>							
3.3.1	Long-term regional strategy for development of TB medicines market (including paediatric formulations) developed by 2012	No	Yes	2013	Regional Office	WHO European Region	Not applicable	Output



Area of intervention	Indicator	Baseline	Target	Frequency	Data source	Layers of analysis	Monitoring mechanism	Input-impact level
<b>3.4 Scale up access to treatment</b>								
3.4.1	Estimated incidence, all MDR-TB per 100 000 population	9.1	Decrease	Annually	WHO Global TB database	53 Member States 18 HPC 15 HMDRC	Routine reporting	Impact
3.4.2	MDR-TB detection rate among notified TB cases	34.5%	85%					Outcome
3.4.3	Percentage of MDR among all notified TB cases	20.5%	16%					Impact
3.4.4	Percentage of MDR among new TB cases	11.7%						
3.4.5	Percentage of MDR among retreated TB cases	36.6%	29%					Output
3.4.6	Percentage of XDR among detected MDR-TB cases	5.0%	Decrease					
3.4.7	Percentage of detected M/XDR-TB covered by treatment according to national guidelines that are in line with WHO recommendations	61.8%	Close to 100%					Outcome
3.4.8	Treatment success rate in MDR-TB patients cohort (%)	57.4%	75%					
3.4.9	Death rate in MDR-TB patients cohort (%)	10.3%	10%					
3.4.10	Failure rate in MDR-TB patients cohort (%)	11.0%	10%					
3.4.11	Percentage of MDR-TB patients lost from follow-up (default, transfer out, not evaluated)	21.3%	5%					

Area of intervention	Indicator	Baseline	Target	Frequency	Data source	Layers of analysis	Monitoring mechanism	Input-impact level
<b>4. Scale up TB infection control</b>								
4.1 <i>Improve administrative and managerial aspects of TB infection control</i>								
4.1.1	Notification rate ratio of TB among health care workers by TB among general population	1.46	Decrease close to 1	Annually	WHO Global TB database	18 HPC 15 HMDRC	Routine reporting	Impact
4.1.2	Number of Member States having endorsed a national plan for TB infection control	Not available	18 HPC					Output
4.2 <i>Strengthen environmental measures of TB infection control</i>								
4.2.1	Percentage of TB hospitals with plans for infection control based on assessment	Not available	Close to 100%	Q3–2011 Q1–2016	National TB programmes	18 HPC 15 HMDRC	Desk review	Process
4.3 <i>Ensure accessibility to personal protection measures</i>								
4.3.1	Number of Member States with functioning respiratory protection programme in TB and M/XDR-TB services	Not available	18 HPC	Q3–2011 Q1–2016	National TB programmes	18 HPC 15 HMDRC	Desk review	Output
<b>5. Strengthen surveillance, including recording and reporting of drug-resistant TB and treatment outcome monitoring</b>								
5.1 <i>Strengthen surveillance</i>								
5.1.1	Number of Member States with routine MDR surveillance among all TB cases	Not available	53 Member States	Annually	WHO Global TB database	53 Member States 18 HPC 15 HMDRC	Routine reporting	Output
5.1.2	Number of Member States with information available on origin of routinely notified TB patients							

Area of intervention	Indicator	Baseline	Target	Frequency	Data source	Layers of analysis	Monitoring mechanism	Input-impact level
5.2 <i>Improve recording and reporting</i>								
5.2.1	Number of Member States with electronic case-based data management at national level, at least for MDR-TB patients	Not available	53 Member States	Annually	WHO Global TB database	53 Member States 18 HPC 15 HMDRC	Routine reporting	Output
<b>6. <i>Expand country capacity to scale up the management of drug-resistant TB, including advocacy, partnership and policy guidance</i></b>								
6.1 <i>Manage programme efficiently</i>								
6.1.1	Number of Member States that have developed, endorsed and started implementing their national MDR-TB response plans	Not available	18 HPC	Q3–2011 Q1–2016	National TB programmes	18 HPC 15 HMDRC	Desk review	Output
6.2 <i>Develop human resources</i>								
6.2.1	Number of Member States with TB component in national human resources plans	Not available	18 HPC	Q3–2011 Q1–2016	National TB programmes	18 HPC 15 HMDRC	Desk review	Output
6.3 <i>Give policy guidance</i>								
6.3.1	Number of Members States which have integrally adopted the Stop TB Strategy	Not available	18 HPC	Q3–2011 Q1–2016	National TB programmes	18 HPC 15 HMDRC	Desk review	Output
6.4 <i>Ensure partnership and coordination</i>								
6.4.1	Regional multi-stakeholders coordination committee established and sustainably funded to assist in scaling up response to MDR-TB	No	Yes	2012	Regional Office	WHO European Region	Not applicable	Output
6.4.2	Number of Member States with a national Stop TB Partnership up and running with meaningful involvement of all stakeholders	Not available	18 HPC	Q3–2011 Q1–2016	National TB programmes	18 HPC 15 HMDRC	Desk review	

Area of intervention	Indicator	Baseline	Target	Frequency	Data source	Layers of analysis	Monitoring mechanism	Input-impact level
<b>6.5</b> <i>Involve ACSM/civil society</i>								
6.5.1	Number of Member States providing knowledge, attitudes and practice relevant to TB study/ies	14	18 HPC	Q3–2011 Q1–2016	WHO Global TB database	18 HPC 15 HMDRC	Routine reporting	Output
6.5.2	Number of Member States with a developed and fully funded national ACSM strategy and workplan	9			National TB programmes		53 Member States 18 HPC 15 HMDRC	Desk review
6.5.3	Number of national Stop TB Partnerships, including patients' associations	Not available	53 Member States	53 Member States 18 HPC 15 HMDRC	Desk review	Output		
6.5.4	Number of Member States that financially support nongovernmental organizations active in TB control with specific emphasis on hard-to-reach populations							
<b>6.6</b> <i>Safeguard ethics and human rights</i>								
6.6.1	Number of Member States with a patients' charter in place to ensure ethics and human rights	13	18 HPC	Q3–2011 Q1–2016	WHO Global TB database	18 HPC 15 HMDRC	Routine reporting	Output
6.6.2	Number of Member States providing palliative care for eligible M/XDR-TB patients	Not available	18 HPC		Annually		National TB programmes	
6.6.3	Number of Member States having carried out client satisfaction assessments in the TB services		18 HPC					
<b>7. Address the needs of special populations</b>								
<b>7.1</b> <i>Improve collaborative TB/HIV activities</i>								
7.1.1	Percentage of notified TB cases tested for HIV	81.5%	Close to 100%	Annually	WHO Global TB database	53 Member States 18 HPC 15 HMDRC	Routine reporting	Output
7.1.2	Number of Member States having endorsed TB/HIV care protocols	Not available	18 HPC	Q3–2011 Q1–2016	National TB programmes	18 HPC 15 HMDRC	Desk review	

Area of intervention	Indicator	Baseline	Target	Frequency	Data source	Layers of analysis	Monitoring mechanism	Input-impact level
7.1.3	Percentage of HIV among TB patients (new and relapsed)	3.8%	Decrease	Annually	WHO Global TB database	53 Member States 18 HPC 15 HMDRC	Routine reporting	Impact
7.1.4	Percentage of TB/HIV patients under antiretroviral therapy	21%	Close to 100%	Annually				Output
7.1.5	Percentage of TB/HIV patients under co-trimoxazole	18%	Close to 100%	Annually			Routine estimation	Output
7.1.6	Detection rate of TB/HIV (notified to estimated)	59%	Increase	Annually			Routine reporting	Outcome
7.1.7	Treatment success rate among cases of TB/HIV co-infection (%)	Not available	Increase	Annually				
<b>7.2 Strengthen MDR-TB control in prisons</b>								
7.2.1	Notification rate ratio of TB among prisoners by TB among general population	Not available	Close to 1	Annually	WHO Global TB database	53 Member States 18 HPC 15 HMDRC	Routine reporting	Impact
7.2.2	Coverage of prison population by national TB programme (%)		Close to 100%					Output
7.2.3	Treatment success rate among prisoners with new laboratory-confirmed pulmonary TB		85%					Outcome
7.2.4	Percentage of released prisoners continuing TB treatment in civil sector		Close to 100%	Q3–2011 Q1–2016	National TB programmes	Desk review	Output	

Area of intervention	Indicator	Baseline	Target	Frequency	Data source	Layers of analysis	Monitoring mechanism	Input-impact level
7.3 <i>Improve access for hard-to-reach populations</i>								
7.3.1	Established mechanism for cross-border TB control and care which enables continuum of treatment for migrant population	No	Yes	2013	Regional Office	European Region	Not applicable	Output
7.3.1	Number of Member States with outreach programmes targeting hard-to-reach populations	Not available	53 Member States	Q3–2011 Q1–2016	National TB programmes	53 Member States 18 HPC 15 HMDRC	Desk review	
7.3.3	Number of Member States including and prioritizing childhood TB in their national strategic plans		53 Member States	Q3–2011 Q1–2016				

<sup>a</sup>High-priority countries.

<sup>b</sup>High-MDR-burden countries.