



World Health
Organization

REGIONAL OFFICE FOR Europe

REGIONAL COMMITTEE FOR EUROPE
65TH SESSION

Vilnius, Lithuania, 14–17 September 2015



© Carl Cordonnier

Tuberculosis action plan for the WHO European Region 2016–2020



Working document



**World Health
Organization**

REGIONAL OFFICE FOR **Europe**

Regional Committee for Europe
65th session

EUR/RC65/17 Rev.1
+ EUR/RC65/Conf.Doc./5 Rev.1

Vilnius, Lithuania, 14–17 September 2015

20 August 2015
150588

Provisional agenda item 5(f)

ORIGINAL: ENGLISH

Tuberculosis action plan for the WHO European Region 2016–2020

With the Global Plan to Stop TB 2006–2015 coming to an end this year, WHO has developed an ambitious post-2015 global End TB Strategy, which was endorsed by the Sixty-seventh World Health Assembly in 2014 through resolution WHA67.1. Since the ultimate success of the Strategy will depend on the commitment of Member States and partners, the resolution urges all Member States to adapt their use of the Strategy to their national priorities and specificities, and invites regional partners to support the Strategy's implementation.

The Tuberculosis action plan for the WHO European Region 2016–2020 has been developed, in a Region-wide participatory process, to operationalize the global End TB Strategy in the regional context, for its subsequent adaptation at the national level according to country specificities. The action plan, which is in line with Health 2020 and other key regional health strategies and policies, sets a regional goal and targets for the care and control of tuberculosis and drug-resistant tuberculosis from 2016 to 2020 by defining strategic directions, and describes activities to be carried out by stakeholders.

This working document contains the action plan and accompanying activities to be implemented by Member States, the WHO Regional Office for Europe and other stakeholders under three areas of intervention: integrated, patient-centred care and prevention; bold policies and supportive systems; and intensified research and innovation. The action plan is also contained in the draft publication entitled "Tuberculosis action plan for the WHO European Region 2016–2020: towards ending tuberculosis and multidrug-resistant tuberculosis", which will be available at the 65th session of the Regional Committee for Europe. The publication includes the monitoring framework, an analysis of strengths, weaknesses, opportunities and threats, an impact analysis and a financial resource analysis.

The Tuberculosis action plan for the WHO European Region 2016–2020, submitted for consideration by the Regional Committee at its 65th session, is accompanied by a draft resolution and financial implications for the Regional Office.

Contents

	page
Introduction	3
Activities related to areas of intervention.....	6
1. Integrated, patient-centred care and prevention	6
A. Systematic screening of contacts and high-risk groups	6
B. Early diagnosis of all forms of tuberculosis and universal access to drug-susceptibility testing, including the use of rapid tests	6
C. Equitable access to quality treatment and continuum of care for all people with tuberculosis, including drug-resistant tuberculosis, and patient support to facilitate treatment adherence	7
D. Collaborative tuberculosis/HIV activities, and management of comorbidities.....	8
E. Management of latent tuberculosis infection and preventive treatment of persons at high risk, and vaccination against tuberculosis	9
2. Bold policies and supportive systems.....	9
A. Political commitment with adequate resources, including universal health coverage policy.....	9
B. Health systems strengthening in all functions, including well-aligned financing mechanisms for tuberculosis and human resources	10
C. Regulatory frameworks for case-based surveillance, strengthening vital registration, quality and rational use of medicines, and pharmacovigilance	12
D. Airborne infection control, including regulated administrative, engineering and personal protection measures in all relevant health- care facilities and congregate settings.....	13
E. Community systems and civil society engagement.....	13
F. Social protection, poverty alleviation and actions on other determinants of tuberculosis, such as migration and prisons.....	14
3. Intensified research and innovation.....	15
A. Discovery, development and rapid uptake of new tools, interventions and strategies.....	15
B. Research to optimize implementation and impact, and promote innovation.....	16

Introduction

1. In 2011, in order to scale up the comprehensive response to the increasing problem of multidrug- and extensively drug-resistant tuberculosis (M/XDR-TB) in the WHO European Region, the Consolidated Action Plan to Prevent and Combat Multidrug- and Extensively Drug-Resistant Tuberculosis in the WHO European Region 2011–2015 was developed for all 53 Member States and partners. It was subsequently endorsed by the WHO Regional Committee for Europe at its 61st session in Baku, Azerbaijan, in September 2011 (resolution EUR/RC61/R7).

2. Since then, much progress has been made in the prevention and control of tuberculosis and M/XDR-TB in the Region. Millennium Development Goal 6 on reversing the incidence of tuberculosis has been achieved; tuberculosis incidence in the WHO European Region has been falling at an average rate of 4.5% per year, which is the fastest decline in tuberculosis rates in any WHO region. Diagnosis of MDR-TB cases has increased from less than one third of the estimated number in 2011 to half in 2013 (the most recent reporting year) and treatment coverage of notified cases has increased from 63% in 2011 to universal coverage in 2013. Furthermore, the incidence of MDR-TB among previously treated patients has levelled off to 48% in 2013, since the implementation of the Consolidated Action Plan.

3. Despite this progress, several key challenges to tuberculosis control remain. The transmission of MDR-TB continues, as shown by the increase in new MDR-TB cases. Tuberculosis in the Region is becoming more difficult to treat due to the increasing resistance of strains; treatment success remains low and similar to the global level (fewer than 50% of MDR-TB cases are treated successfully). Tuberculosis is one of the leading causes of death among people living with HIV, and this deadly combination is increasing in the Region: HIV prevalence among tuberculosis patients increased from 3.4% in 2008 to 7.8% in 2013.

4. With the Global Plan to Stop TB 2006–2015 coming to an end this year, WHO has developed an ambitious post-2015 global End TB Strategy, which was endorsed by the World Health Assembly in 2014 through resolution WHA67.1. The Strategy comprises three main pillars and several milestones, for 2020 and 2025, and targets, for 2030 and 2035, with the goal of ending the tuberculosis epidemic. The Strategy's ultimate success depends on the commitment of Member States and partners. With this in mind, the resolution urges all Member States to adapt their use of the Strategy to their national priorities and specificities, and invites regional partners to support the Strategy's implementation.

5. The year 2015 also marks the end of the Consolidated Action Plan to Prevent and Combat Multidrug- and Extensively Drug-Resistant Tuberculosis in the WHO European Region. Thus, in order to continue to move forward and address the challenges to tuberculosis and M/XDR-TB prevention and care, the WHO Regional Office for Europe has developed this new Tuberculosis action plan for the WHO European Region 2016–2020. The action plan is based on lessons learned in the implementation of the seven areas of intervention of the Consolidated Action Plan. It is applicable to all Member

States in the WHO European Region, including high-priority countries¹ and those with a low incidence of tuberculosis, and is intended to implement the new global End TB Strategy in the regional context, for its subsequent adaptation at the national level according to country specificities. It is aligned with Health 2020, the Framework Action Plan to Fight Tuberculosis in the European Union of the European Centre for Disease Prevention and Control, and the strategy towards eliminating tuberculosis in the European Union supported by WHO and the European Respiratory Society.

6. The long-term vision that the action plan serves is to bring “an end to the tuberculosis epidemic with zero affected families facing catastrophic costs due to tuberculosis”. The action plan sets a regional goal and targets for the care and control of tuberculosis and drug-resistant tuberculosis from 2016 to 2020 through strategic directions and describes activities to be carried out by stakeholders. Additional components, including the monitoring framework, an analysis of strengths, weaknesses, opportunities and threats, an impact analysis and a financial resource analysis, can be found in the draft publication entitled “Tuberculosis action plan for the WHO European Region 2016–2020: towards ending tuberculosis and multidrug-resistant tuberculosis”.

7. This working document provides an outline of the action plan (see Table 1), as well as activities to be implemented by Member States, the Regional Office and other stakeholders, under each of the following three areas of intervention:

- integrated, patient-centred care and prevention
- bold policies and supportive systems
- intensified research and innovation.

8. The Regional Office, in developing the action plan, worked with an advisory committee comprising representatives of WHO headquarters, seven Member States (Armenia, Austria, Belarus, Germany, Kazakhstan, the Netherlands and the United Kingdom), technical and funding agencies, civil society organizations and a former MDR-TB patient. The advisory committee met twice – on 3 October 2014 and 4 March 2015 – to review the draft action plan.

9. The draft action plan was also reviewed at a consultation meeting with representatives of 53 Member States and partners, which took place on 27 November 2014, and through a public consultation with stakeholders, civil society organizations and communities conducted from April to May 2015. At its third session on 16–17 May 2015, the Twenty-second Standing Committee of the Regional Committee for Europe (SCRC) reviewed the draft plan and provided comments. The draft plan was finalized during the meeting of national tuberculosis programme managers at the Wolfheze Workshops on 27 May 2015. Contributions and suggestions were incorporated into the draft at each stage of review.

¹ The 18 high-priority countries in the WHO European Region are: Armenia, Azerbaijan, Belarus, Bulgaria, Estonia, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, the Republic of Moldova, Romania, the Russian Federation, Tajikistan, Turkey, Turkmenistan, Ukraine and Uzbekistan.

Table 1. Outline of the Tuberculosis action plan for the WHO European Region 2016–2020

TUBERCULOSIS ACTION PLAN FOR THE WHO EUROPEAN REGION 2016–2020	
VISION	An end to the tuberculosis epidemic with zero affected families facing catastrophic costs due to tuberculosis.
GOAL	To end the spread of drug-susceptible and drug-resistant tuberculosis by achieving universal access to prevention, diagnosis and treatment in all Member States in the WHO European Region, thereby contributing to the End TB Strategy goal of ending the tuberculosis epidemic.
TARGETS (to be achieved by 2020)	<ul style="list-style-type: none"> • 35% reduction in tuberculosis deaths • 25% reduction in tuberculosis incidence rate • 75% treatment success rate among the MDR-TB patient cohort
STRATEGIC DIRECTIONS	
<ol style="list-style-type: none"> 1. <i>Work towards tuberculosis elimination by strengthening health systems response to tuberculosis and drug-resistant tuberculosis prevention, control and care</i> 2. <i>Facilitate intersectoral collaboration to address the social determinants and underlying risk factors of tuberculosis</i> 3. <i>Work in national, regional and international multistakeholder partnerships, including with civil society and communities</i> 4. <i>Foster collaboration for the development and use of new diagnostic tools, medicines, vaccines and other treatment and preventive approaches</i> 5. <i>Promote the rational use of existing resources, identify gaps and mobilize additional resources to ensure sustainability</i> 6. <i>Ensure that the promotion of sound tuberculosis ethics, human rights and equity is embedded in all areas of the strategic interventions listed above</i> 	
AREAS OF INTERVENTION	
1. INTEGRATED, PATIENT-CENTRED CARE AND PREVENTION	
<ol style="list-style-type: none"> A. Systematic screening of contacts and high-risk groups B. Early diagnosis of all forms of tuberculosis and universal access to drug-susceptibility testing, including the use of rapid tests C. Equitable access to quality treatment and continuum of care for all people with tuberculosis, including drug-resistant tuberculosis, and patient support to facilitate treatment adherence D. Collaborative tuberculosis/HIV activities, and management of comorbidities E. Management of latent tuberculosis infection and preventive treatment of persons at high risk, and vaccination against tuberculosis 	
2. BOLD POLICIES AND SUPPORTIVE SYSTEMS	
<ol style="list-style-type: none"> A. Political commitment with adequate resources, including universal health coverage policy B. Health systems strengthening in all functions, including well-aligned financing mechanisms for tuberculosis and human resources C. Regulatory frameworks for case-based surveillance, strengthening vital registration, quality and rational use of medicines, and pharmacovigilance D. Airborne infection control, including regulated administrative, engineering and personal protection measures in all relevant health-care facilities and congregate settings E. Community systems and civil society engagement F. Social protection, poverty alleviation and actions on other determinants of tuberculosis, such as migration and prisons 	
3. INTENSIFIED RESEARCH AND INNOVATION	
<ol style="list-style-type: none"> A. Discovery, development and rapid uptake of new tools, interventions and strategies B. Research to optimize implementation and impact, and promote innovations 	

Activities related to areas of intervention

1. Integrated, patient-centred care and prevention

A. Systematic screening of contacts and high-risk groups

Case finding

1.A.1 Member States, with support from the Regional Office, will develop or revise strategies for systematic screening, including active case finding and/or contact investigation (and potentially source case investigation), including among high-risk and vulnerable populations with limited or no access to health services (by the end of 2017).²

1.A.2 Member States will ensure that TB and M/XDR-TB screening is available in relevant congregate settings, including penitentiary services, across the Region (by 2016).

1.A.3 Member States will ensure systematic engagement of communities and civil society organizations in order to support screening of contacts and high-risk groups (ongoing activity).

B. Early diagnosis of all forms of tuberculosis and universal access³ to drug-susceptibility testing, including the use of rapid tests

Tuberculosis laboratory network and quality

1.B.1 The Regional Office, in collaboration with partners, will prepare a guide and diagnostic algorithms for expanded and accelerated quality-assured new diagnostic technologies (taking into account paediatric tuberculosis and extrapulmonary tuberculosis diagnostics) (by 2016).⁴

1.B.2 The Regional Office and partners will strengthen national tuberculosis laboratory networks for diagnosis of all forms of tuberculosis⁵ to ensure effective treatment with first- and second-line drugs, as appropriate (by 2017).

1.B.3 The Regional Office and partners will help national tuberculosis programmes to develop strategies to maximize the benefits of rapid diagnostic tools for hard-to-reach and vulnerable populations (by 2017).²

² These include, but are not limited to: (undocumented) migrants, refugees, stateless populations, homeless people and those suffering from alcohol and drug misuse, people with mental health disorders, prisoners and those with a history of imprisonment.

³ 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.

⁴ This includes the use of rational diagnostic algorithms for resistance to first- and second-line drugs, using WHO-endorsed diagnostic tests, for effective diagnosis.

⁵ Including, but not limited to, strengthening planning, infrastructure, biosafety, validation, maintaining equipment, sputum collection and transportation, procurement and supply, laboratory information systems and human resources.

1.B.4 The Regional Office will facilitate the provision of technical assistance to national tuberculosis laboratory networks, including reference laboratories, to ensure the uptake of quality-assured WHO diagnostic technologies (ongoing activity).

1.B.5 The Regional Office will support the national tuberculosis programmes of high-priority countries⁶ in finding ways to increase efficiency in sample transportation and subsequent communication of results (by 2018).

1.B.6 All Member States will ensure the availability of rapid tests endorsed by WHO, using national resources and donor funding. The Regional Office will liaise with donors and countries to facilitate sustainable arrangements for funding (ongoing activity).

1.B.7 Member States will ensure that quality management systems are in place within the laboratory network, covering all tests (by 2017).

1.B.8 The Regional Office and key partners will support the national tuberculosis programmes of high-priority countries in developing sustainable strategies for laboratory maintenance (by 2018).

C. Equitable access to quality treatment and continuum of care for all people with tuberculosis, including drug-resistant tuberculosis, and patient support to facilitate treatment adherence

1.C.1 Member States will ensure that their tuberculosis and drug-resistant tuberculosis treatment guidelines, including childhood tuberculosis guidelines, are regularly updated and implemented according to the latest available evidence and WHO recommendations (ongoing activity).

1.C.2 Member States will develop a plan for achieving universal access to treatment, including the treatment of vulnerable populations and children, and uninterrupted drug supply (ongoing activity).

1.C.3 Member States will ensure the rational, safe and effective introduction of new tuberculosis medicines, including for children, according to the most recent WHO policy guidance (as soon as possible and not later than 2016). (See section 2.C.)

1.C.4 Member States will sustain countrywide use of first-line fixed-dose combination drugs (for adults and children) and paediatric drug formulations in the treatment of drug-susceptible tuberculosis, where possible (by the end of 2016).

1.C.5 Member States will ensure that surgery is available for eligible M/XDR-TB patients where indicated (by 2017).⁷

⁶ See footnote 1.

⁷ WHO Regional Office for Europe Task Force on the Role of Surgery in MDR-TB. The role of surgery in the treatment of pulmonary TB and multidrug- and extensively drug-resistant TB. Copenhagen: WHO Regional Office for Europe; 2014 (<http://www.euro.who.int/en/health-topics/communicable-diseases/tuberculosis/publications/2014/the-role-of-surgery-in-the-treatment-of-pulmonary-tb-and-multidrug-and-extensively-drug-resistant-tb>, accessed 24 July 2015).

1.C.6 All high-priority countries will specify strategies and mechanisms for ensuring people-centred tuberculosis services and for expanding and maintaining the provision of ambulatory treatment integrated into the different levels and settings of service delivery (by 2016).

1.C.7 All Member States will specify strategies and mechanisms for patient-centred support to tuberculosis patients and their families in order to enable effective treatment adherence and completion (by 2016).

1.C.8 The Regional Office and partners will continue to provide technical assistance to Member States on measures to strengthen integrated delivery of tuberculosis services, including primary care and community-based tuberculosis prevention and care with increasing use of modern information and communication technologies (ongoing activity).

1.C.9 Member States will improve access to tuberculosis prevention and care and appropriate support for hard-to-reach and vulnerable populations (by 2018).⁸

1.C.10 The Regional Office and Member States will implement a mechanism for cross-border tuberculosis control and care that enables a continuum of treatment for internal and external migrants and stateless populations (by 2017).

1.C.11 The Regional Office, in collaboration with partners, will assist Member States in developing further cooperation between penitentiary and civilian services to ensure continuity of care for patients transferred between penitentiary and civilian institutions (ongoing activity).

1.C.12 Member States will ensure that palliative care services are available for all tuberculosis patients with the aim of relieving suffering from the disease and its treatment, with priority given to patients with poor chances of a cure due to limited treatment options. Specific protocols to assess and to provide care to M/XDR-TB patients who fail to respond to treatment should be established (by the end of 2016).⁹

1.C.13 The Regional Office, in collaboration with partners, will provide technical support in designing and implementing appropriate hospice/end-of-life care for M/XDR-TB patients who fail to respond to treatment and for whom all other curative treatment options, including surgery, new and repurposed drugs, are exhausted (by the end of 2016).

D. Collaborative tuberculosis/HIV activities, and management of comorbidities

1.D.1 The Regional Office, in collaboration with partners, will assist Member States in establishing effective coordination mechanisms at the national and regional levels to facilitate the delivery of integrated tuberculosis and HIV services (by 2018).

⁸ See footnote 1.

⁹ These should assess the patient's clinical condition and determine whether treatment using new or repurposed drugs is appropriate or whether the patient should be referred for end-of-life care.

1.D.2 Member States will ensure that all tuberculosis patients have access to HIV counselling and testing supported by national HIV and tuberculosis guidelines (as soon as possible and not later than 2016).

1.D.3 Member States will ensure that people living with HIV are screened and treated for latent and active tuberculosis, without exposing them to possible tuberculosis infection, and will provide preventive treatment where indicated (as soon as possible and not later than 2020).

1.D.4 Member States will ensure that all TB/HIV patients have access to early and monitored (according to the most recent WHO recommendations) antiretroviral therapy and co-trimoxazole preventive therapy (as soon as possible and not later than 2016).

1.D.5 Member States will ensure implementation of collaborative frameworks and mechanisms for the integrated management of the most frequently occurring conditions associated with tuberculosis, such as diabetes mellitus, alcohol and drug use disorders, conditions related to smoking tobacco, lung diseases, immune compromising disorders and so on. (by 2018).

1.D.6 The Regional Office, in collaboration with partners, will provide assistance for the development of collaborative frameworks and mechanisms for the integrated management of tuberculosis and its most frequent comorbidities (by 2018).

E. Management of latent tuberculosis infection and preventive treatment of persons at high risk, and vaccination against tuberculosis

(See also activities in 1.D.)

1.E.1 Member States will adopt and adapt their national policies according to the most up-to-date WHO recommendations on diagnosis and treatment of latent tuberculosis infection for high-risk populations (by the end of 2017).

1.E.2 Member States will ensure that WHO policy recommendations on bacillus Calmette-Guérin (BCG) vaccination for infants are implemented and BCG revaccination is discontinued (immediately).

1.E.3 Member States will ensure that people accessing harm reduction services for drug misuse will be provided the option of tuberculosis preventive therapy (by 2016).

2. Bold policies and supportive systems

A. Political commitment with adequate resources, including universal health coverage policy

2.A.1 Member States will improve leadership and participatory governance for tuberculosis control, including implementation of whole-of-government and whole-of-society approaches, in the light of Health 2020. At the same time, the Regional Office will provide technical assistance to Member States to ensure an improved, accountable and effective central coordination of tuberculosis control and implementation of results-based management approaches to improve performance (by 2020).

2.A.2 Member States, with the assistance of the Regional Office and partners, will ensure the rational use of existing financial and other resources, the identification of gaps and the mobilization of additional resources to ensure sustainable and effective prevention and control of tuberculosis (by 2018).

2.A.3 Member States will ensure universal coverage of tuberculosis services through the provision of a full range of high-quality tuberculosis prevention, diagnosis, treatment and care, free of charge and of equitable access to all in need, especially the most vulnerable populations (by 2020).

2.A.4 The Regional Office and partners will assist Member States in updating their national tuberculosis plans in line with the Tuberculosis action plan, including updated guidance on new tools and interventions (including e-health) (by the end of 2016).¹⁰

2.A.5 Member States will ensure that external reviews of their national tuberculosis programmes/interventions are undertaken every three to five years by the Regional Office and other partners with the involvement of civil society organizations and communities (ongoing activity).

B. Health systems strengthening in all functions, including well-aligned financing mechanisms for tuberculosis and human resources

2.B.1 The Regional Office, in collaboration with partners, will assist Member States in identifying and addressing gaps and will provide technical assistance to improve institutional capacity for all functions of tuberculosis programmes within the health system (stewardship/governance, financing, service delivery and resource generation) towards universal health coverage and rational use of hospital care (as soon as possible).

2.B.2 Member States will ensure that national tuberculosis programmes have the institutional capacity to develop, implement, analyse and adapt the tuberculosis policy, and will manage and allocate resources towards ensuring effective universal access to treatment. Health authorities will also engage the tuberculosis provider network and/or programme in health systems reform initiatives (by 2020).

Health financing for tuberculosis control and care

2.B.3 The Regional Office and partners, in collaboration with Member States, will conduct an in-depth health financing review for more effective tuberculosis prevention and control (by the end of 2016).¹¹

¹⁰ The plans will include organograms endorsed health systems and national tuberculosis programmes, with explicit roles and responsibilities (executive decrees and administrative orders), lines of authority and operational plans up to provider level. These plans will take into account health systems and financial reforms undertaken during 2011–2015, social determinants of tuberculosis and ethical and human rights concerns. These plans will also ensure that the role of primary health care, prison services, tuberculosis hospitals and general hospitals, nongovernmental organizations and private services are included, with the aim of improving public-private partnerships.

¹¹ Analysis of current resources available for tuberculosis prevention and control interventions at the regional level, including the organization of funding flows, in order to identify: sources of fragmentation, potentially misaligned provider payment incentives associated with different types of tuberculosis intervention, formal or informal out-of-pocket payments (catastrophic costs) that hinder access to care,

2.B.4 The Regional Office will provide technical assistance to Member States to develop sustainability plans to increase domestic funding and shared responsibility schemes for tuberculosis control and care in countries that have received donor funding (immediately).

2.B.5 The Regional Office will support the development of performance assessment frameworks for national tuberculosis control programmes, including evaluation of cost efficiency and effectiveness (by 2017).

Human resources

2.B.6 Member States will revise and implement strategic plans for the development of the human resources required to adapt and subsequently implement the Tuberculosis action plan at the national level (by the end of 2017).¹²

2.B.7 The Regional Office, in collaboration with the European Tuberculosis Laboratory Initiative and the Global Laboratory Initiative, will support the Tuberculosis Supranational Reference Laboratories Network in building sustainable human resources capacity (by 2018).¹³

2.B.8 Member States will continue to ensure supervised and continuous training (including on infection control), increased application of e-learning methods, coaching and support for health-care staff in case detection and in scaling up the treatment of tuberculosis, M/XDR-TB and TB/HIV patients (by 2016).

2.B.9 The Regional Office and partners (such as WHO collaborating centres and national tuberculosis programmes) will support the building of human resources capacity (ongoing activity).¹⁴

2.B.10 In coordination with the WHO Collaborating Centre on Prevention and Control of Tuberculosis in Prisons, in Baku, Azerbaijan, the Regional Office will assist Member States in improving tuberculosis control in penitentiary services by supporting training activities facilitated by the collaborating centre (immediately).

and other financial (for example, levels of insurance) and non-financial barriers to access, as well as the role of private and public providers and the financial incentives in place for each. Recommendations for measures to improve health financing reform in line with the defined service delivery strategies will be made.

¹² These plans will include human resources policies, finance, education, leadership, job descriptions and workload assessment, and will determine staff needs, supervision and monitoring, performance-based assessment and remuneration (both monetary and non-monetary) of the staff, in line with plans for national health systems.

¹³ This will be done through regular country visits to monitor the performance of laboratory networks and through the provision of technical assistance (for example, on exchange of data, information and samples) both in-country and through internships of one to two months in their supranational reference laboratories.

¹⁴ Human resources capacity-building will be carried out through (i) regular country visits to monitor the performance of national and subnational health authorities and primary health-care providers involved in tuberculosis prevention, control and treatment, and (ii) the provision of technical assistance in-country (for example, in programme management, the efficient use of resources, operational research and the application of new diagnostic and programme tools).

C. Regulatory frameworks for case-based surveillance, strengthening vital registration, quality and rational use of medicines, and pharmacovigilance

Surveillance and data management

- 2.C.1 The Regional Office, together with WHO headquarters, partners and Member States, will develop a minimum set of social determinant variables to be included in routine surveillance at the country level (by 2016).¹⁵
- 2.C.2 The Regional Office will provide technical assistance for subregional workshops on surveillance standards and benchmarks and for the development of country plans for their implementation at the national level (immediately).
- 2.C.3 All Member States will implement the new standards and benchmarks for the tuberculosis surveillance system (immediately).
- 2.C.4 Member States will implement the WHO-recommended tuberculosis case definitions and reporting framework to ensure the categorization of tuberculosis cases in order to facilitate appropriate treatment and cohort reporting (as soon as possible and not later than 2016).
- 2.C.5 Member States, with the support of the Regional Office, will facilitate the establishment of laboratory information management systems (by 2017).
- 2.C.6 Member States will establish interoperable links between different sources of data useful for tuberculosis surveillance, including demographic and vital statistics, clinical management, geopositioning, and laboratory and drug management systems (by 2020).

Uninterrupted supply and rational use of quality medicines

- 2.C.7 The Regional Office will support Member States and other partners with data collection to assist in the reliable estimation of drug needs (immediately).
- 2.C.8 The Regional Office, partners and Member States, in their respective roles, will ensure the use of quality-assured (WHO prequalified and stringent drug regulatory authority-approved) drugs and will request fast-track registration of such drugs (by 2017).
- 2.C.9 The Regional Office and partners will conduct a gap analysis of pharmaceutical legislation and regulations (as a follow-up to that conducted under the Consolidated Action Plan) and facilitate their update, revision and improvement (by 2019).
- 2.C.10 The Regional Office will assist Member States in the development of procedures for the procurement of medical supplies with an emphasis on quality assurance through strengthened regulatory authorities and particular emphasis including, but not limited to, paediatric tuberculosis diagnostics and treatment (drug formulations), and limiting the

¹⁵ This will enable the monitoring of upstream and downstream risks factors for tuberculosis disease and treatment outcomes.

availability of new drugs on the free market (over the counter) without a tuberculosis-indicated prescription sale (by 2017).

2.C.11 The Regional Office and partners will engage countries in the WHO Good Governance for Medicines programme and pharmacovigilance (immediately).

2.C.12 Member States will ensure continued capacity-building in planning, procurement and supply management of anti-tuberculosis medicines at all levels of the health-care system according to WHO recommendations (immediately).

2.C.13 The Regional Office will deliver guidance to Member States on a continuous basis to develop their legal frameworks at the national and subnational levels for compassionate use of medicines under development (ongoing activity).

Pharmacovigilance and management of adverse events

2.C.14 Member States will strengthen or establish the mechanism to routinely collect data on adverse drug events at the country level for patients on new and novel regimens (by the end of 2016).

2.C.15 The Regional Office, in collaboration with other partners and Member States, will establish a sufficiently resourced data repository on drug-related adverse events (by the end of 2016).

D. Airborne infection control, including regulated administrative, engineering and personal protection measures in all relevant health-care facilities and congregate settings

2.D.1 Member States will ensure that all health-care facilities serving tuberculosis or suspected tuberculosis patients implement sound infection control standard operating procedures, including individual respiratory protection programmes (by the end of 2016).

2.D.2 Governments in high-priority countries will ensure that environmental (engineering) preventive measures are available in high-risk facilities and congregate settings (by 2016).

E. Community systems and civil society engagement

2.E.1 Member States and WHO will systematically include representatives of affected communities and civil society in national and regional tuberculosis programme reviews, design, planning, implementation and monitoring, as well as assessments of quality of services (immediately).

2.E.2 In order to achieve systematic involvement and engagement of civil society and people affected by tuberculosis, Member States will regularly assist and coordinate with local civil society organizations and community representatives in devising and implementing effective plans in line with national tuberculosis programme policies and priorities. This may include subcontracting activities when civil society and community organizations have a comparative advantage, such as in case-finding and social support (ongoing activity).

2.E.3 High-priority countries, together with civil society and communities, will review their advocacy, communication and social mobilization strategy and develop community systems strengthening plans in order to increase knowledge of and access to improved health service delivery. This includes capacity-building of community organizations, strengthening infrastructures and systems, partnership-building and developing sustainable financing solutions. These plans should be implemented and fully funded (by 2016).

2.E.4 Member States, recognizing the special value, contribution and support that patient groups can provide, will assist and support the creation, development and involvement of such groups wherever possible (as soon as possible and not later than 2020).

2.E.5 Member States will continue to develop innovative communication strategies together with affected communities, religious and community leaders and civil society, making use of the Internet and other media (TV, radio, press, social media) to reduce tuberculosis-related stigma (ongoing activity).

2.E.6 The Regional Office will strengthen the involvement of and foster collaboration between national and international partners and private providers to raise awareness about tuberculosis, advocate resource mobilization and catalyse an exchange of best practices regarding tuberculosis and M/XDR-TB prevention and care through the Regional Collaborating Committee on Tuberculosis Control and Care (ongoing activity).

F. Social protection, poverty alleviation and actions on other determinants¹⁶ of tuberculosis, such as migration and prisons

2.F.1 Member States will measure the occurrence of catastrophic costs to patients and their households due to tuberculosis, according to WHO guidelines (by 2019).

2.F.2 Member States will develop tuberculosis-specific mechanisms of social protection, with the allocation of relevant funds (by 2017).

2.F.3 The Regional Office, in collaboration with partners, will provide technical assistance for developing effective social protection mechanisms for tuberculosis patients and their families (by 2017).

2.F.4 Member States will ensure effective mechanisms for the promotion and protection of human rights and ethical principles as part of social protection measures, including capacity-building, legal support and accountability mechanisms (ongoing activity).

¹⁶ Social determinants are defined as the conditions in which people are born, grow, work, live and age, as well as the wider set of forces and systems shaping the daily life environment. These forces and systems include economic policies and systems, development agendas, social norms, social policies and political systems.

2.F.5 The Regional Office and partners will work together with Member States in an interdepartmental and intersectoral approach to explore a legal mechanism for cross-border tuberculosis control and care (by 2017). (See also 1.C.9.)

2.F.6 Member States, in collaboration with civil society organizations, will assist with cross-border tuberculosis care among migrant communities to help increase awareness of tuberculosis and knowledge of local health services so that symptomatic individuals refer and enrol themselves appropriately for treatment in the host country (ongoing activity).

3. Intensified research and innovation

A. Discovery, development and rapid uptake of new tools, interventions and strategies

3.A.1 The Regional Office, in close consultation with WHO headquarters, will coordinate the development/establishment of the European Tuberculosis Research Initiative (by 2017), under which the Regional Office and key partners will work with Member States to:

- identify needs, capacities and gaps (financial support for basic research, operational research, language/translation support and so on);
- develop research agendas at the regional and national levels;
- develop a platform for sharing new research and study results (for example, on equity, indicators, costs of non-action and so on) and create networks for research;
- map collaboration between major research institutes and identify new areas for cooperation;
- motivate funding agencies to link with civil society organizations for research advocacy; and
- serve to provide the evidence base for policy and practice for tuberculosis prevention, control and care.

3.A.2 Member States will identify key partners, such as nongovernmental organizations and institutions, to carry out respective research agendas on the basis of sound methodology and ethical principles (by 2017).

3.A.3 The Regional Office will work with all Member States and regional partners to promote and secure funding for national research priority areas and agendas (ongoing activity).

3.A.4 The Regional Office will assist Member States in assessing and ensuring that adequate research ethics mechanisms are in place within key institutions and partner organizations that carry out national research agendas (ongoing activity).

3.A.5 The Regional Office will facilitate the research and development of new tools, including tuberculosis treatment regimens, with Member States and, through the European Tuberculosis Research Initiative, will help Member States to hold sound clinical trials on a continuous basis and to report on progress (ongoing activity).

3.A.6 The Regional Office and partners will advocate the continuous involvement of European research institutes in the development of new diagnostic tools, medicines and other treatment modalities, vaccines, research on basic mechanisms of drug resistance and so on (ongoing activity).

3.A.7 The Regional Office and partners will advocate the mobilization of regional (such as European Union) and national resources using of planning/budgeting tools aimed at developing new technologies (ongoing activity).

B. Research to optimize implementation and impact, and promote innovations

3.B.1 The Regional Office will provide guidance and technical assistance to Member States to develop operational research priorities within national research platforms and the corresponding social science research on health seeking behaviour, adherence to treatment, stigma and discrimination to inform policies and practices (ongoing activity).

3.B.2 Member States will develop an operational research plan (covering both quantitative and qualitative research) according to priority areas and key working partners (and coordinated with other existing research plans), to be considered by national and international funding sources, including the Global Fund to Fight AIDS, Tuberculosis and Malaria. Research generated under these plans should serve as the basis for improving programme performance (by 2016).

3.B.3 The Regional Office, together with key partners, will assist Member States in building capacity for research training and for translating research into action (ongoing activity).

3.B.4 Member States will ensure that the results of operational research and other studies are included in the development of tuberculosis control policies (ongoing activity).

3.B.5 In collaboration with partners, the Regional Office will continuously document best practices in the implementation of models of care and patient support (inpatient, outpatient, home/community-based models of care, financing/avoidance of catastrophic costs, prevention and so on) in different settings and will share these practices with Member States (ongoing activity).

= = =