

# Combating drug-resistant tuberculosis

*Report of a Regional Meeting  
Bangkok, Thailand, 25–26 June 2013*



**World Health  
Organization**

Regional Office for South-East Asia



SEA-TB-350  
Distribution: General

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Printed in India

# Contents

	<i>Page</i>
Acronyms .....	v
1. Introduction .....	1
2. Opening session .....	2
3. Regional and country responses to M/XDR-TB.....	3
3.1 Regional situation .....	3
3.2 The challenge of M/XDR-TB .....	6
3.3 Country poster session.....	8
4. Health system perspective in prevention of M/XDR-TB.....	10
4.1 Social determinants and universal access .....	10
4.2 Implementation of resolution WHA62.15 .....	14
5. Engaging all care providers in preventing and managing TB .....	15
5.1 Private sector response .....	15
5.2 Addressing ethical aspects in TB prevention care and control .....	17
6. Supporting structures and agencies.....	19
6.1 The regional Green Light Committee .....	19
6.2 The Global Fund to Fight AIDS, Tuberculosis and Malaria .....	20
6.3 The role of development agencies in TB prevention, care and control: the example of USAID.....	21
7. Scaling up the treatment and care of DR-TB.....	26
8. Conclusions and recommendations.....	26
8.1 Conclusions.....	26
8.2 Recommendations for Member States .....	27
8.3 Recommendations for WHO, technical and financial partners.....	29

## Annexes

1. Agenda.....	30
2. List of participants.....	31
3. Opening address by Dr Samlee Plianbangchang, WHO Regional Director for South-East Asia .....	35

## Acronyms

ACSM	advocacy, communication and social mobilization
AIDS	Acquired Immune Deficiency Syndrome
CDC	Centers for Disease Control, Atlanta, USA
DR-TB	drug-resistant tuberculosis
DM	drug management
DST	drug susceptibility testing
FDA	Food and Drug Administration (United States of America)
FLD	first line (anti-TB) drugs
GDF	Global TB drug facility
GF	Global Fund (to fight HIV/AIDS, TB and Malaria)
GLC	Green Light Committee
rGLC	Regional Green Light Committee
HIV	Human Immune deficiency Virus
IC	infection control
ISTC	international standards of TB care
MDG	Millennium Development Goal
MDR-TB	multidrug-resistant tuberculosis
M&E	monitoring and evaluation
NTP	national tuberculosis programme
PEPFAR	President's Emergency Plan for AIDS Relief
PMDT	programmatic management of drug-resistant tuberculosis
PPM	public-private Mix
RDMA	Regional development mission for Asia
SEA	South-East Asia
SEAR	WHO South-East Asia Region

SD	social determinants
SDH	social determinants for health
SLD	second line (anti-TB) drugs
SS+	sputum smear positive
TB	tuberculosis
TBTEAM	TB technical assistance mechanism
USAID	United States Agency for International Development
WHO	World Health Organization
XDR-TB	extensively drug-resistant TB

# 1. Introduction

Drug-resistant tuberculosis (DR-TB) threatens global tuberculosis (TB) control and is a major public health concern in several countries. The challenges and bottlenecks, and the need to confront the various issues, highlight the crucial importance of advocacy and commitment. They also make us understand that solutions cannot be found solely within national TB control programmes (NTPs), but will require high-level policies and broad strengthening of essential elements of the entire health system.

Over the past few years, countries in the WHO South-East Asia Region have made significant progress towards the TB-related Millennium Development Goals (MDGs). The estimated incidence of all forms of TB, estimated prevalence of all forms of TB and the estimated TB mortality all continue to show a downward trend. The treatment success rate among new smear-positive pulmonary TB cases has remained above 85% since 2005, and was 88% in 2010.

However, progress in responding to multidrug-resistant TB (MDR-TB) remains slow. While the South-East Asia Region has relatively low levels of multidrug-resistance (MDR) among newly detected cases (less than 2.5%), the rates among previously treated TB cases range from 12 to 19 % (16%). However, given the large absolute numbers of TB cases in the South-East Asia Region, this translates to 89 000 MDR-TB cases, accounting for nearly one fourth of the world's MDR-TB cases that was estimated to exist among notified cases in 2011. About 9000 MDR-TB cases were registered for treatment in the Region that year, representing only 10% of the cases estimated to occur<sup>1</sup>.

Multidrug-resistant tuberculosis has emerged as a result of underinvestment in all of the elements of the Stop TB Strategy. The emphasis for action is, therefore, to both strengthen basic control to prevent

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<sup>1</sup> Tuberculosis Control in the South-East Asia Region, Annual Report 2013, World Health Organization, New Delhi, 2013, ISBN 978-92-9022-430-3

the emergence of drug resistance, and to diagnose and treat the cases of multidrug- and extensively drug-resistant TB (XDR-TB) effectively in order to prevent transmission.

The frameworks for controlling both drug-susceptible and drug-resistant TB disease exist in the Stop TB Strategy and WHO guidelines for the programmatic management of drug-resistant tuberculosis (PMDT). Nevertheless, major obstacles persist, which include: weak general health systems, with consequent gaps in basic TB control; the health workforce crisis; inadequate laboratory capacity; insufficient expansion of the activities of NTPs to treat drug-resistant TB; non-engagement of private-care providers; inadequate collaboration between HIV and TB programmes; problems with production, supply and the rational use of antituberculosis medicines; inattention to infection control (IC); insufficient funding for research and development; and inadequate financial resources.

All health-care facilities used by patients with symptoms of TB must be engaged, with the need to involve general and specialized hospitals, academic institutions and the array of diverse private-care providers as a priority. A network of patient-friendly health clinics and staff is essential to ensure that treatment is supervised in a supportive manner and is quality-assured, free of cost, and easy to access. If patients discontinue their treatment, there must be mechanisms to trace them and re-establish treatment. Moreover, informed, motivated and resourced communities can contribute to case-finding and adherence support, especially in resource-poor settings.

## **2. Opening session**

A regional meeting on combating drug-resistant TB was held in Bangkok, Thailand, 25–26 June 2013. Dr Brenton Burkholder, Acting WHO Representative to Thailand, welcomed the participants. The Deputy Permanent Secretary, Ministry of Public Health, Royal Government of Thailand addressed the meeting. Subsequently, the opening address was delivered by Dr Samlee Plianbangchang, WHO Regional Director for South East Asia. (For text of the address see Annex 3.)

The objectives of the meeting were presented by Dr Md Khurshid Alam Hyder, Regional Adviser-TB, WHO Regional Office for South-East Asia. The general objective was to increase awareness, recognition and commitment to prevent and treat drug-resistant TB. The specific objectives were:

- (1) to review the status of drug-resistant TB (MDR and XDR) and national response to its prevention and management;
- (2) to augment awareness on control of drug-resistant TB and its consequences to communities and the health system;
- (3) to identify administrative, financial and technical mechanisms to ensure universal access to high-quality care to all people with TB;
- (4) to identify the way forward in Member States and possible support from international partners.

The agenda of the meeting and list of participants are given in Annexes 1 and 2.

### **3. Regional and country responses to M/XDR-TB**

#### **3.1 Regional situation**

The Global Plan to Stop TB 2006–2015 recognized the need to scale up diagnosis and effective treatment of MDR-TB. The plan set a target to increase the number of diagnosed and treated MDR-TB cases to around 100 000 per year by 2015, with all patients to be enrolled in programmes following international guidelines. This target was made more ambitious in the Global MDR/XDR Response Plan that was launched in 2007. In this updated version of the Global Plan, the target was to expand diagnosis and treatment, such that 85% of TB patients with MDR-TB would be diagnosed and treated by 2015. The efforts to address the problems of MDR- and XDR-TB received a momentum and saw renewed commitment in 2009. A ministerial conference held in Beijing, People's Republic of China, in April 2009 brought together high-level representatives from the 27 high MDR-TB burden countries, which collectively account for around 85% of the world's cases of MDR-TB, and issued a call to action on the part of

governments and international agencies. In May 2009, resolution WHA62.15 urged Member States “to achieve universal access to diagnosis and treatment of multidrug-resistant and extensively drug-resistant tuberculosis”. The Global Plan to Stop TB 2011–2015 calls for a renewed focus on certain areas to strengthen the fight against M/XDR-TB.

The South-East Asia Regional Response Plan for DR-TB Care and Control for 2011–2015 complements the regional strategic plan with its goal of reducing morbidity, mortality and transmission of DR-TB. The overall aim of the plan is to achieve universal access to DR-TB prevention, care and control services by 2015. The plan includes the following components.

- (1) Preventing the emergence of resistance through sustained and enhanced efforts to reach all TB patients with quality care:
  - strengthening basic TB control services to improve case notification and treatment success;
  - promoting the adoption of International Standards of TB Care (ISTC) by all care providers;
  - promoting the rational use of anti-TB drugs and pharmacovigilance;
  - strengthening TB–HIV collaboration.
- (2) Scaling up PMDT:
  - screening and testing for resistance to first- and second-line anti-TB drugs, as well as HIV testing among confirmed cases of MDR-TB;
  - providing access to effective treatment for drug-resistant TB;
  - providing patient-centric care and promoting adherence.
- (3) Implementing TB-IC in health-care facilities and congregate settings.
- (4) Strengthening surveillance, including recording and reporting of drug-resistant TB.
- (5) Strengthening health systems to ensure capacity for PMDT integrated with primary health care.

- (6) Forging partnerships and ensuring coordination with stakeholders to mobilize the requisite resources.
- (7) Supporting PMDT through ACSM.
- (8) Undertaking research.

While progress has been made, the challenges remain significant across the Region:

- A case-detection rate of 61% for all cases suggests that more than one third of estimated cases are not registered by NTPs.
- While the geographical coverage for DOTS in all Member States has reached 100%, there are challenges to access for underserved or marginalized populations.
- Studies in the Region have demonstrated that the private sector is the first contact for 65% TB patients in India and 73% in Myanmar. A study in Indonesia reveals that the majority of people in the rural area preferred private practitioners for treatment of TB.
- Despite significant progress, the involvement of private and other health sectors in TB control in the Region is yet far from being optimal.
- Evidence suggests that the success rates of TB treatment in the private sector (unless they are part of a PPM initiative) are usually <50%.
- Less than 7% of the estimated MDR-TB cases are registered for treatment by NTPs. A huge proportion of cases are either not getting treatment or being treated under unknown conditions with high chance of the use of a non-standardized regimen.
- Poor drug regulation – anti-TB drugs (both first and second line) are available over the counter in several countries in the Region.

- Overburdened health infrastructure, specifically overcrowded hospitals, with limited or no infection control policies.
- Several countries in the Region face poor housing conditions and specifically overcrowding in urban areas that facilitate spread of infections.
- There is a need to address children, DR-TB, drug management, mobile populations and cross-border issues.

Prevention of acquired M/XDR-TB remains of critical importance by ensuring higher case detection and cure rates through universal access to high-quality TB prevention, care and control services. This requires establishing effective collaboration with other sectors, as well as coordination within the health sector; strengthening key health systems elements, such as health financing, human resources, laboratory capacity, regulation of quality and use of anti-TB medicines; and the stewardship role of governments vis-à-vis the private sector. It requires advocacy and increased resources; a coordinated support from technical and financial partners as well as research into new drugs, new regimens and simplified models or care.

However, it needs to be acknowledged that in countries such as Thailand, it is observed that the largest numbers of MDR-TB cases may exist among the new patients. Addressing this issue will require bold and innovative action on the part of Member States.

### **3.2 The challenge of M/XDR-TB**

Progress towards global targets for reductions in TB cases and deaths continues. However, the global burden of TB remains enormous. Access to TB care has expanded substantially, but progress in responding to (and curing) multidrug-resistant TB remains slow. There has been progress in implementing collaborative TB–HIV activities; innovations in diagnostics are being implemented; the development of new drugs (two drugs nearly or already approved by the American Food and Drug Administration and the European Medicines Agency) and work on new vaccines (further away). However, critically wide funding gaps for TB care and control remain.

Geographically, the burden of TB remains the highest in Asia and Africa. China and India together account for almost 40% of the world's TB cases. About 60% of cases are in the South-East Asia and Western Pacific regions. The African Region has 24% of the world's cases and the highest rates of cases and deaths per capita.

Worldwide, 3.7% of new cases and 20% of previously treated cases are estimated to have MDR-TB. China, India, the Russian Federation and South Africa have almost 60% of the world's cases of MDR-TB. The highest proportions of TB patients with MDR-TB are found in eastern Europe and central Asia.

Almost 80% of TB cases among people living with HIV reside in Africa. There were an estimated 0.5 million cases and 64 000 deaths among children in 2011.

Globally, treatment success rates have been maintained at high levels for several years. In 2010, the treatment success rate among all newly diagnosed cases was over 85% among patients with smear-positive pulmonary TB; however, these fall towards 50% in MDR-TB cases. Extensively drug-resistant TB, or XDR-TB, has been reported by 84 countries; the average proportion of MDR-TB cases with XDR-TB is 9.0%.

The target for the treatment success rate of 75% or higher for patients with MDR-TB was, however reached by only 30 of 107 countries that reported treatment outcomes. The WHO recommendations support the wider use of rapid drug susceptibility testing for isoniazid and rifampicin, or rifampicin alone, using molecular techniques. Monitoring by sputum culture is important for early detection of failure during treatment. Regimens lasting  $\geq 20$  months and containing pyrazinamide, fluoroquinolone, second-line injectable drug, ethionamide (or prothionamide), and either cycloserine or *p*-aminosalicylic acid are recommended in the 2011 WHO PMDT Guidelines, although the shorter regimen (previously termed the "Bangladesh regimen") has many advantages in selected patients and will likely become more widely adopted. The WHO guidelines promote the early use of antiretroviral agents for TB patients with HIV on second-line drug regimens. Systems that primarily employ ambulatory models of care are recommended over others based mainly on hospitalization. Scientific and medical associations should promote the recommendations among practitioners and public health

decision-makers involved in MDR-TB care. Controlled trials are needed to improve the quality of existing evidence, particularly on the optimal composition and duration of MDR-TB treatment regimens.

### **3.3 Country poster session**

As a step towards fulfilling the objectives of the meeting, Member States had been requested to prepare posters to highlight the M/XDR-TB situation. The posters were very well prepared and presented with both achievements and challenges clearly illustrated. Major progress in TB control has been achieved; however, none of the countries in the Region is currently in a position to achieve universal access to prevention, care and control services for all forms of TB. While the size of the population, as well as the geographical situation of the Member States in the Region display a huge variety, challenges in addressing M/XDR-TB and scaling up the response are relatively homogenous.

Key challenges presented in the posters include, but are not limited to the following:

- (1) Insufficient access to DR-TB centres and diagnostic facilities:
  - sputum transportation systems;
  - availability of newer rapid diagnostic tools;
  - development of infrastructure for decentralized TB culture facilities;
  - establishing GeneXpert sites for diagnosis and follow-up culture, and updating existing diagnostic algorithms to include GeneXpert;
  - ensuring equipment maintenance, including recalibration of the GeneXpert machines;
  - ensuring laboratory certification.
- (2) Ensuring the availability of second line anti-TB drugs:
  - procurement;
  - regulation and rational use of anti-TB drugs;

- supply chain management.
- (3) Management of treatment:
- ensuring use of DOT in patient-centred approaches;
  - management of side-effects, particularly if patient is also on ARVs;
  - providing and sustaining social support to DR–TB patients;
  - addressing socioeconomic constraints to patients such as cost of travel, time required to comply with clinic-based DOT, loss of employment, need to migrate to areas away from home to access PMDT services, and loss of support of family, relatives and friends due to stigma and the “high” cost of supporting patients through MDR–TB treatment.
- (4) Human resource development – ensuring adequate number of competent staff in current sites and for the scaling up of services (all levels of the health system, private providers and the community):
- chronic shortages, high turnover especially at peripheral level;
  - limited number of staff for management at central level;
  - limited capacity of health care staff at community level to provide care for M/XDR-TB patients.
- (5) Infection control – for patients, for staff and for the community.
- (6) Engaging the large unregulated private sector in TB control activities:
- a large proportion of drug-susceptible and drug-resistant patients seek care in large, unregulated private health sectors;
  - halting irrational prescription and management practices;
  - limited involvement of private health sector providers in PMDT activities.

- (7) Addressing the social determinants of TB control:
  - ensuring access to TB prevention, care and control services for vulnerable populations.
- (8) Ensuring sustainable funding, via domestic and external sources.

## **4. Health system perspective in prevention of M/XDR-TB**

### **4.1 Social determinants and universal access**

Countries have made great strides in the fight against TB since WHO declared TB a global emergency in 1993 and called for immediate action to save millions of preventable deaths due to TB. However, many countries are still facing challenges in providing universal access to quality TB services: prevention, diagnosis, treatment and care. Hence, TB still continues to be among the top 10 causes of global morbidity and mortality. Several factors may have constrained the fight against TB and many of them can be linked to the weaknesses of the respective health systems. Among others, one of the major causes is the lack of specific programmatic approach to understand and address the wider social determinants of health including TB, and lack of health system stewardship to ensure universal access to TB care.

International discourse in TB control has two specific strands: the traditional approach that relies on narrowly defined, technology-based medical and public health interventions, and which has more of a biomedical way of dealing with health and ill-health conditions; and an understanding of TB as a social phenomenon, requiring more complex forms of intersectoral policy action that sees human health through a social lens which is also linked to a broader discourse of social justice.

#### ***Social determinants of health and TB***

Social and environmental factors resolutely influence people's health. Much of the work of the founding fathers of modern public health echoed awareness of the strong relationship between people's social position, their

living conditions and their health outcomes. Similarly, the various contexts of people's birth, work, growth, livelihood and age including the health system strongly influence their health. These contexts are often determined by the distribution of money, power, and resources at global, national and local levels which are influenced by policy choices. The WHO Constitution (WHO, 1948) articulates the impact of social and political conditions on health and calls for collaboration with sectors such as agriculture, education, housing and social welfare to achieve health gains. However, the social dimensions of health were overshadowed during the post-1950 era that favoured an approach which was technology-driven and vertical in nature. Though health strategies often pointed to the need of extending services to disadvantaged groups, in reality, missing links were evident between the health strategies and identification of specific health issues; target groups within populations and specific area-based strategies. The movement for *Health For All* was crystallized through the Alma-Ata declaration (1978) and further adoption of the *Primary Health Care Strategy* manifested a re-emergence of social determinants (SD) as a major public health concern. In TB control, the increasing number of TB cases and their inequitable distribution throughout the world has been a key driver leading to address social determinants.

The social determinants for health (SDH) approach looks at *variation in health*. Variation could have emerged because of social structure or due to people's lifestyles. SDH include *people's living conditions* and their *access to power, money and resources*. Unequal access to these resources leads to health *inequalities*. As these inequalities are construed by the social systems and through social relation, inequities in health are avoidable and remediable.

### ***Social determinants and TB control: vulnerability of and risk factors for TB***

Key structural determinants of TB epidemiology include global socioeconomic inequalities, and high levels of population mobility, along with rapid urbanization and population growth. These conditions give rise to unequal distributions of key social determinants of TB, including food insecurity and malnutrition, poor housing and environmental conditions and financial, geographic and cultural barriers to health-care access.

Urbanization has been identified as a major risk factor for TB due to the fact that it leads to increased population density, crowded living and working conditions, and increased mobility, as poor and urban populations migrate in search of temporary work. Likewise, frequent migrations pose a great challenge for completion of TB treatment. Cross-border migrants, including those from countries with a high TB burden, are more likely to settle in urban areas. Changing lifestyle factors are causes of increased vulnerability to TB infection, such as smoking, alcohol abuse and unhealthy diets.

### ***Vulnerable groups***

From the SDH perspective, some groups of people could be considered as vulnerable to ill-health and health problems because of their living conditions and lifestyles. These groups consist of people from different walks of social life such as slum dwellers, the homeless, migrants, drug abusers, prisoners, indigenous people, ethnic minorities, elderly people, people suffering from physical and mental disabilities, and people living with HIV. Likewise, female-headed households are also considered vulnerable, due to higher rates of poverty, lack of economic opportunities and social marginalization.

### ***Imperative of addressing social determinants for developing countries***

In developing countries, not only are there large numbers of people living below the absolute poverty level, but there is also a huge gap between the rich and poor people. Along with the increasing population size, every year many people are migrating from the countryside to cities and urban areas.

People's lifestyles and the conditions in which they live and work strongly influence their health. It is not simply that poor material circumstances are harmful to health; the social meaning of being poor, unemployed, socially excluded, or otherwise stigmatized also matters. Ten different factors have been identified as detrimental social determinants to health: the social gradient, general life stresses, early life, social exclusion, work stress, unemployment, social support, drug abuse, food and transport. It is true and needs to be recognized that finding the poor and vulnerable populations, and reaching out to them poses both cultural and logistical concerns to the NTPs, as wider social determinants of TB often lie outside the parameters of the health sector and are beyond its authority purview.

### ***Universal health care (UHC) including TB care***

Various terms have been used to denote 'universal health care' such as universal health coverage, universal health care, universal access to health care. Universal health care/coverage means accessible and affordable health care services to all. Primarily, it stands on two major constituents: the attainment of effective and equitable access to healthcare by all individuals in any society on the basis of need; and financial protection, which is the prevention of catastrophic and impoverishing payments by individuals and families when using needed health-care services.

In TB control, the meaning of universal TB prevention, care and control services can be defined as: all people infected and affected with TB must have full access to affordable quality TB services: prevention, diagnosis, treatment and care on the basis of need. Achieving universal access to TB care requires a bold and concerted drive on many fronts of TB care, and increased financing. Universal access should be with preconditions that all TB services should be: equitable, accessible, available, affordable, acceptable, and provide comprehensive coverage (services and area) to the people, especially the poor and vulnerable.

### ***Way forward***

It is crucial that NTP should focus on improving early detection of TB cases by addressing access barriers. It should be supported by locally appropriate and culturally feasible intensified TB case-finding mechanisms, with a greater focus on TB vulnerable populations and the poor. Similarly, a comprehensive package of patient support and supervision is crucial to improve TB treatment outcomes by reducing the burden due to TB placed on the patient and their families.

Based on the above discussions, the following could be regarded as ways forward to address social determinants of TB and universal access to TB care:

- undertake a comprehensive analysis to identify the poor and TB-vulnerable populations and know how they are distributed within communities by undertaking detailed mapping exercises;

- develop innovative mechanisms for intensified TB case-finding and costed implementation plans;
- formulate policies addressing SDH and universal access to TB care in the context of the respective country situation;
- identify and prioritize SDH entry points;
- coordinate and collaborate to ensure actions not only by and beyond TB control programmes, but also by and beyond the health sector;
- ensure operational research takes place within the routine programme and informs the programme interventions and the future development.

## **4.2 Implementation of resolution WHA62.15**

The Sixty-second World Health Assembly in May 2009 urged Member States to develop and implement long-term plans for tuberculosis including M/XDR-TB prevention and control, in line with Global Plan to Stop TB 2006–2015. The Beijing Call for Action on Tuberculosis Control and Patient Care earlier in April 2009, and resolution WHA62.15 “Prevention and Control of Multidrug-resistant and Extensively Drug-resistant tuberculosis” reiterated the need for urgent action to address M/XDR-TB. Delays will result in greater numbers of TB including M/XDR-TB cases, deaths, reversing progress made so far towards achieving the TB targets. Managing DR-TB requires much stronger TB control. This, in turn, requires addressing key weaknesses of the health systems through which TB prevention, care and control services are delivered.

The resolution urges Member States to achieve universal access to diagnosis and treatment of multidrug-resistant and extensively drug-resistant tuberculosis as part of the transition to universal health coverage, thereby saving lives and protecting communities, by means of:

- developing a comprehensive framework for management and care of multidrug-resistant and extensively drug-resistant tuberculosis;
- strengthening health information and surveillance systems;

- ensuring the removal of financial barriers;
- making available sufficiently trained and motivated staff;
- strengthening laboratory systems;
- engaging all relevant public and private health care providers;
- ensuring that national airborne infection control policies are developed and implemented;
- ensuring uninterrupted supply of first and second line medicines for TB treatment;
- strengthening mechanisms to ensure that tuberculosis medicines are sold on prescription only and prescribed and dispensed by accredited providers;
- undertaking effective advocacy, communication and social mobilization;
- enhancing the quality and coverage of DOTS.

## **5. Engaging all care providers in preventing and managing TB**

### **5.1 Private sector response**

#### ***Why a public–private mix for the programmatic management of multidrug-resistant TB (PPM MDR-TB)?***

In South-East Asia and Sub-Saharan Africa, the source of health-care provision, even for those living on less than US\$ 1.25 per day, is mainly from the private sector and not the subsidized public health sector. Despite the availability of free care under NTPs, a similar picture is thought to exist in relation to the provision of care for patients with TB. The reality is that in many countries, NTP is just one among many providers who offer care to TB patients. These private providers range from large ‘for profit’ hospitals, single handed medical practitioners, nongovernmental health facilities,

informal health care providers, and a host of public sector agencies who provide health care outside of the NTP purview.

Component 4 of WHO's Stop TB Strategy comprises "Engage all care providers in TB control". A public-private mix for TB (PPM) represents a comprehensive approach to engage all relevant health-care providers in the delivery of TB services. It encompasses all forms of collaboration: public-private (between public and private providers); public-public (between national TB programmes and other public sector providers); and private-private (between an NGO or a private hospital and neighbourhood private practitioners). In many countries, a significant amount of progress has been made in engaging a wide range of care providers in the activities of NTPs for drug-susceptible TB cases. In 2011, PPM activities led to a contribution of between 10 and 40% of the new smear-positive pulmonary TB case notifications in a set of 21 countries.

However, information is lacking on the management of MDR-TB cases in the private sector to date. It is known that there is some, however limited, availability of diagnostic facilities to detect drug resistance amongst TB patients, and there is good documentation of the major quantities of first and second line anti-TB drugs sold in the private market in many settings with high TB and MDR-TB burdens. Globally, it is estimated that more patients with MDR-TB and extensively drug resistant TB (XDR-TB) are being managed outside the NTPs than within, with serious concerns over the quality of drugs used and the treatment practices followed. TB care providers not linked to NTPs may be major contributors to the creation and mismanagement of M/XDR-TB, and to continued transmission within communities.

Such private providers could, however, potentially, contribute significantly to the prevention and control of M/XDR TB. Hence, engagement of all relevant care providers is essential for effective scale-up of MDR-TB response. There is a potential role for every provider.

### ***Taking PPM for MDR-TB forward***

Over the past decade, guidance and tools for PPM have been developed by WHO and partners to assist countries implement PPM activities for drug-susceptible TB. There is now an urgent need to extend these activities to

include MDR-TB patients and PMDT. Countries should initially undertake a national situational assessment for the engagement of all relevant care providers in PMDT. An assessment tool has been developed by WHO, which will assist countries to: review the TB and MDR-TB situation within the country health system context; document the management of MDR-TB and assess the capacity of existing and potential PPM MDR-TB management in the country within and outside of the NTP; and suggest new approaches and country-specific PPM models for MDR-TB. If existing models are implemented in the respective countries, the NTPs should document best practices and these models. Out of this work, the NTPs should then develop national frameworks for PPM MDR-TB activities, which then should be initiated and/or scaled up in the relevant settings.

## **5.2 Addressing ethical aspects in TB prevention care and control**

### ***Why ethics matters in tuberculosis prevention, care and control***

The emergence of MDR-TB has increased the visibility and urgency of ethical dilemmas that health care workers face when providing diagnosis, treatment and care. Both policy-makers and health care workers will thus increasingly be confronted with ethical challenges. At the centre of the most frequent ethical dilemmas in TB control, as in public health in general, lies the duty to protect public interest while respecting and promoting the rights of individuals.

In 2010, WHO launched the document '*Guidance on ethics of tuberculosis prevention, care and control*' to assist NTPs, TB service providers, policy-makers and civil society to scale up access to diagnosis, treatment and care of MDR-TB in an ethical manner. This guidance document addresses a broad range of ethical issues that arise in NTPs, ranging from informed consent and isolation to health care workers' rights and obligations, and clinical and epidemiological studies.

### ***Rights and obligations in TB prevention, care and control***

Governments have an ethical responsibility to provide free and universal access to the diagnosis and treatment of TB. This obligation is grounded in their duty to fulfil the human right of all to health. There is also the ethical

imperative of financial and social protection of patients and their families, as well as the right to healthy living conditions, all of which are essential for TB prevention.

Key aspects include information, counselling and (verbal) informed consent. Patients need to be fully informed and counselled about their treatment.

Supporting adherence to treatment is another important concern. Health care providers have an obligation to support patients and not to abandon them. Even if and when curative treatment fails, there is still an obligation to provide care. The gap between drug susceptibility testing (DST) and access to treatment for drug-resistant TB (DR-TB) is considered. Ideally, all patients should undergo DST and have access to the appropriate therapy. However, many countries are still in the process of scaling up diagnostic and treatment capacity for DR-TB. As an interim measure, and if the patient agrees, the provision of testing in the absence of treatment can be legitimate, as it is useful to estimate the magnitude of the problem, guide decisions about how best to treat MDR-TB patients while promoting the implementation of infection control measures and advocating for proper treatment capacity.

Health care workers have an ethical obligation to care for their patients, even if doing so involves some degree of risk. However, they should not be expected to assume risks that result from inadequate conditions to provide care; governments and health care institutions must provide the necessary goods and services to allow for a safe working environment. Furthermore, health care workers who are at heightened risk of contracting TB themselves, such as those who are HIV-positive, may be exempted from their duty to care for this group of patients.

An essential aspect of ethics in TB control is a discussion of involuntary isolation and detention. If a patient refuses treatment, this is likely to be due to insufficient counselling or a lack of treatment support. In very rare cases, where all efforts to engage a patient to adhere to treatment fail, the rights of other members of the community might justify efforts to involuntarily isolate the contagious patient. However, involuntary isolation should always be used as a very last resort, and it is essential that the

manner in which it is implemented complies with applicable ethical and human rights principles.

Finally, ethics in TB control must include ethical issues in research on TB care and control. Given the poor record of innovative tools for the diagnosis and treatment of TB, with the recent exception of a rapid diagnostic tool, the international public health community has an obligation to foster more research in TB. Sponsors have an obligation to ensure that both clinical as well as epidemiological research are always conducted in an ethical manner with input from and to benefit for the afflicted community.

## **6. Supporting structures and agencies**

### **6.1 The regional Green Light Committee**

To understand the role of the Regional Green Light Committee (rGLC), the Advisory Committee on MDR TB, it is important to appreciate the reasons why this approach was recommended by WHO. In 1998–1999, WHO and international partners observed that to have an impact on the problem of drug resistance in the world, it was important to shift from the existing individualized practitioner approach to the community-based programmatic approach. This led to newer terms such as the DOTS Plus Strategy (1999), the Green Light Committee (GLC) (2000) and the Programmatic Management of Drug Resistant TB (PMDT). The role of the Green Light Committee was to facilitate countries in developing their strategies for PMDT, the provision of quality assured second line anti-TB drugs at concessional price and to monitor the implementation of the strategy.

The Global Framework was subsequently revised to facilitate faster expansion and access for treatment of MDR-TB patients. Within this new framework, the role of the existing Green Light Committee at the global level was revised and the concept of decentralization of activities to regional level was mooted. Hence, six regional GLCs were envisaged which would be supported by a secretariat housed within the respective WHO Regional Office. The rGLCs would support the development of the MDR-TB plans of the different countries, assist in the procurement of the required second line anti-TB drugs through the GDF, assist the countries in the

implementation of DR-TB management, monitor and evaluate the function of the programme at country level, and provide recommendations to the country for further scale-up. The rGLCs would also assist in fund raising, capacity building and advocacy at the country level.

The SEAR rGLCs was constituted in May 2012, and had its first and second meetings in May and December 2012 respectively, wherein the members selected the Chair and Vice-Chair and laid out the objectives and plans of action for the role of the rGLCs in the context of different country programmes in the Region. An rGLCs Secretariat was established at the WHO South-East Asia Regional Office to facilitate the functioning of the rGLC, and its role was also defined. Since then, the rGLC has been meeting at regular intervals and its third meeting was held in Bhutan in April 2013. Different issues have been discussed in these meetings, and by examining the various country mission reports, the rGLC has been able to identify the general concerns which were challenging the scale up of PMDT in the Region. The Committee also discussed and made various recommendations to resolve these challenges, and laid out the plans for the future.

## **6.2 The Global Fund to Fight AIDS, Tuberculosis and Malaria**

At its meeting in November 2011, the Global Fund Board adopted a new strategy for the period 2012–2016. The Strategy comes at a crucial juncture in the lead-up to the 2015 Millennium Development Goals deadline. Promising new technologies and interventions are emerging and there is now a real opportunity to significantly alter the trajectory of the epidemics.

The Global Fund aspires to contribute substantially to international goals by saving 10 million lives and preventing 140–180 million new infections from HIV/AIDS, tuberculosis and malaria between 2012 and 2016. These goals are complemented by disease-specific targets aligned with the global targets set by UNAIDS, WHO, and the Stop TB and Roll Back Malaria Partnerships.

To achieve this, the Global Fund (GF) will “invest for impact, based notably on three strategic objectives: (1) invest more strategically; (2) evolve the new funding model; and (3) actively support grant implementation success through more active grant management and better engagement with partners.

As of June 2013, the GF supported the case detection and treatment of 9 700 000 new sputum smear positive (SS+) TB persons through 217 active TB grants. Globally, US\$ 4.1 billion was approved for TB grants (16% out of the total US\$ 25.45 billion approved by the GF). The disbursed amount, for TB grants, is US\$ 3.12 billion (out of a total of US\$ 20.01 billion). The performance of TB grants is mostly adequate (B1), and often meets (A2) or exceeds (A1) expectations.

The Global Fund announced a goal of raising US\$ 15 billion in late 2013 so that it can effectively support countries in fighting these three infectious diseases in the 2014–2016 period. Together with other funding, including an estimated US\$ 37 billion from domestic sources in implementing countries and US\$ 24 billion from other international sources, a US\$ 15 billion contribution to the GF would allow the collective work to address close to 90 percent of the global resource needs to fight these three diseases, estimated at a total of US\$ 87 billion.

This aggregate level of funding would mean that 17 million patients with TB and with MDR-TB could receive treatment, saving almost 6 million lives over this three-year period.

In addition, the new funding model recently launched by the GF can achieve greater impact by encouraging ambitious programmes and by focusing interventions and financing for specific populations and catchment areas. By reaching highly vulnerable, marginalized and stigmatized groups, including women and girls, sex workers, people who inject drugs, men who have sex with men, people in prison and migrants, more programmes will maximize impact while advancing human rights.

### **6.3 The role of development agencies in TB prevention, care and control: the example of USAID**

The roles of donors in TB control are related to strategy development, funding of TB programmes, oversight of project implementation and donor coordination. Figure 1 gives an example of the donors present in selected countries of the South-East Asia Region.

**Figure 1: TB donors in select countries in the South-East Asia Region**

<b>Donor</b> <small>*Donors with MDR-TB activities</small>	<b>Bangladesh</b>	<b>Myanmar</b>	<b>India</b>	<b>Indonesia</b>	<b>Thailand</b>
Asian Development Bank	✓				
The Australian Agency for International Development		✓			
Bill & Melinda Gates Foundation			✓		
Central Emergency Response Fund		✓			
The Eli Lilly MDR-TB Partnership			✓		
European Union		✓			✓
German Leprosy Relief Association			✓		
Global Fund to Fight AIDS, Tuberculosis and Malaria	✓	✓	✓	✓	✓
Japan Debt Cancellation Fund	✓				
Japan International Cooperation Agency		✓	✓		
Three Diseases Fund		✓			
DFID	✓		✓		
UNITAID	✓	✓	✓	✓	✓
USAID	✓	✓	✓	✓	✓
The US CDC					✓
The World Bank	✓		✓		

Source: USAID Regional Development Mission for Asia (RDMA)

The United States Agency for International Development (USAID) is providing support to countries based on the following key development principles:

- implement a women- and girl-centered approach;

- increase the impact through strategic coordination and integration;
- strengthen and leverage key multilateral organizations, global health partnerships and private sector engagement;
- encourage country ownership and invest in country-led plans;
- improve monitoring, metrics and evaluation;
- promote research and innovation.

The key interventions of USAID's Global TB Strategy include: accelerated detection and treatment of TB in up to 24 countries; scaled up prevention and treatment of MDR-TB; expanded coverage of interventions for TB–HIV co-infection in coordination with US Government HIV efforts under President's Emergency Plan for AIDS Relief (PEPFAR); and improvement in health systems. Subsequently, the key approaches for MDR TB management are as follows:

- (1) MDR–TB diagnosis
  - in-country drug-sensitivity testing/rapid-testing and ongoing external quality assessments by supranational reference laboratories;
  - long-term on-site technical assistance to help build and/or rapidly expand capacity to perform TB culture, DST, and rapid molecular genetic tests for drug-resistant tuberculosis;
  - in-country laboratory networks for specimen transport and data management;
  - certification and coordination of private laboratories.
- (2) Access to high quality second line drugs
  - motivating more manufacturers to be interested in manufacturing second line drugs;
  - increasing the quality of existing and new second-line drugs;
  - decreasing the price of second-line drugs through various market shaping interventions.

- (3) Treatment delivery–care, treatment and support including management of side effects and socioeconomic support
- promote universal treatment for MDR-TB within national TB control strategies–side by side with drug-susceptible disease and integrated with HIV treatment services;
  - support long-term technical assistance involving on-site implementation teams;
  - draw on the experience of successful MDR-TB treatment for scaling up;
  - promote community/ambulatory-based MDR-TB treatment, and active collaboration; with private sector laboratories and tuberculosis treatment providers;
  - integrate infection control;
  - social support.

The regional and country-specific strategies of the USAID Regional Development Mission for Asia (RDMA) has adopted the following strategic objectives and interventions related to MDR-TB.

**Strategic objective:** Reduce TB prevalence and mortality, with emphasis on MDR-TB and TB/HIV co-infection

- IR1: Strengthened MDR-TB prevention
- IR2: Strengthened MDR-TB management
- IR3: Improved strategic information for MDR-TB
- IR4: Strengthened enabling environment for MDR-TB
- IR5: Strengthened TB–HIV collaboration.

Table 1 illustrates the TB-related activities of RDMA.

**Table 1:** RDMA support to TB prevention, care and control

Partner	Main activities	Countries
CDC, Atlanta	<ul style="list-style-type: none"> <li>• Operations research and technical assistance for rolling out new diagnostic tests and operating procedures</li> <li>• Surveillance, recording, and reporting of MDR-TB outbreaks</li> <li>• Infection control</li> <li>• TB-HIV diagnosis and care</li> </ul>	Cambodia China Thailand Viet Nam
WHO, Western Pacific Regional Office	<ul style="list-style-type: none"> <li>• Strategic support and planning for scaling up MDR-TB control at the national level</li> <li>• Strengthening laboratory capacity</li> <li>• Regional training and technical assistance in a range of areas (such as PMDT, ACSM, diagnostics, surveillance, infection control)</li> </ul>	Regional, China, Lao People's Democratic Republic, Mongolia, Papua New Guinea, Philippines, Viet Nam
WHO South-East Asia Regional Office	<ul style="list-style-type: none"> <li>• Strategic support and planning for scaling up MDR-TB control at the national level</li> <li>• Strengthening laboratory capacity</li> <li>• Regional training and technical assistance in a range of areas (such as PMDT, ACSM, diagnostics, surveillance, infection control)</li> </ul>	Regional, Bangladesh, Bhutan, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand, Timor-Leste
FHI360	<ul style="list-style-type: none"> <li>• Development of model approaches for scaling up PMDT</li> <li>• Capacity building support for local organizations and private partners in expansion of MDR-TB control</li> <li>• Strengthening intensified case-finding and diagnostics</li> <li>• Procurement and forecasting of second line anti-TB drugs</li> <li>• Support for drug quality assurance</li> <li>• Standardized reporting systems</li> </ul>	Regional China, Myanmar, Thailand
PSI	<ul style="list-style-type: none"> <li>• ACSM, including community-based outreach and education</li> <li>• Intensified case-finding and referral</li> <li>• TB-HIV screening and diagnosis</li> </ul>	Myanmar

Source: USAID Regional Development Mission for Asia (RDMA)

## 7. Scaling up the treatment and care of DR-TB

The participants were tasked with discussing the following issues in groups:

- identifying key administrative, financial and technical mechanisms essential to ensure scaling up the treatment and care of TB patients in the public and private sectors;
- analysing factors hampering the scale-up of treatment and care in the public and private sectors;
- reviewing where improvements can be made;
- sharing positive and negative experiences.

## 8. Conclusions and recommendations

### 8.1 Conclusions

- (1) Considerable progress continues to be made in the WHO South-East Asia Region in reaching the TB-related MDG targets. The South-East Asia Region being home to 27% of the world population, accounts for 40% of the world TB burden.

The burden of TB includes an estimated 89 000 cases of MDR-TB; that may be just the tip of the iceberg of TB problem faced in the Region. The progress in implementation and expansion of PMDT in the Region has been limited. In 2011, only 9000 patients with MDR-TB were registered for treatment, illustrating the need for urgent and significant expansion in the scale and scope of the TB control activities and to fully implement resolution WHA 62.15 on “Prevention and control of multi-drug resistant tuberculosis and extensively drug-resistant tuberculosis”.

- (2) National TB control programmes still face a number of challenges that relate to uncertainties regarding sustainable financial and operational resources, suboptimal technical and management capacity, weak procurement and supply

management mechanisms, and national laboratory networks. Health systems are underfinanced and overstretched.

- (3) The emergence and spread of M/XDR-TB is facilitated by not detecting sufficient cases of TB and not treating them appropriately based on WHO recommended guidelines. While it is essential to rapidly move forward with the scale-up of management of drug-resistant TB, continued efforts to improve the quality of and access to basic services for TB prevention care and control should not be compromised.
- (4) Action by TB control programmes alone will not be enough to address the challenges. It is only through bold and radical policy changes, going well beyond the remit of national TB control programmes, that M/XDR-TB can be halted. These changes are integral to the strengthening of health systems and services, which is a primary responsibility of all governments as well as the private sector. TB prevention, care and control services should be equitable, accessible, available, affordable, acceptable and have a comprehensive coverage to ensure effective prevention, early diagnosis and prompt treatment.
- (5) TB is a disease of poverty, underlining the importance of addressing various issues including the social determinants of TB, the economic and social conditions and risk factors – and their distribution among the population – that influence individual and group differences in health status and access to health care. The risk factors are found in one's living and working conditions (such as the distribution of income, wealth, influence, and power), and influence the risk of being exposed to TB infection and disease.

## **8.2 Recommendations for Member States**

- (1) A re-invigorated high level political commitment to prevent and combat M/XDR– TB must be ensured.
- (2) National TB programmes and the private sector should acknowledge and promote TB prevention, care and control services for the public good based on evidence, public health approaches, ethical values and human rights principles.

- (3) Policies and strategies addressing the underlying social determinants of TB should be included in comprehensive country- specific national strategic plans.
- (4) Efforts to achieve universal access to diagnosis and treatment of M/XDR TB, should be accelerated, in particular:
  - strengthening collaboration and coordination between different components of public health services, and between public and private health care providers;
  - strengthening joint planning and coordination between NTP and key partners;
  - ensuring early and increased case detection of all TB cases;
  - implementing mandatory TB case notification;
  - strengthening and expanding laboratory networks by introducing new diagnostic tools, implementing quality assurance systems and utilizing all existing and newly established laboratories;
  - promoting the rational use of anti-TB drugs and pharmacovigilance in the public and private sectors;
  - ensuring uninterrupted availability of sufficient amounts of first and second line anti-TB drugs free of charge to patients via NTPs and innovative PPM mechanisms;
  - strengthening and implementing patient support mechanisms;
  - strengthening coordination and collaboration for cross-border TB prevention, care and control activities;
  - ensuring adequate TB infection control measures in health care facilities and congregate settings;
  - making available sufficient numbers of competent and motivated staff at all levels.
- (5) Comprehensive national strategic plans should be updated, based on an in-depth assessment of the epidemic, including the full financial demand to ensure universal access and

identification of funding gaps, to secure sufficient domestic and external financing for TB prevention, care and control.

- (6) Regional collaboration and coordination for TB prevention, care and control activities targeted at migrant populations should be strengthened.
- (7) Operational research promoting new interventions in diagnostics and treatment such as shorter drug regimens for the treatment of MDR-TB should be encouraged.

### **8.3 Recommendations for WHO, technical and financial partners**

- (1) Technical support should be provided to countries in the South-East Asia Region to develop and implement national strategic plans by which universal access to diagnosis and treatment of M/XDR in the public and private sectors is ensured by WHO and technical partners.
- (2) Establishment of regional PMDT training centre to provide support to strengthening managerial and technical capacities for the management of drug-resistant TB within the region should be explored by WHO.
- (3) It must be ensured by The Global Fund that funding decisions are based on a comprehensive analysis of the burden of disease as well as the GDP, are need-based and realistic and allow for appropriate re-programming for combatting DR-TB.
- (4) Support to Member States and organizations to conduct relevant operational research that will feed into future policy development should be provided by WHO and technical partners.
- (5) The possibility of a regional proposal to address cross-border issues and the treatment of migrants should be explored by WHO, technical partners and The Global Fund.
- (6) Technical assistance should be provided to countries, upon their request, in designing appropriate protocols for the introduction of the shorter treatment regimen for MDR-TB patients and in implementing said regimen by WHO and technical partners.

## **Annex 1**

# **Agenda**

- (1) Introduction
- (2) Regional and country response to the M/XDR-TB and challenges
- (3) Health systems perspective in prevention of M/XDR-TB
- (4) Engaging all care providers in preventing and managing TB
- (5) Turning off the tap – supporting structures and agencies
- (6) Scaling up the treatment and care of drug-resistant TB
- (7) Conclusions, recommendations and next steps

## Annex 2

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### **Annex 3**

## **Opening address by Dr Samlee Plianbangchang, WHO Regional Director for South-East Asia**

Dr Chanvit, Distinguished participants; Honourable guests; Ladies and gentlemen;

With great pleasure, I welcome you all to the Regional Meeting on Combating Drug-resistant TB.

I very much thank all participants for sparing their valuable time to attend this important meeting especially in view of the fact that drug-resistant TB is an emerging regional and global concern. Drug-resistant TB is potentially threatening the global health security. For the South-East Asia Region, given the large number of TB cases, there is an estimate of almost 90 000 multidrug-resistant TB cases.

It may, however, be kept in mind that this number could be only the “tip of an iceberg”. In 2011, MDR-TB in the Region accounted for nearly one quarter of the world’s estimate. Extensively drug-resistant TB (XDR-TB), which is the most severe form, has been reported from five countries of the Region.

The treatment of MDR-TB or XDR-TB needs second or third line drugs which are expensive. The situation creates financial burden to TB control programme. The priority in addressing MDR-TB remains the prevention of “acquired” drug resistance by ensuring higher case detection and higher cure rate from treatment, particularly through the high-quality DOTS services.

The national TB control programmes have recognized the need for urgently addressing the existing pool of MDR-TB cases. In this connection, in 2011, WHO South-East Asia Regional Office published and disseminated the Regional Response Plan for Care and Control of MDR-TB.

In 2012, the regional Green Light Committee Secretariat was established in the Region. It is an advisory body to help ensure scaling up of the implementation of programmatic management of drug-resistant TB. Under this secretariat, a Regional Advisory Committee on MDR-TB was formed to provide policy and strategy guidance.

While attempting to overcome MDR-TB and XDR-TB, we must understand our constraints in TB control in the Region. In both technical and managerial terms; our health systems infrastructures are weak, under financed, and, therefore overstretched. These constraints must be overcome if we are to ensure universal access to critical interventions in TB control. We must ensure reaching the 'hard-to-reach' or 'unreached' through community actions and primary health care approach, which are multidisciplinary and multisectoral. Ladies and gentlemen; in recognition of TB as a disease of poverty, effective TB control has to go far beyond DOTS to encompass, among other things, nutrition and environmental factors.

Along with medical interventions, related social and economic issues have to be simultaneously tackled. These non-medical aspects of TB control are important indeed in the prevention and control of MDR-TB and XDR-TB for achieving long-term results.

While highlighting the global and regional emergency of MDR-TB and XDR-TB, I would like to see that during this meeting we renew our firm commitment to intensifying TB control efforts in both public and private sectors. Successful TB control activities indeed need support from all partners and stakeholders in both short and long terms. Successful interventions against MDR and XDR-TB can be achieved only through universal access to effective prevention, early diagnosis, and prompt treatment.

These efforts will certainly contribute to the achievement of related targets of MDG6 by 2015. Robust information systems are needed at different levels of health care facilities in countries to ensure accurate reporting of MDR-TB, under the national TB control programmes.

Opportunity during this meeting should be mainly used to learn from the experiences in our Region and elsewhere which will be useful for more effective planning of the next steps in addressing the drug-resistant TB in the South-East Asia Region, keeping in mind that our efforts in MDR and XDR-TB prevention and control, are our contribution to the global health security.

With these words, ladies and gentlemen, I wish the meeting all success in meeting its planned objectives.

Thank you.

Drug-resistant tuberculosis (DR-TB) threatens global and regional tuberculosis (TB) control and is a major public health concern in several countries. The challenges and bottlenecks, and the need to confront the various issues, highlight the crucial importance of advocacy and commitment. They also make us understand that solutions cannot be found solely within national TB control programmes, but will require high level policies and broad strengthening of essential elements of the entire health system.

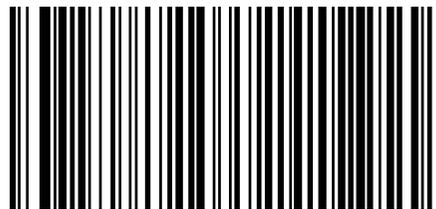
The meeting of the National TB Control Programme Managers of the South-East Asia Region has provided a great opportunity to review the status of drug resistant TB and national response to its prevention and control, augment awareness on control of drug-resistant TB and the consequences to communities and health systems, and identify the way forward in Member States in ensuring universal access to high-quality care to all people with TB and seeking possible support from various international partners.



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