The Regional Advisory Committee on MDR-TB, also known as the regional Green Light Committee (r-GLC), functions as an advisory committee to the WHO Regional Office for South-East Asia, WHO Member States in the South-East Asia Region, as well as donors and partners.

The eighth meeting of the SEA r-GLC was held in Bangkok, Thailand, on 8–10 March 2016. Participants at the meeting discussed challenges and opportunities in controlling DR-TB in the Region and reviewed and endorsed the country mission reports on the programmatic management of drug-resistant tuberculosis (PMDT) undertaken during 2015 and in early 2016.

Participants also discussed extensively technical issues related to universal access to MDR-TB services; the safety monitoring of drugs used to treat DR-TB patients; and supporting the scale-up of MDR-TB in countries in the Region. The current overarching WHO PMDT policies and guidance, including recommendations on the use of Group V drugs and repurposed drugs in the treatment of DR-TB patients, as well as ethics and palliative care was also discussed thoroughly along with next steps in PMDT implementation in the South-East Asia Region.
Multidrug-resistant Tuberculosis

Report of the Eighth Meeting
of the Regional Advisory Committee
on MDR-TB (r-GLC SEAR)
Bangkok, Thailand, 8–10 March 2016
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acronyms</td>
<td>v</td>
</tr>
<tr>
<td>1. Background</td>
<td>1</td>
</tr>
<tr>
<td>2. Objectives</td>
<td>2</td>
</tr>
<tr>
<td>3. Opening session</td>
<td>2</td>
</tr>
<tr>
<td>4. Endorsement of the “Seventh MDR-TB Advisory Meeting Report”</td>
<td>3</td>
</tr>
<tr>
<td>5. Field visit</td>
<td>3</td>
</tr>
<tr>
<td>6. Challenges and opportunities in controlling drug-resistant TB in the South-East Asia Region</td>
<td>5</td>
</tr>
<tr>
<td>7. Recommendations from the regional NTP managers’ meeting on MDR-TB (October 2015)</td>
<td>6</td>
</tr>
<tr>
<td>8. Review of country mission reports</td>
<td>8</td>
</tr>
<tr>
<td>9. Recommendations on experience-sharing workshop on the introduction of new drugs for DR-TB in South-East Asia and Western Pacific Regions</td>
<td>8</td>
</tr>
<tr>
<td>10. Update on current overarching WHO PMDT policies and guidance, including recommendations on the use of Group V drugs and repurposed drugs in the treatment of DR-TB patients and ethics and palliative care</td>
<td>8</td>
</tr>
<tr>
<td>11. Safety monitoring of drugs used to treat DR-TB patients</td>
<td>9</td>
</tr>
<tr>
<td>12. Next steps</td>
<td>9</td>
</tr>
</tbody>
</table>

### Annexes

<table>
<thead>
<tr>
<th>Annex</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Agenda</td>
<td>11</td>
</tr>
<tr>
<td>2. List of participants</td>
<td>12</td>
</tr>
</tbody>
</table>
### Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BDQ</td>
<td>Bedaquiline</td>
</tr>
<tr>
<td>DST</td>
<td>Drug susceptibility test</td>
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<tr>
<td>FQ</td>
<td>Fluoroquinolone</td>
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<tr>
<td>EQA</td>
<td>External quality assessment</td>
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<tr>
<td>GF</td>
<td>Global Fund</td>
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<tr>
<td>GDF</td>
<td>Global Drug Facility</td>
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<tr>
<td>GDI</td>
<td>Global Drug-Resistant Tuberculosis Initiative</td>
</tr>
<tr>
<td>IEC</td>
<td>Information, education and communication</td>
</tr>
<tr>
<td>IOM</td>
<td>International Organization for Migration</td>
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<td>KNCV</td>
<td>Royal Dutch Tuberculosis Association</td>
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<tr>
<td>MDR-TB</td>
<td>Multidrug-resistant tuberculosis</td>
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<tr>
<td>MoU</td>
<td>Memorandum of understanding</td>
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<tr>
<td>NSP</td>
<td>National strategic plan</td>
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<tr>
<td>NTP</td>
<td>National tuberculosis programme</td>
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<td>NTRL</td>
<td>National tuberculosis research laboratory(ies)</td>
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<td>PMDT</td>
<td>Programmatic management of drug-resistant tuberculosis</td>
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<tr>
<td>PPM</td>
<td>Public–private mix</td>
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<tr>
<td>PV</td>
<td>Pharmocovigilance</td>
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<td>rGLC</td>
<td>Regional Green Light Committee</td>
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<td>RR TB</td>
<td>Rifampicin-resistant Tuberculosis</td>
</tr>
<tr>
<td>R&amp;R</td>
<td>Recording &amp; Reporting</td>
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<tr>
<td>SEAR</td>
<td>South-East Asia Region</td>
</tr>
<tr>
<td>SLD</td>
<td>Second-line drugs</td>
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<tr>
<td>Acronym</td>
<td>Definition</td>
</tr>
<tr>
<td>--------</td>
<td>------------------------------------------------</td>
</tr>
<tr>
<td>SLI</td>
<td>Second-line injectable</td>
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<tr>
<td>TB</td>
<td>Tuberculosis</td>
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<tr>
<td>TWG</td>
<td>Technical working group</td>
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<td>UHC</td>
<td>Universal health coverage</td>
</tr>
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<td>XDR-TB</td>
<td>Extensively drug-resistant tuberculosis</td>
</tr>
</tbody>
</table>
1. **Background**

In South-East Asia Region (SEAR), 33,264 (MDR-TB) cases were confirmed as Rifampicin-resistant or multidrug-resistant TB and 28,536 cases were started on MDR-TB treatment in 2014, which represented only 34% and 29%, respectively, out of the estimated 99,000 MDR-TB cases among notified TB cases. The treatment success rate of MDR-TB in SEAR in 2014 was 49% as oppose to the global average of 50%. Extensively drug-resistant TB (XDR-TB) had been reported by six countries in SEAR.

MDR-TB is a form of TB that is difficult to treat with standard first line anti-TB drugs because of resistance to isoniazid and rifampicin, the most efficacious drugs developed so far. At the Sixty-Second World Health Assembly in May 2009, Resolution WHA62.15 was adopted and Member States urged to develop and implement long-term plans for TB, including MDR-TB and extensively drug-resistant tuberculosis prevention and control, in line with the Global Plan to Stop TB 2006–2015. One of the actions taken to implement this resolution was to establish the Green Light Committee Initiative to help countries gain access to high-quality second-line anti-TB drugs, to enable them to provide treatment for people with MDR-TB in line with WHO guidelines, the latest scientific evidence and country experiences. In response to the need for scaling up the programmatic management of drug-resistant tuberculosis (PMDT) in the WHO South-East Asia Region, a Regional Advisory Committee on MDR-TB, also known as the regional Green Light Committee (rGLC SEAR), was established in 2012. The rGLC functions as Advisory Committee to the WHO Regional Office for South-East Asia, WHO Member States in the South-East Asia Region (SEAR), as well as donors and partners.

The first and second meetings of the Committee were held in May 2012 and December 2012 at the WHO Regional Office for South-East Asia, New Delhi, India; the third and fourth meetings were held in April 2013 and November 2013 in Thimphu, Bhutan, and in Jakarta, Indonesia, respectively; the fifth, sixth and seventh meetings were held in May 2014, February 2015 and August 2016 in Mumbai, India; Dhaka, Bangladesh;
and Mandalay, Myanmar, respectively. During these meetings, the Committee reviewed and endorsed the country mission reports on PMDT and extensively discussed issues related to the scale-up and implementation of PMDT in countries of the Region. The eighth meeting of the rGLC was held in Bangkok, Thailand, from 8–10 March 2016.

2. **Objectives**

Dr Md Khurshid Alam Hyder, Regional Adviser – Tuberculosis (RA-TB), WHO Regional Office for South-East Asia, presented the objectives of the meeting. As stated, the overall objective of the meeting was to provide guidance on PMDT to the rGLC SEAR.

Specific objectives of the eighth meeting were to:

1. Organize a field visit to provide an opportunity to the rGLC SEAR to review the current progress and further guide on the planned scale-up of PMDT in Bangkok;

2. Review activities planned and progress made based on recommendations of the seventh MDR-TB Advisory Committee meeting;

3. Share and discuss new technical updates on PMDT;

4. Set the way forward for the next six months on PMDT scale-up in countries of the Region

(see Annex 1 for agenda of the meeting).

3. **Opening session**

Dr Daniel Kertesz, WR Thailand, conveyed his regrets for not being able to attend the eighth meeting of the Regional Advisory Committee on MDR-TB due to other impending priorities and sent his best wishes to the Committee. Dr Mukta Sharma, Technical Officer, WHO Thailand, welcomed all the participants on his behalf.

Dr Hyder commenced by sharing the process undertaken by the rGLC Secretariat on renewal of the regional advisory committee and the steps taken on the appointment of the new Chair and Co-Chair of the
Committee based on voting by members. He announced and invited Dr Sarabjit Chadha, Deputy Regional Director, The Union South-East Asia Regional Office, New Delhi, and Dr Si Thu Aung, National TB Programme Manager, Myanmar, to take their positions as Chair and Co-Chair of the regional advisory committee, respectively.

This was followed by a round of introductions by all appointed members of the regional advisory committee, the NTP representatives from Thailand and WHO Country Office staff from India, Myanmar, Thailand and Democratic People’s Republic of Korea; and high MDR-TB burden countries of the region.

The Chair and Co-chair welcomed all participants and expressed gratitude to the members of the regional advisory committee for entrusting them to lead the Committee for the new tenure. They also requested all participants for their cooperation to fulfill the responsibilities and expectations from the rGLC regional advisory committee in their advisory role to the WHO Regional Office for South-East Asia, WHO Member States in SEAR, as well as donors and partners in promoting scale-up of PMDT in the Region.

4. **Endorsement of the “Seventh MDR-TB Advisory Meeting Report”**

Dr Sarabjit Chadha, Chair of MDR-TB Advisory Committee SEAR, requested all members of the newly appointed regional advisory committee to provide their observations and inputs on the recommendations of the seventh meeting. As there were no specific observations and inputs from any of the members including the members who participated in the seventh MDR-TB advisory committee, the report was endorsed by the Committee.

5. **Field visit**

A field visit was organized on the first day of the meeting to provide an opportunity for Committee members to review the current progress and further guide on planning the scale-up of PMDT in Bangkok, Thailand. Members visited the Bureau of Tuberculosis, Department of Disease
Control, Ministry of Public Health, Nonthaburi, Bangkok, where the Bureau of TB (BTB) presented the progress and plans of PMDT scale-up in Thailand. The discussion covered differential access of services among beneficiaries of various national health insurance schemes for insured patients, challenges in national TB data pooling from various health insurance in “TB CM online”, the initiatives proposed under the Global Fund New Funding Model to cover the uninsured patients, its transition planning and the updated PMDT guidelines and service delivery layout in Thailand. This was followed by a visit to the Central Chest Institute of Thailand where the detailed epidemiological and programmatic updates were presented that lead to deliberations around the need for a national Drug Resistance Surveillance (DRS), addressing Isoniazid monodrug- and polydrug-resistance with rifampicin susceptible, the new diagnostic algorithms and treatment regimens including Bedaquiline introduction plans were discussed. At the institute, members also visited the TB clinic and supra-national reference laboratory to observe patient management, diagnosis and treatment services for drug-resistant TB cases and infection control practices in the institute. Overall, the members made the following observations:

- Commendable National Health Security Office integration to cover cost of diagnosis and treatment
- Good infection control (IC) policies and practices
- Good information, education and communication (IEC) material
- PMDT services appeared centralized posing access challenges to patients from distant rural districts.

In relation to the deliberation made during the session based on the field visit, the following recommendations were made by the rGLC to BTB Thailand:

- A repeat DRS is planned in 2017 by BTB Thailand. The regional MDR-TB advisory committee suggests the following points to be considered:
  - Use phenotypic and genotypic methods for DST to at least Rifampicin (R), Isoniazid (H), Fluoroquinolone (FQ), second-line injectable (SLI) and other WHO-recommended DST as relevant to programmatic practice in Thailand.
Consider reframing the DRS to include an adequate representation of insured and uninsured TB patients and possibly children and revise the sampling methodology accordingly.

Calculate the budget implication of the aforesaid revisions (e.g., adding genotyping methods, FQ, and SLI; new sampling frame) and mobilize funds accordingly from domestic and external sources.

Consider requesting external technical assistance (TA) to support protocol revision, survey implementation and survey analysis from WHO, KNCV, USA CDC and countries from the Region.

The country must plan to ensure that DRS results, when available, are translated into public health action and evidence-based PMDT policy and systems updates (e.g., surveillance, target setting, screening algorithm, treatment cascade, regimen selection, decentralization, etc.).

- Ensure a uniform policy for diagnosis and case management for both insured and uninsured DR-TB patients.
- Develop harmonized real-time TB surveillance, data management and monitoring system to avoid duplication across various fragmented databases (TBCM, NHSO, etc.).
- Based on the brief and limited observations and discussions during the field visit, the Committee recommends that a more comprehensive PMDT review be made that may be combined with other planned national TB review missions for Thailand.

6. Challenges and opportunities in controlling drug-resistant TB in the South-East Asia Region

Dr Hyder, RA-TB, WHO/SEAR, gave a presentation on the DR-TB situation, challenges, opportunities and priority issues in addressing DR-TB in the SEA Region. He highlighted the challenges in the Region such as the need for sufficient prevention measures and efforts, low case detection and low treatment outcome. However, he also mentioned that there are opportunities in the Region to capitalize on, such as the growing global
attention on TB and DR-TB (World Health Assembly resolution on MD-TB in 2009 and TB elimination in 2015). There are several global guidance tools in the process of finalization such as the End TB Strategy and its operation essentials; regional and country adaptation and implementation plans. Furthermore, there is growing government commitment and increased domestic funding on TB and MDR-TB; support of many partners and donors; universal health coverage and social protection issues coming in a big way globally, regionally and in countries where there is an opportunity for TB to be included in the essential package of UHC. Development of new drugs and diagnostics and strong partnerships with strong engagement of the private sector, CSOs’ and community power are providing impetus to the collective response against MDR-TB.

The Regional Advisor TB also highlighted four priority actions that are crucial to accelerate the response against the MDR-TB epidemic: (1) Prevent MDR-TB as a first priority: scale-up rapid testing and detection of all MDR-TB cases. (2) Ensure prompt access to appropriate MDR-TB care including adequate supplies of quality drugs and scaled-up country capacity to deliver services. (3) Prevent transmission of MDR-TB through appropriate infection control. (4) Underpin and sustain the MDR-TB response through high level commitment, strong leadership across multiple government sectors, ever-broadening partnership, and financing for care and research.

7. **Recommendations from the regional NTP managers’ meeting on MDR-TB (October 2015)**

Dr Hyder, RA-TB, WHO/SEAR also presented the recommendations of the regional NTP managers’ meeting on MDR-TB held in Colombo, Sri Lanka, on 26–30 October 2015.

Both of the above presentations were followed by deliberations by the Committee members that covered the need for countries to know their DR TB epidemic among patients managed both in the public and private sectors; preventing transmission at health-care facility as well as at community levels; need to have ambitious scale-up plans and accelerate progress towards End TB strategy with universal DST and appropriate treatment of DRTB; enhancing DOT with engagement of family and community of patients; developing plans for laboratory capacity-building, infection control, biosafety and quality assurance in low-resource countries;
developing appropriate research questions that lead to better understanding of the transmission dynamic to guide on the best intervention within available scarce resources; unacceptably low treatment outcomes in MDR-TB with need for greater government commitment to address cost, psycho-socioeconomic issues, social determinants that promote acceptance and adherence to treatment.

As per the discussion, the following recommendations were made:

**rGLC Secretariat**

- Recommendations to countries from the regional advisory committee as well as the rGLC PMDT missions need to be strategic, practical, implementable and result-oriented.
- Preparation of a dashboard indicating progress, plans, challenges and actions are required for PMDT services in countries to the Committee. The rGLC Secretariat will coordinate to compile the information from countries to facilitate this.

**Member States**

- Countries need to invest in better understanding of the DR-TB epidemiology (inclusive of the private sector).
- Interventions for preventing transmission need to be taken beyond health facilities to the community level.
- Countries need to further strengthen patient-centred care harnessing the strengths of family and community with optimal use of e/m health solutions to support treatment adherence.
- To maximize defined public health benefits, allocation of resources for PMDT should be informed by robust, evidence-based and accepted methodologies.
- There is a need to closely monitor the uptake of DST for TB patients at risk of MDR-TB (retreatment, nonconverters and DR-TB contacts) to identify issues leading to delayed diagnosis of DR-TB.
- Countries need to systematically analyse and review progress of MDR-TB patients (quarterly cohort analysis), identifying and
addressing issues related to poor treatment adherence and unfavourable outcomes.

8. **Review of country mission reports**

Mission reports for Bangladesh, Bhutan, Nepal and Timor-Leste were reviewed and discussed by the Committee. The Committee suggested some minor changes to be incorporated in the final report and communicated these to countries, and in principle endorsed the four country mission reports.

9. **Recommendations on experience-sharing workshop on the introduction of new drugs for DR-TB in South-East Asia and Western Pacific Regions**

Dr Agnes Cornelle Gebhard, Director, KNCV Indonesia, presented the recommendations of the experience-sharing workshop on the introduction of new drugs for DR-TB in SEAR and WPR held in Bangkok, Thailand, on 20–23 October 2015. She clarified the queries and concerns raised by the members before moving to the next presentation.

10. **Update on current overarching WHO PMDT policies and guidance, including recommendations on the use of Group V drugs and repurposed drugs in the treatment of DR-TB patients and ethics and palliative care**

Dr Agnes, continued presenting the update on current overarching WHO PMDT policies and guidance, including recommendations on the use of Group V drugs and repurposed drugs in the treatment of DR-TB patients, and ethics and palliative care. She clarified the queries and concerns raised by the members before moving to the next presentation.
11. **Safety monitoring of drugs used to treat DR–TB patients**

Dr Agnes Cornelle Gebhard continued with her final presentation on safety monitoring of drugs used to treat DR-TB patients. She clarified the queries and concerns raised by members.

12. **Next steps**

Dr Sarabjit Chadha, Chair of the SEAR rGLC advisory committee, lead the process of framing the next steps for introduction of new/repurposed drugs (ND&R) for the treatment of DR–TB patients with inputs from the Committee members. The following next steps were recommended for the rGLC Secretariat and countries:

- Promote NTP and government commitment for early uptake of the new drugs and regimens (ND&R) for PMDT
  - Communication to countries and the rGLC consultants
  - rGLC reporting format should include this point

- Identify clinical centres of excellence for early adoption of ND&R (for instance, through compassionate use) while simultaneously developing national regulatory framework and support systems
  - Include in dashboard
  - rGLC consultants to report on this during the review mission

- Develop advocacy and training modules for establishing integrated aDSM systems (aligning PV and NTP requirements and systems, tools for clinicians)
  - Module development in progress (KNCV, SIAPS and WHO)
  - Identify master trainers from countries for capacity-building in the Region

- Ensure community engagement and advocacy as an essential element of the introduction and roll-out of the use of new and repurposed drugs
- Include in dashboard
- rGLC consultants to report on this during the review mission

➢ Promote and emphasize the importance of lab capacity: expansion of Xpert testing and deployment of SL LPA to ensure rapid patient triage: immediate and more accurate treatment selection;

➢ Promote development of effective engagement of private-sector providers in diagnosis and treatment of TB and MDR TB (push/pull/health insurance)

➢ Develop algorithms, tools and guidelines to provide support to clinicians

➢ Deploy effective sustainable community-based systems for patient support

➢ Actively promote the confidence-building for NTPs and clinicians by exchange with early implementer countries/clinics

➢ Actively identify support needs of countries, especially related to quantification/procurement/access to new and repurposed drugs – and facilitate access to TA

➢ Promote with manufacturers the registration of their products in countries

- Include in dashboard

➢ Promote the treatment of MDR-TB in children using Delamanid

- Include in dashboard

The draft recommendations that emerged from the eighth meeting were presented by Dr Malik Parmar, National Professional Officer, DR-TB, WHO India, and inputs were provided by the Committee members for finalization. These have been finalized and included at the relevant sections above in this report.

The meeting concluded with a vote of thanks by Dr Hyder, RA-TB, WHO SEARO.
Annex 1

 Agenda

1. Field visit to PMDT centers in Bangkok
2. Opening session
3. Objectives of the meeting
4. Endorsement of the “Seventh MDR-TB Advisory Meeting Report”
5. Discussion on the field visit
6. Challenges and Opportunities in Controlling Drug Resistant TB in SEAR- An update
7. Recommendations from Regional NTP Managers Meeting on MDR-TB (October 2015)
8. Review Country mission reports (Bangladesh, Bhutan, Nepal and Timor-Leste)
9. Discussion on the Recommendations on Experience Sharing Workshop on the introduction of new drugs for DR-TB in South East Asia and Western Pacific Regions
10. Update on current overarching WHO PMDT policies and guidance, including recommendations on the use of group V drugs in the treatment of DR-TB patients and ethics and palliative care
11. Safety monitoring of drugs used to treat DR-TB patients
12. Universal access to MDR-TB services
13. Supporting the scale-up of MDR TB
14. Next Steps: rGLC SEARO activities
15. Conclusions, Recommendations and closing
Annex 2

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Regional Adviser - Tuberculosis
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