

**Joint WHO SEARO-WPRO-HQ “Experience  
sharing workshop on the introduction of new  
drugs for DR-TB treatment in the WHO South  
East Asia and Western Pacific Regions”**

**24<sup>th</sup>-25<sup>th</sup> February 2016**

## **Day 1 (24th February 2015)**

### **Morning Session**

The Joint WHO South-East Asian Regional Office (SEARO)-Western Pacific Regional Office (WPRO)-Headquarter (HQ) “Experience sharing workshop on the introduction of new drugs for drug-resistant TB (DR-TB) treatment in the WHO South East Asia and Western Pacific Regions” was opened jointly by Dr Fraser Wares, Global TB Programme (GTB)/Laboratories, Diagnostics and Drug Resistance Unit (LDR) - Global Drug Resistant Initiative (GDI) Secretariat, Dr Khurshid Hyder, Regional Advisor, TB-WHO SEARO and Dr. Nobu Nishikiori, Coordinator, Stop TB and Leprosy Elimination, WPRO.

Dr Hyder welcomed the participants to the experience sharing meeting and informed the floor that the meeting will be informal without the usual formal inaugural session. Technical presentations and country experiences will be presented by the presenters followed by discussions. He also thanked the host country and the counterparts in Thailand led by Dr Chawetsan Namwat, the NTP Manager and Director of Bureau of Tuberculosis (BTB) for their support in hosting the meeting in Bangkok.

Dr Fraser Wares, WHO HQ/GTB/LDR-GDI secretariat, presented the background and objectives of the meeting.

### **Background**

Despite recent progress in the scale-up of MDR-TB services and care, progress is not keeping up with the targets of the 2009 World Health Assembly resolution 62.15. Case notifications are increasing slowly, but successful outcomes globally are only around 50%. New approved drugs, namely bedaquiline (Bdq) and delamanid (Dlm), as well as re-purposed drugs (classified by WHO as Group 5 drugs), are increasingly being used to treat multi-/extensively-drug resistant TB (MDR-TB<sup>1</sup>/XDR-TB<sup>2</sup>) patients. WHO issued interim policy guidance on Bdq use in mid-2013 and on Dlm in October 2014. But use of the drugs to date has been limited. It is imperative that adequate provisions for safe, rational and effective use of these drugs be put in place, including establishment of active drug safety monitoring and management (aDSM) systems, and it is important that regional Green Light Committee (rGLC) members are kept up to date with current WHO policy recommendations on the use of new drugs, as well as those in Group 5.

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<sup>1</sup> Multidrug resistance: resistance to at least both isoniazid and rifampicin

<sup>2</sup> Extensively drug resistance: resistance to any fluoroquinolones and at least one of the three second-line injectable drugs (amikacin, capreomycin and kanamycin) in addition to multidrug resistance.

**Objectives of the meeting were to:**

- provide an update on current WHO policy recommendations on the use of new drugs, as well as those in Group 5, in the treatment of DR-TB patients, and how to introduce the drugs into programmatic use;
- share experiences of countries and partner organizations who have introduced new and/or re-purposed drugs in to the treatment of DR-TB countries; and
- plan the next steps for the introduction of new drugs and re-purposed drugs for treatment of DR-TB patients in countries of the WHO South-East Asian and Western Pacific Regions.

Dr Fraser Wares presented the WHO Strategic Plan for rational introduction of new TB drugs and regimens in countries, the WHO Policy Implementation Package for introduction of new TB drugs/regimens in countries, and using the working example of the case of introduction of bedaquiline and the lessons learnt.

He also appraised the meeting on the WHO interim policy guidance on the use of bedaquiline in the treatment of MDR-TB and the five required conditions for introduction of the drug, namely: proper selection of patients; patient informed consent; treatment design based on WHO recommendations; close monitoring conditions; and active pharmacovigilance and management of adverse events.

**Discussions**

The meeting deliberated:

- 1) On the public health challenges of introduction of the new anti-TB drugs in countries and the implications for TB control programmes which requires determination of the optimal regimens for treatment of drug susceptible TB (DS-TB) and DR-TB under programmatic conditions; evaluation of patients' eligibility; assessment programmatic feasibility; evaluation of effectiveness and cost-effectiveness; ensuring proper safety monitoring – especially in case of accelerated/conditional approval; responsible use (appropriate indication, doses, drug combination(s); and treatment duration and preventing emergence of resistance.
- 2) On the operational challenges of developing an optimal regimen and introduction of new drugs under programmatic conditions.
- 3) The need for the WHO generic global guidance to be contextualized to the specific country context.
- 4) The need for the WHO interim policy guidance to be quickly updated in line with the changing and available evidence from the field.
- 5) Ensuring the availability of delamanid to the countries as WHO promotes the wider use of both bedaquiline and delamanid where appropriate.

- 6) Countries and partners need to rely on each other and share information and experiences.
- 7) The need to rapidly develop laboratory capacity for evaluating second line drug susceptibility and drug susceptibility testing (DST) for the new anti-TB drugs in the future.
- 8) The need for strengthening reporting systems for identification and triaging of patients and the appropriate use of the new anti-TB drugs.

Dr Dennis Falzon, WHO HQ/GTB/LDR presented on Active Drug Safety Monitoring and Management (aDSM) and its importance given the limited experience in use of the new anti-TB drugs and the risk of as yet unrecognized drug-drug interactions with the combination use of new and old anti-TB drugs, and the risk for loss of public confidence and NTP credibility. He presented the key steps in aDSM implementation and reminded the participants on the WHO advice to countries in relation to the use of the so termed “shorter regimens for MDR-TB”.

**Discussions focused on that:**

- 1) aDSM is a new concept and country adaptation of the implementation framework is crucial.
- 2) aDSM monitoring forms have been implemented in the UNION sites, and countries can learn from such experiences.
- 3) Countries should build on the existing system and avoid parallel systems of collection of data.
- 4) Countries and partners should follow the key steps in the implementation of aDSM, and make immediate use of the data, and contribute to global level information and data linkage.
- 5) There is need for causality assessment using the information collected.

The respective chairs of the rGLC SEAR, Dr Rohit Sarin, and the rGLC WPR, Dr Lee Reichman, updated the workshop on the progress of the SEAR and WPR rGLCs. Dr Rohit informed that SEAR has increased enrollment of the laboratory confirmed MDR-TB cases and reiterated the rGLC's role in providing technical support following the global level guidance for the shorter regimen and new drug introduction. Dr Lee Reichman in his presentation highlighted the rGLC mission to and the DR-TB status in Papua New Guinea, and the regional stockpile of second line drugs managed by the WPRO rGLC Secretariat.

It needs to be remembered that there are more than 9.6 million new active cases of TB globally that could be feeding into the pool of drug resistance. It might be a less exciting concept, but all these cases must be appropriately treated with current strategies (as well as new diagnostics, drugs, vaccines, and proper infection control measures) to avoid preventable MDR-TB and XDR-

TB being created. **Preventing active, drug-sensitive tuberculosis, or treating it properly, should be everybody's priority in order to prevent the development of further MDR-TB and XDR-TB cases.**

### **Afternoon session**

The representative of USAID informed participants on the USAID's perspective on the introduction and access to new drugs for DR-TB treatment, and presented an update on the bedaquiline "donation programme" and its coordination with other partners and programmes. The Memorandum of Understanding between USAID and Janssen was signed in December 2014, with the Donation Program starting on 1 April 2015 as a four-year program which will provide up to 30,000 treatments for eligible patients in 100 low and middle income countries. The bedaquiline will be provided through the Global Drug Facility (GDF). Eligible countries can go on the GDF website and fill out the drug procurement form. Countries can also request technical assistance (TA) to strengthen or develop any of the five areas listed in the WHO Interim Guidance on bedaquiline introduction. The main channels of TA provision for the introduction of Bdq are via the Challenge TB Project, led by KNCV and which is active in 24 countries, the MSH/SIAPS Project for the pharmacovigilance component, and the UNITAID supported endTB Project which aims to introduce both Bdq and Dlm in 17 countries.

### **Discussions focused on:**

- 1) The common barriers faced by countries including drug regulation issues, need for more evidence, and lack of funding for the companion drugs (mainly for linezolid [Lzd] and clofazimine [Cfz]). It was highlighted that USAID provides funds for the Bdq, but not for the companion drugs.
- 2) That the rGLCs can provide TA to support National TB Programmes (NTPs) to develop treatment protocols, assist with drug quantification and ordering, and support to build the required laboratory and human resource (HR) capacity (particularly for aDSM).
- 3) That the GDF negotiated price for Bdq may go down if more countries utilize larger quantities of the drug.
- 4) That the lead time for drug delivery is currently long (up to 6 -7 months for the production and 40-60 weeks for delivery). GDF is working on stockpiling of medicines. However drug regulation issues need to be sorted out long before the arrival of medicines to the countries.
- 5) In some countries the treatment duration is beyond 6 months e.g. in South Africa, the national consilium consisting of group of experts makes the decision to extend the administration of the drug beyond the current WHO recommendation of 6 months .
- 6) For compassionate use, the drug importation waiver in many countries is usually issued for just the one consignment.
- 7) The registration of new medicines is a major challenge in many countries. SIAPS is helping some countries to obtain the importation waiver for new drugs.

Dr Ernesto Jaramillo, WHO HQ/GTB/LDR, then presented on the current overarching WHO policies and guidance related to the programmatic management of drug-resistant TB (PMDT),

including recommendations on the use of Group 5 drugs and repurposed drugs in the treatment of DR-TB patients, ethics and palliative care. He informed the workshop participants that WHO is currently updating its policy on shorter regimens for MDR-TB based on advice received during a meeting of the Guidelines Development Group on the “WHO Guidelines for treatment of drug-resistant tuberculosis” held in November 2015. Bdq, Dlm, teridizone and Lzd were included in the WHO Essential medicines List (EML) in April 2015. He informed the workshop that in 2016, updated versions of several WHO TB and PMDT guidelines will be published, including: Drug Resistant TB Treatment guidelines; Guidance on use of bedaquiline; Drug Susceptible TB Treatment guidelines; Ethics of TB care prevention, treatment and control; TB infection control; and an updated edition of the PMDT Companion Handbook.

Later, there were presentations from countries and partner organizations who have introduced new and / or re- purposed drugs in to the treatment of DR-TB in SEAR countries.

**Bangladesh:** The presenter provided information on the endTB project funded by UNITAID. The objectives of the project are to accelerate uptake of new TB drugs and novel regimens, to generate evidence on safety and efficacy of new TB drugs and to facilitate change in evidence-based WHO recommendations. The endTB project aims to treat 2,600 patients in 15 countries. In Bangladesh, eligible patients for enrolment in the project are “pre-XDR-TB” and XDR-TB cases, contacts of DR-TB patients, patients having drug intolerance, patients who have failed an MDR-TB treatment regimen, and MDR-TB patients with other co-morbid diseases. The enrollment target for 2015-2019 years is 252 patients in Bangladesh, with enrolment of patients on treatment anticipated in March 2016. Key challenges faced during the implementation of the project have been the frequent changes in the NTP leadership, resource constraints (HR, technical, and financial), limited availability of drugs, problems with the registration of delamanid, and establishment of pharmacovigilance systems and inadequate resources for the monitoring of drug adverse events (AEs).

**Indonesia:** The presenter provided information on bedaquiline treatment and active pharmacovigilance (PV) implementation in Indonesia. The enrollment target is 100 patients and starting from September 2015, to date 16 patients have been initiated on treatment. Four treatment regimens are used. A total of 41 AEs have been observed in 16 patients. Serious Adverse Effects usually happened during the first 5 days of treatment. The most common AEs observed are nausea and vomiting. The main challenges faced are the low and slow intake of new patients onto treatment, moving from passive to active PV (time is needed to adapt people’s mindsets and the systems), delays in the custom clearance process, and the long lead time for procurement of the Bdq and the short expiry period of the drug.

**Thailand:** Dr Chawetsan Namwat, Director of the Bureau of TB, shared Thailand’s experience in introduction of new DR-TB drugs. To date, Thailand has enrolled 80 patients on new drugs - 20 XDR-TB cases and 60 “difficult to treat” MDR-TB and “pre-XDR-TB” patients. The country has followed the clearly defined PV framework and legal frame work under different terms and

conditions, including for compassionate use or in pilot projects, and using importation waivers, etc. for introducing new TB drugs.

**Myanmar:** Myanmar is implementing the endTB project with the support of MSF-H. Under the project, annually 20 patients will be enrolled onto treatment (10 HIV/TB co-infected patients from MSF cohorts and 10 non-co-infected patients from the Ministry of Health [MoH] cohorts). All non-co-infected patients will be treated by the regimen containing Bdq (provided by MoH). Co-infected patients may have access to Dlm as well as Bdq. Importation of new and repurposed drugs (Bdq, Dlm, Lzd, Imp, Cfz) to Myanmar is possible as an importation waiver for programmatic use of the drugs can be obtained if the drugs are donated by the funding agency or are supplied through the GDF.

#### **Discussions:**

- 1) Janssen first provided Bdq for compassionate use in 2011, and Otsuka Dlm in 2014. However Otsuka does not have clear guidelines on how to access Dlm for compassionate use. Partners in Health (PIH) are in discussion with Otsuka regarding access to Dlm.
- 2) Under the Challenge TB Project, KNCV currently does not have agreement regarding the provision of TA to countries to introduce Dlm.
- 3) Smart phone apps can be used to easily record and report AEs.
- 4) Some countries are implementing SMS-based PV to report AEs.
- 5) Indonesia has enrolled prisoners in to the on-going project in order that they have access to the new drugs. Of the 16 patients enrolled on treatment to date, 7 are prisoners.
- 6) It will be easy to follow patients beyond the treatment cohort in Myanmar as they are HIV-co-infected patients and come to health facilities on a regular basis.

#### **Day 2 (25th February 2015)**

##### **Morning Session**

Presentations continued from countries and partners in the WHO WPR.

**KNCV:** Dr Agnes Gebhard shared KNCV's approach to the introduction of the new anti-TB drugs. She shared KNCV's concept of patient triage leading to the appropriate treatment of MDR-TB patients with rational introduction of the new drugs. She also introduced the bedaquiline TA core project and activities, and introduction of Bdq with Challenge TB Project support and reasons for slow uptake of new drugs in the countries. In addition, she shared information on the EQUIP (Enhanced use of Quality drugs and Utilization of Innovative diagnostics for TB management in the Private sector) Project whose goal is increasing demand for quality TB drugs (first and second line) among private sector providers in Chennai, south India.

Dr Mamel Quelapio also shared KNCV's experiences of supporting the introduction of new anti-TB drugs in the Philippines and Vietnam. Although work in the Philippines started in 2013,

various delays, including the obtaining of ethical and regulatory clearances, slowed down the introduction of Bdq and Dlm in the country.

**Vietnam:** Dr M Phuong shared the country's systematic step by step approach to introduction of new anti-TB TB drugs in Vietnam, which led to a decision by the MoH to implement bedaquiline under an exploratory study, with a requirement for the study protocol to be approved by the national ethical committee, in three pilot sites. The first patient was enrolled on treatment in December 2015, and up to February 2016 a total of 10 patients had been enrolled on treatment. Strong commitment has been shown by the MoH to the introduction of the new drugs, and there has been excellent technical support provided by the partners (WHO, USAID, KNCV, etc).

**Papua New Guinea (PNG):** Dr S Hiashiri shared the experiences and challenges in introducing the new TB drugs in PNG. In particular, he shared the challenges and lessons learnt from use of new drugs and repurposed DR-TB drugs in Daru, Western Province, PNG.

**South Africa:** Dr Hanneljie Ferreira shared the experiences of introducing new drugs into the NTP in South Africa under the "Bedaquiline Clinical Access Programme (BCAP)" which started initially in five sites from March 2013, with staff trained in Good Clinical Practice (GCP) and with strict PV. After the first 200 patients, by which time Bdq had been registered in South Africa, the country wide roll out of Bdq was planned and the country has budgeted for 3,000 patients to receive bedaquiline in the coming 2 years. Major difficulties have been experienced in obtaining the companion drugs, especially Lzd, for use along with the Bdq.

A delamanid CAP is now planned for 200 patients who do not qualify being treated with Bdq.

Dr Jennifer Furin from the Department of Global Health and Social Medicine, Harvard Medical School, USA, shared global level experiences of the introduction of the new anti-TB drugs as monitored by the DR STAT Task Force of GDI. Globally 760 patients have received Bdq through expanded access/compassionate use programmes in Armenia, France, Georgia, Latvia and South Africa, with overall excellent outcomes seen in culture conversion rates of 76 to 99%.

## **Discussions**

- 1) A key component in the introduction of new anti-TB drugs is the requirement of adaptation of WHO global policy at the country level through the inputs of national expert committees and implementing partners.
- 2) There is the need for rigorous strengthening of national PMDT coordination and clinical committees.
- 3) There is the need to look at the social aspects of MDR-TB and XDR-TB disease, and for increased funding for patient enablers and psychological support.
- 4) Limited financial and human resources are an ongoing challenge in many countries.



- 5) There is an urgent need for increased access to delamanid.
- 6) Countries need to learn from the experiences of those countries who have introduced newer drugs successfully – there is no need to re-invent the wheel!

### **Global Fund (GF)**

Dr Fraser Wares presented on behalf of Dr Mohammed Yassin, Senior Disease Advisor, GF, on “Introduction and access to new drugs under the Global Fund’s new funding model”. Global Fund support has contributed significantly to scale-up of MDR-TB responses in many countries. MDR-TB and treatment targets are revised and more ambitious than ever before, and requests for GF support are aligned with the respective country’s National TB Strategic Plan, the WHO’s End TB Strategy, and the Stop TB Partnership’s Global Plan to Stop TB, 2016 - 2020. Countries are already accessing Global Fund support for the introduction of new drugs and shorter MDR-TB regimens following WHO recommendations. GF grants are already supporting the introduction of bedaquiline in a number of countries and will support the introduction of delamanid when the drug is available in the market. The agreement with WHO related to the work of the rGLCs was revised in mid-2015, and its term extended from April 2015 until December 2016.

### **Global Drug Facility (GDF)**

Ms Nigor Muzafarova presented on behalf of the GDF on improving access for quality assured TB medicines and diagnostics. GDF is an operating mechanism to support the Stop TB strategy to facilitate world-wide, equitable access to TB medicines and diagnostics, including new tools, across public and private sectors. GDF began supplying first line drugs in 2001 and added second line drugs and pediatric medicines in 2007. By 2010, GDF was the key source of GeneXpert, in 2014 of bedaquiline, and now in 2016 of delamanid. She also appraised the workshop on the GDF policies that are in place, and the availability of Group 5 drugs and the new dispersible paediatric anti-TB formulations via GDF.

### **Discussions**

- 1) The challenges related to delays of import license and waiver and off label use were deliberated on, with countries sharing their respective in-country processes.
- 2) Slow uptake of the new drugs, the short shelf life of the new drugs, their high price and the low demand are currently key challenges.
- 3) Several barriers to the use of bedaquiline and delamanid were identified. Major barriers identified included new drugs and companion drugs not being registered in many countries, the high cost of the drugs, and concerns over the potential side effects of the drugs. Countries need to identify the potential barriers in their respective settings and resolve as many of the identified issues prior to the and scale-up of the new drugs in the country.

- 4) The meeting suggested that all future GDF and PMDT/rGLC missions should include a needs assessment, and quantification and costing estimate for new drugs, such as bedaquiline and delamanid.

### **Afternoon session**

The afternoon session started with group discussions by the respective SEAR and WPR participants to plan the next steps for the introduction of new and re-purposed drugs for treatment of DR-TB patients in the two regions.

The next steps for the introduction of new drugs and re-purposed drugs for the treatment of DR-TB patients in the countries of the SEAR included:

- 1) To promote NTPs' and governments' commitment to the early uptake of new drugs and regimens for DR-TB patients under PMDT.
- 2) To promote the early implementation of the new drugs and regimens in centres of excellence, while simultaneously developing the wider regulatory frameworks and support systems.
- 3) To promote community engagement and advocacy as essential elements of the introduction and roll-out.
- 4) To promote and emphasize the importance of building the required laboratory capacity; expansion of Xpert machines.
- 5) To promote engagement of the private sector.
- 6) To develop algorithms, tools and guidelines to provide support to clinicians.
- 7) To advocate and develop tools for integrated aDSM .
- 8) To promote the confidence of NTPs and clinicians by exchanging of information and best practices with early adopters.

The next steps for the introduction of new drugs and re-purposed drugs for the treatment of DR-TB patients in the countries of the WPR included:

1. Quick country mapping for identification of respective country needs.
2. Based on the mapping exercise:
  - Provide TA on paediatric MDR-TB (new drugs)
  - Provide TA on PV
  - Issue recommendations for the administration of new drugs and shorter regimens (for example, increase of treatment duration beyond 6 months, etc)
  - Strengthen linkages with expert advice from the beginning
  - Strengthen linkages of the rGLC with the GDI
  - Quick assessment of laboratory capacity for 2<sup>nd</sup> line DST
  - Provide operational support during the process of introduction of new drugs
  - Advocate to increase political commitment, including funding
  - Provide TA on drug quantification and forecasting
  - Advocate for elimination of catastrophic costs related to access to PMDT services, including new drugs, for both patients and family

The meeting was closed with summary statements from the respective WHO Regional TB Advisors and rGLC Chairs, the Vice Chair of the GDI, and the representative of the GDI Secretariat. The respective rGLCs and Secretariats will now review and finalise the draft set of next step recommendations presented during the workshop in order to take the process forwards swiftly.

## Annex 1

### Agenda

Day 1 (24 February 2016)

Chair: Dr Rohit Sarin, SEAR rGLC Chair

09.00 – 09.15	Welcome and Workshop objectives	K Hyder, WHO SEARO, N Nishikiori, WHO WPRO, F Wares, GTB/ LDR – GDI Secretariat
<b>Session 1</b> 09.15 – 10.30	Objective: To provide updates on current WHO global and regional policies, guidance and plans <ul style="list-style-type: none"> <li>How to introduce the new and repurposed drugs into programmatic use for the treatment of DR-TB patients</li> <li>Update on current WHO policy recommendations on the use of new drugs (i.e. Interim Guidance on Bedaquiline and Delamanid) in the treatment of DR-TB patients</li> </ul>	GTB (F Wares)  GTB (F Wares)
<b>10.30 – 11.00 Coffee</b>		
<b>Session 1 ctd</b> 11.00 – 13.00	<ul style="list-style-type: none"> <li>Update on activities and progress of the SEAR and WPR rGLCs</li> <li>Safety monitoring of drugs used to treat DR-TB patients</li> <li>Discussions</li> </ul>	R Sarin, SEAR rGLC Chair & L Reichman, WPR rGLC Chair  GTB (D Falzon)  ALL
<b>13.00 - 14.00 Lunch</b>		
<b>Session 1</b> 14.00 – 15.30	<ul style="list-style-type: none"> <li>Perspectives on the introduction and access to new drugs for DR-TB treatment, and an update on the bedaquiline "donation programme" and its coordination with other partners and programmes</li> <li>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</li> <li>Discussions</li> </ul>	USAID (A Golubkov)  GTB (E Jaramillo)  ALL
<b>15.30 – 16.00 Coffee</b>		

<b>Session 2</b> 16.00 – 18.00	Objective: To share experiences of countries and partner organizations who have introduced new and/or re-purposed drugs for the treatment of DR-TB cases <ul style="list-style-type: none"> <li>• Presentation from countries and partner organizations who have introduced new and / or re-purposed drugs in to the treatment of DR-TB countries (SEAR)</li> <li>• Discussions</li> </ul>	H Hussain, IRD Bangladesh; T Salman (KNCV) & MD Augustin (NFDA), Indonesia; N Zarkua, MSF-H Myanmar; Representative, MoPH, Thailand  ALL
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**Day 2 (25 February 2016)**

**Chair: Dr L Reichman, WPR rGLC Chair**

<b>Session 2 continued</b> 09.00 – 10.30	<ul style="list-style-type: none"> <li>• Presentation from countries and partner organizations who have introduced new and/or re-purposed drugs in to the treatment of DR-TB countries (WPR)</li> <li>• Experiences from GDI DR STAT Task Force and South Africa</li> <li>• Discussions</li> </ul>	M Quelapio (KNCV), The Philippines; M Phuong (NTP) Viet Nam; S Hiashiri (HIV & Health System Improvement Project), PNG  J Furin (DR STAT Core Group representative); H Ferreira, South Africa  ALL
<b>10.30 – 11.00 Coffee</b>		
<b>Session 2 ctd</b> 11.00 – 13.00	<ul style="list-style-type: none"> <li>• Introduction and access to new drugs for DR-TB treatment under the Global Fund's funding model</li> <li>• Role of WHO in the introduction of new and re-purposed drugs for DR-TB treatment</li> <li>• Update from GDF on Group V products availability, policy to access these drugs and updated prices</li> <li>• Discussions</li> </ul>	Global Fund (F Wares on behalf of M Yassin)  WHO (SEARO, WPRO & HQ)  GDF (N Muzafarova & B Waning)  ALL
<b>13.00 - 14.00 Lunch</b>		
<b>Session 3</b> 14.00 – 15.30	Objective: To plan the next steps for the introduction of new drugs and re-purposed drugs for the treatment of DR-TB patients in the countries of the WHO South-East Asian and Western Pacific Regions <ul style="list-style-type: none"> <li>• Discussions</li> </ul>	ALL
<b>15.30 – 16.00 Coffee</b>		
<b>Session 3 ctd</b>	<ul style="list-style-type: none"> <li>• Discussions continued</li> </ul>	ALL

16.00 – 16.30		
16.30 – 17.30	Wrap up, next steps and closure	K Hyder, N Nishikiori, A Gebhard, R Sarin, L Reichman, F Wares

## Annex 2

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## Annex 3

### Group photo of the participants

