

**TUBERCULOSIS PROCUREMENT AND MARKET-SHAPING ACTION TEAM (TPMAT)
SUMMARY MEETING REPORT OF THE EIGHTH GENERAL MEETING**

21 June 2023, 9:00-11:00am EST / 3:00–5:00pm CET
Meeting Held Virtually

Background and Introduction

TPMAT—established in July 2016—is the key global forum bringing together stakeholders to address common market shaping and procurement challenges related to fragile TB commodity markets. TPMAT is comprised of procurers, donors, implementers, international organizations, regulators, WHO, civil society organizations (CSOs), and National TB Programmes (NTPs).

TPMAT serves as an umbrella for all stakeholders to align on issues and coordinate activities, irrespective of procurement modalities or funding sources, and works end-to-end across the TB product cycle. TPMAT’s goal is to create fast, expansive access to the highest quality TB products for people living with TB and the NTPs that serve them. TPMAT uses a number of tools including the GDF-managed [TB medicines dashboard](#) which shows the status of all TB medicines in relation to different institutional guidance documents.

Objectives and Overview

TPMAT’s June 21st virtual meeting was attended by 48 people including national programme representatives from Georgia, Ghana, Uganda, and Ukraine. The agenda and list of participants can be found in **Annexes 1 and 2**.

The objectives of the meeting were to:

- Review current formulations and use for the components of the BPaLM regimen to identify and align on potential development priorities for new formulations and fixed-dose combinations (FDCs) in the near term.
- Review the pricing trends of key medicines and regimens and discuss potential target prices for these medicines and regimens.
- Hear from one of TPMAT’s key partners—Unitaid—on the organization’s insights and priorities for TB.

The Global Drug Facility (GDF) opened the meeting by providing an overview of the TB Procurement and Market-Shaping Action Team (TPMAT) and summarizing recent TPMAT progress.

1. Progress on Priority Products and Regimens - Presenter: Brenda Waning (GDF)

TPMAT Progress Update

The TB medicines dashboard now shows that components of BPaLM—in particular, bedaquiline 100mg and pretomanid 200mg—are mostly aligned across the guidance documents. The exceptions are: 1) WHO prequalification for generic bedaquiline, although three products have been submitted and at least one product is anticipated to be approved within the year; 2) EML listing for pretomanid, although an application for inclusion of pretomanid was submitted in 2022 (the revised EML is expected by the end of 2023).

Paediatric formulations now exist for every WHO-recommended medicine, and child-friendly formulations are on the list of products prioritized for Global Fund investments in the new round of funding requests. Prices for BPaL and BPaLM are not far off the 2016 Médecins Sans Frontières (MSF) target price of US \$500¹ (\$563 and \$592 per treatment course respectively). Paediatric regimens start at \$640 for shorter regimens with prices increasing depending on treatment duration, age, and regimen composition.

Since a change in WHO guidance in 2022, 64 countries have requested pretomanid from GDF, resulting in a spike in demand for this medicine. This has led to an increase from 700 treatments per year to 27,570 treatments by mid-March 2023, a 3,500% increase, with 67% requested for urgent delivery.

GDF provides prospective procurement-related technical assistance in 50 priority countries, with countries at various stages of planning for/scaling up BPaLM following the December 2022 guideline release. Thirty-two GDF priority countries have now included BPaLM in their Global Fund funding requests, out of which 31 were supported by GDF to do so and 11 plan to do so in their Global Fund funding requests in the future.

Questions and Discussion

Palatability/Tolerability of Dispersible Medicines

“It is important to move beyond the idea of ‘relatively acceptable’ and move into the realm of ‘absolutely acceptable’.”

A point was raised about taste and palatability of dispersible/child-friendly medicines leading to the question of how acceptability should be measured, along with a discussion of innovations or practices that might make formulations more palatable or tolerable. There was a recognition that taste varies from culture-to-culture and individual-to-individual, and that this is not simply a problem unique to children with DR-TB (i.e., consideration should also be given to palatability for adults). An action point was recommended to follow up on this issue with the planning group.

Session 1: BPaLM for Drug-Resistant TB: Optimal Formulations and Target Prices - Facilitator: Lindsay McKenna, Treatment Action Group (TAG)

2. The TB-PRACTECAL Regimens for the treatment of RR/MDR-TB: Clinical Considerations in Implementation - Presenter: Jennifer Furin (Harvard Medical School and The Sentinel Project)

TB-PRACTECAL was a Phase III trial looking at a 24-week regimen composed of bedaquiline, linezolid, pretomanid, and moxifloxacin (BPaLM) for the treatment of drug-resistant tuberculosis (DR-TB). This evidence was used to support a WHO recommendation suggesting the use of the BPaLM regimen rather than 9-month or longer regimens. Countries are excited to roll out a shorter regimen with fewer drugs but there are implementation considerations. Key considerations for implementation include questions around 1) linezolid safety and how to manage drug toxicity; 2) different approaches towards bedaquiline dosing; 3) data on the safety of pretomanid. Other issues to be considered include 1) access to/availability of pretomanid; 2) countries electing to roll out BPaLM only in the context of operational research; 3) lack of eligibility of a number of populations with DR-TB (children, pregnant women, people with prior use of bedaquiline, linezolid, or nitroimidazoles); 4) new data are

¹ All further references to “\$” refer to USD.

due in the coming year (e.g., [EndTB](#)) and so guidelines may soon change. These questions influence the feasibility of developing a BPaLM fixed-dose combination (FDC).

3. Target Pricing for DR-TB Regimens: Revising the \$500 Target Cost - Presenter: Christophe Perrin (MSF Access Campaign)

The \$500 target price for generic DR-TB regimens was first put forth in 2016 following [a study of estimated generic prices for novel TB medicines](#) that could be achievable in the context of large-scale, competitive manufacturing. In the last 7 years, the TB market has changed rapidly. Older compounds now have multiple manufacturers. Due to work by GDF and other partners to stimulate competition among manufacturers, the price of most of these compounds has decreased significantly. Such outcomes demonstrate that target prices can serve to support competition and price reduction even with medicines for DR-TB which have very small markets. The example of these older compounds suggests ways in which supply security for newer medicines might evolve over time.

Even as prices for bedaquiline, delamanid, and pretomanid have decreased, there is potential for further price reductions. With the decrease in prices of component medicines, some organizations are already suggesting that a target price of \$150 BPaLM is achievable. MSF is revisiting its 2016 target price while taking several points into consideration: 1) the \$500 target price remains extremely high for many countries, especially if they are not procuring through GDF; 2) many countries (including those that have graduated from Global Fund or other donor support) are introducing flexibility in procurement rules to procure DR-TB medicines through GDF; 3) there has been little progress in terms of improving case finding and increasing the percentage of people with DR-TB on treatment, thus there is a stagnating market for DR-TB products despite price reductions.

4. Georgia - Presenter: Dr. Irma Khonelidze, National Centre for Disease Control and Public Health, Georgia

Georgia has a strong national TB programme (NTP) and is part of many clinical research projects, such as—since 2018—the ZeNix study. It has implemented the BPaL regimen in research contexts since January 2021, first with linezolid 1200mg, switching to linezolid 600mg in July 2022. The NTP hopes to begin BPaLM implementation in July 2023, and is expecting to treat 54% of all DR-TB cases with the regimen each year through 2025. Bedaquiline in Georgia has been implemented since 2015 and is used in all regions. Current drug order quantification is based on product label dosing (400mg once daily for 2 weeks, then 200mg 3 times per week), but treatment guidelines were also revised in June to also allow for ‘ZeNix dosing’ (200mg daily for 8 weeks followed by 100mg daily).

Decisions in Georgia on DR-TB regimen choice are driven by treatment protocols and the best interests of people with DR-TB, following updates to WHO guidance. Savings due to lower drug prices enable the government and donors to introduce new regimens and support improved treatment outcomes. Government savings from DR-TB medicine price reductions have been used for the introduction of new treatment regimens. Global Fund grant savings have been redirected to focus on case finding and other priority areas. Currently, 100% of first-line drugs and more than 80% of second-line drugs are covered by government funds with the intent to eventually cover 100% with government resources.

5. Ghana - Presenter: Dr. Yaw Adusi-Poku, National TB Control, Ghana Health Service

Ghana is preparing to transition to BPaLM. During operational research in Ghana, severe adverse events (e.g., bone marrow suppression) due to linezolid were reported. A major question for the NTP is how to adjust the dosing of linezolid moving forward and how an FDC of BPaLM could make this linezolid adjustment more difficult. Ghana intends to use BPaL (without moxifloxacin) for pre-XDR but is looking to its regional network—The West African Regional Network of Scientists—and WHO to guide it.

The dosing of bedaquiline in BPaLM follows WHO MDR-TB guidelines, which have been updated in Ghana's national guidelines. Bedaquiline dosing is 3 times per week. With respect to price reductions, Ghana's Global Fund funding has been reduced. While the NTP will advocate for the most effective and safe regimen, it also requires a lot of assistance. The \$500 target is good, but Ghana needs to engage with partners to see how savings from price reductions can be best used.

6. Uganda - Presenters: Dr. Raymond Byaruhanga, National TB and Leprosy Programme and Dr. Akello Atukun Susan, Mulago National Referral and Teaching Hospital, Uganda

Uganda expects to start BPaLM implementation in early-2024. The country is in the process of updating its MDR-TB guidelines and beginning to build capacity among health workers. The supply chain team is to start on quantification and procurement plans for BPaLM. They expect to scale up from 15% to 75% of DR-TB patients in a year. According to the NTP, linezolid 600mg will be maintained as much as possible but a dose reduction to 300mg, or total exclusion, will be considered on a case-by-case basis depending on the severity of side effects. Uganda is strengthening its adverse effects system to detect side effects early and manage them appropriately. Uganda also plans to maintain its current bedaquiline dosing of 400mg daily for the first two weeks, reduced to 200mg 3 times a week, and is continuing to use bedaquiline 3 times per week in other bedaquiline-based regimens

Uganda is committed to using regimens based on WHO recommendations and believes the large price reductions (from ~\$1500 to ~\$500) have been extremely important for MDR-TB programs in low-income countries. Further price reductions will help Uganda procure more doses of DR-TB medicines. The country is in the process of carrying out a drug resistance survey to give a better understanding of the burden of DR-TB in the country, which should also help increase the targets for number of people with DR-TB in care.

7. Ukraine - Presenter: Dr. Yana Terleieva, National TB Program, Ukraine

Ukraine approved the use of BPaL and BPaLM for eligible patients in programmatic conditions in January 2023, as per the new WHO recommendations. The NTP estimates that 45% of people with DR-TB are eligible for BPaLM (2,000-3,000 people per year). Therefore, Ukraine urges improved access to pretomanid. Ukraine also emphasizes that the new shorter regimens require access to reliable molecular diagnostics, social support, health worker and peer mentor training, and other technical inputs. Ukraine's NTP found 15% of people on linezolid develop side effects, with anaemia or neuropathy occurring in every 4 to 5 patients. Doctors typically prescribe 600mg every other day or reduce the linezolid dose to 300mg by dividing the tablet. The NTP plans to use the BPaL regimen for pre-XDR patients, who represent around 15% of all MDR cases. Ukraine doses bedaquiline according to its National Standards for the Treatment of TB and WHO recommendations: either 4 tablets per day for 14 days (2 weeks), then going to 2 tablets, 3 times per week or 2 tablets per day for 8 weeks (2 months) then

going to 100mg per day. In practice, doctors use both options. Ukraine plans to use the intermittent bedaquiline regimen in a subset of people who are more likely to adhere to avoid drug resistance

Ukraine receives Global Fund and GDF support but is looking for ways to achieve sustainable financing. Ukraine had been planning to transition to the financing of first-line and second-line medicines by the Ministry of Health. Presently, Ukraine is still dependent on donor support, and funding remains insufficient. Price reductions therefore remain necessary.

Summary of Country Programme Presentations

- Country programmes aim to implement WHO recommended regimens. Price is less of a determining factor to the selection of DR-TB treatment regimens, but savings do make a difference to scale-up of BPaLM and other innovations and enable programs to fill gaps.
- Side effects from linezolid and corresponding dose adjustments are commonplace in programmes.
- There is some variety in terms of what programs are planning to do with bedaquiline dosing in the BPaLM regimens (e.g., daily dosing versus intermittent dosing).

Facilitated Discussion

Facilitator: Christophe Perrin, MSF

KEY POINTS

Perspectives on the Need for BPaL/BPaLM FDCs and Possible Solutions

“There is a lot of space to look at practical delivery of these regimens in the field, especially in those sites where it is difficult to administer medications to the elderly, very sick people in hospital, or children.”

Discussion centred around the issues with implementation of BPaLM that challenge the development of FDCs, including lack of consensus around dosing of bedaquiline, dose adjustment/discontinuation of linezolid, and uncertainties around use of moxifloxacin. Additionally, there remains a lack of data on some subpopulations. As additional data is published, guidelines on dosing may change. Co-packaging and innovative delivery technologies were both raised as potential options in lieu of an FDC.

Perspectives on the \$500 Target Price: Focus on Medicine Price Reduction or Case Finding?

“If you cannot access diagnostics, the best treatment regimens in the world will have very little impact.”

Several participants raised the point that DR-TB treatment demand was presently stagnant, suggesting that significant decreases in price have not led to scale up of DR-TB treatments, particularly among priority populations. A key area discussed was case finding, in particular diagnostics for case finding. Countries are seeking Global Fund financing for the BPaLM regimen and have been including diagnostics and case finding in their grants. Further reduction of BPaLM prices might result in savings that can be redirected to finding more people with DR-TB and supporting them to complete care. It was recognized that price, demand, diagnostics, and support for treatment adherence are all interconnected issues and priorities are increasingly moving toward offering the best diagnostic pathways.

BPaLM Scale Up Challenges

The big challenges countries mention in relation to BPaLM scale up are sub-optimal drug susceptibility testing and lack of full understanding of countries' DR-TB burdens, as well as case finding among priority groups

BPaLM and Side Effects

Country program representatives mentioned concerns related to BPaLM adverse effects such as severe anaemia and testicular toxicity. Technical stakeholders noted the role that linezolid plays in bone marrow suppression and that it is frequently associated with anaemia (up to 25% of patients) in the first 8 weeks of treatment. There are some studies going on now to look at how to optimally dose linezolid in different circumstances. Some studies are examining every other day dosing with the 600mg tablet since it is difficult to split tablets. When providers must stop linezolid, they typically need to switch to a longer regimen.

In terms of testicular toxicity, this was seen only in animal studies. The finding in animals led to the US FDA mandating a semen study in human males. The study is ongoing and results should be out later in 2023. Hormone levels in human males on pretomanid have not shown an effect. The pretomanid package insert states "Reproductive effects: Pretomanid caused testicular atrophy and impaired fertility in male rats. Advise patients of reproductive toxicities seen in animal studies and that the potential effects on human male fertility have not been adequately evaluated."

It was pointed out that trial populations are often very different to those accessing regimens in real life. There are priority groups such as pregnant women, children, and others who are excluded from BPaLM. However, in some countries there are many elderly people (or people not living with HIV) who have other comorbidities (e.g., chronic cardiovascular disease, etc.). It is important not to underestimate the populations that have been excluded from BPaLM research. There is a need to generate operational research data that leads to active surveillance of all these populations, do pharmacovigilance, and look at long-term outcomes. Programmes need to produce routine data, report on implementation and experiences of rolling out these regimens and collaborate regionally. WHO should provide support to do this.

BPaLM for People with Additional Resistance to Fluoroquinolones

In the TB-PRACTECAL trial, there were only 29 people with additional resistance to fluoroquinolones so, although their outcomes did not look different, the sample was still very small. There is presently the endTB-Q trial that looks specifically at fluoroquinolone resistance, but results are not yet out. The Nix-TB and ZeNix studies also included people who had fluoroquinolone resistance, but these were not controlled trials (i.e., they did not have a control regimen), and the numbers for these studies were also small. Countries are taking different approaches to treatment in the case of documented resistance to fluoroquinolones.

Bedaquiline Dosing

For bedaquiline, most providers use it 3 times per week though some programmes have daily dosing in their treatment guidelines.

SUMMARY OF FACILITATED DISCUSSION

- Participants feel it is important to carry on promoting implementation of the BPaLM regimen.
- Though it is important to continue aiming for more affordable TB regimens, it is also important that countries put savings to other purposes, including finding more people with TB.
- Countries are putting WHO recommendations and the needs of people with DR-TB before economic constraints.
- FDCs for BPaLM are not a priority at the moment.

Session 2: Partner Profiles and Updates - Facilitator: Denis Godlevsky (ITPC Eastern Europe and Central Asia (ITPC EECA), Eurasian Community for Access to Treatment (ECAT))

8. Unitaids Strategic Priorities - Presenter: Cherise Scott (Unitaid)

Unitaid's strategic objectives are to 1) accelerate introduction and adoption of key health products; 2) create systematic conditions for sustainable, equitable access; and 3) foster inclusive, demand-driven partnerships for innovation. They do this across 16 programmatic priority areas, many of which crosscut with Unitaid TB priorities (i.e., HIV and co-infection, diagnostics, long-acting technologies, and intellectual property, regulatory and other supply models).

Unitaid works across the entire care pathway on challenges related to prevention, testing, treatment, and support for people with DR-TB. For TB, UNITAIDs priorities are to 1) to enable TB prevention tools, including long-acting injectable TB preventative treatment (TPT) for high-risk groups; 2) accelerate access to new detection tools; 3) accelerate adoption of new drugs and regimens; and 4) evidence generation and optimization of adherence. There is also cross-cutting support and partner grants (i.e., Medicines Patent Pool (MPP), WHO Prequalification, and WHO Global TB Programme).

For prevention, Unitaid works to expand access to, and optimize use of, new and existing TB prevention tools, especially for high-risk groups. Active investments include [TB CHAMP](#) and [IMPACT4TB](#). For diagnostics, Unitaid seeks to accelerate and scale up new screening and detection tools, looking at integration of these tools with services and products targeting other disease areas and bringing these closer to communities. Active investments include the [Seq&Treat](#), [DriveDx4TB](#), and [Start 4-All](#). For treatment, Unitaid seeks to accelerate access to new drugs and regimens. Active investments include [ASCENT](#), [endTB](#) (including observational studies and clinical trials with the most recent endTB-Q study that seeks to enable the simplification of DR-TB treatment for people resistant to fluoroquinolones), and [BENEFIT Kids](#). The Unitaid board has also just endorsed new areas for intervention, including: 1) market shaping through coordination and reaching sustainable price and supply targets for key drugs and shorter TB regimens; 2) informing implementation in different geographies and contexts (including optimizing linkages to services and other disease programs); 3) demand creation and generation (including uptake of newer packages of care that think through responsible product introduction).

Facilitated Discussion

Facilitator: Dennis Godlevsky, ITPC/EECA and ECAT

KEY POINTS

Priorities for Unitaid

Unitaid has a number of priorities and active investments that crosscut TB. In the advanced HIV disease space, there is a package that includes TB. TB detection is also extremely important and Unitaid is trying to focus on diagnostics. There is an opportunity to leverage existing investments and think about how these link to the roll out of the new TB regimens. There is also a role for Unitaid in investing in adherence. Additionally, Unitaid is interested in how pharmacovigilance, operational guidance, and safety monitoring come into play. Unitaid would also like to play a role in ensuring a more holistic conversation around what needs to be introduced.

WRAP-UP

Brenda Waning thanked participants for attending and noted that presentations and a meeting report would be shared with participants, as would action points.

Consolidated Action Points

- Have a follow up discussion to think about taste and acceptability of dispersible medicines (not only for children, but also more broadly).
- Explore how TPMAT and partners can support adherence to TB regimens and to continue to monitor the landscape for new formulation, packaging, etc., need.
- Explore linkages with Unitaid's new strategy (market-shaping, informing implementation, demand generation).

Annex 1: Agenda

TB Procurement and Market-Shaping Action Team (TPMAT) Meeting

June 21, 2023, 9:00-11:00am New York / 3:00–5:00pm Geneva

Background

The TB Procurement and Market-Shaping Action Team (TPMAT) brings together procurers, donors, implementers, international organizations, NGOs, WHO, civil society, NTPs, and other stakeholders to address common procurement & market-shaping challenges inherent to fragile TB commodity markets. The group meets regularly to identify and prioritize issues and then align and coordinate on action plans towards a mutual goal of expedited and optimized access to TB products.

Objectives

The objectives of this TPMAT meeting are to:

- Review current formulations and use cases for components of the BPaLM regimen to identify and align on development priorities for new formulations and fixed-dose combinations (FDCs).
- Review the pricing trends of key medicines and regimens and discuss potential target prices for these medicines and regimens.
- Describe one of TPMAT’s key partners’ insights and priorities for TB.

Chair: Brenda Waning

15:00 – 15:20	Opening: Progress on priority products, regimens	Brenda Waning, GDF
Session 1. BPaLM for Drug-Resistant TB: Optimal formulations and target prices. Facilitator: Lindsay McKenna, Treatment Action Group (TAG)		
15:20 – 15:45	• Clinical considerations for FDCs of second-line medicines based on current evidence	Jennifer Furin, Sentinel Project
	• Target pricing for DR-TB regimens: Revisiting the \$500 target price Questions for participants	Christophe Perrin, MSF
15:45 – 16:10	• Georgia	Dr. Irma Khonelidze, National Centre for Disease Control and Public Health, Georgia
	• Ghana	Dr. Yaw Adusi-Poku, National TB Control Programme, Ghana
	• Uganda	Dr. Stavia Turyahabwe, National TB and Leprosy Programme, Uganda
	• Ukraine	Dr. Yana Terleieva, National TB Program, Ukraine
16:10 – 16:25	• Discussion, wrap-up, and next steps	Christophe Perrin, MSF
Session 2. Partner profiles and priorities Facilitator: Denis Godlevsky, ITPC Eastern Europe and Central Asia (ITPC EECA); Eurasian Community for Access to Treatment (ECAT)		
16:25 – 16:45	• TB Priorities at Unitaid	Cherise Scott, Unitaid
16:45 – 16:50	• Q&A	
AOB and Meeting Closure		
16:50 – 16:55	• AOB	
16:55 – 17:00	• Meeting closure and wrap up	Brenda Waning, GDF

Annex 2: List of Participants

Brenda Waning (Chair)

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