

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

23 October 2023, 9:00-11:00am EST / 2:00-4:00pm CET Meeting Held Virtually

Background and Introduction

The Tuberculosis Procurement and Market-Shaping Action Team (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, the World Health Organization (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 October 23rd virtual meeting was attended by 45 people. The agenda and list of participants can be found in Annexes 1 and 2. The objectives of the meeting were to:

- Summarize recent TB product price decreases, and identify next steps to optimize use of savings from these price decreases
- Provide stakeholder input on a current Global Fund strategic initiative on country readiness, and a process for establishing KPIs on new product uptake

SESSION 1: Pricing of TB Commodities, Progress, and Goals - Facilitator: Sharonann Lynch (O'Neil Center for Global Health Policy & Politics) and Denis Godlevskiy (ITPC-EECA)

1: Updates on Recent Changes in Pricing of TB Commodities - <u>Presenter</u>: Brenda Waning (Global Drug Facility)

There have been significant savings achieved from recent price reductions to fixed-dose combinations (FDC) of rifapentine and isoniazid for the three month, once weekly (3HP) regimen for TB preventative treatment (TPT), adult bedaquiline for drug-resistant TB (DR-TB) treatment, pretomanid, delamanid, and GeneXpert cartridges, resulting in expected savings of more than \$70 million per year globally (\$27 million in medicines alone). Over the 3-year Global Fund grant cycle, this equates to more than \$200 million in total global savings. TPMAT and its partners have



played a key role in creating an enabling environment for price reductions, most notably for bedaquiline in which interventions to expedite generic entry began taking place five years prior to patent expiry. The entry of multiple suppliers and resulting price reductions, however, creates challenges to market shaping. If demand does not increase despite these large savings, it becomes harder to support multiple suppliers for these products and more difficult to get price reductions from suppliers in the future. GDF regional technical advisors have started working proactively with National TB Programmes (NTPs) to see how NTPs can apply these savings to procurement of additional TB products.

2: Global Fund Grants and Price Reductions: What Does It Mean and What Next? Presenter: Grania Brigden (Global Fund)

The Global Fund is looking into the impact of the price reductions for Global Fund grants. In Grant Cycle 6 (GC6; 2021-2023), Global Fund invested \$730 million in TB health products, split almost 50/50 across various TB screening and diagnostic tools (\$378 million) and TB medicines (\$352 million). The impact of these price reductions is potentially immense. GC6 investment in GeneXpert cartridges was \$173 million for 15.7 million cartridges; with price reductions, total commodities could have amounted to 19.3 million cartridges. GC6 investment in bedaquiline was \$48 million for 166,000 treatment courses of bedaquiline; with price reductions, total commodities could have amounted to 369,000 treatment courses with J&J or 247,000 treatment courses with Lupin. GC6 investment in 3HP was \$27.9 million for 1.86 million treatment courses of 3HP; with price reductions, total commodities would have amounted to 2.79 million treatment courses of 3HP. The Global Fund notes that, within the Grant Cycle 7 (GC7; 2023-2025) grant application windows, many essential commodities are (particularly in Year 3) being placed within the Prioritized Above Allocation Requests (PAAR). The Global Fund has disseminated the price decreases to country teams and is advising that country savings coming from price-reduced commodities should go to covering commodity gaps. A Global Fund partner webinar was held in October to provide an overview of price reductions. An associated briefing note on FAQs around GeneXpert price reductions was created.

FACILITATED DISCUSSION — Facilitators: Sharonann Lynch and Denis Godlevskiy

KEY POINTS

Perspectives on How Savings from Price Reductions Should be Used

Many participants concurred with the Global Fund's assessment that essential commodity gaps in GC7 grants need to be covered as a priority, as many countries have bold targets for prevention, diagnosis and treatment. In particular, there remain serious commodity shortfalls around diagnostics, which were highlighted as a critical issue (i.e., countries cannot benefit from medicine/regimen price reductions if people with TB are not diagnosed). Countries' main objective, then, should be for savings from price reductions to be put toward ensuring these essential commodity gaps are filled. The Global Fund emphasized that their expectation is that countries should work to translate savings into finding more people with TB and enrolling them



on treatment. Attention needs to be directed toward advocacy by the global TB community around ensuring the TB space's limited resources are used in the best possible way.

Importance of Funding Interventions around Access to Commodities

One potential barrier to accelerating the scale up of both existing and new TB innovations identified by participants is technical assistance (TA) to countries. Innovations and new recommendations are now coming in extremely quickly, and some countries may have difficulty in absorbing new tools and products. It was also noted that there are many local partners that have the technical expertise to do this work and may only need limited support to implement. If countries use savings to fill existing commodity gaps, partners can then look to provide wraparound TA to support access. Scaling up diagnostics for DR-TB remains the biggest issue and this must be the priority in the coming years, as there will not be scale-up of medicines otherwise.

Research and Messaging Around the Benefits of Recent Price Reductions is Essential

Further analysis and discussion should take place to better understand how savings can translate into increased commodities and improved access, as well as how such issues are messaged. There already exist established coordination mechanisms to review countries' essential commodities gaps, as well as to analyze savings from price reductions in relation to Global Fund grants and national procurement plans. The message of what can be achieved dollar-for-dollar with savings is a good message, as is the message of how savings might translate into getting more people diagnosed and on treatment. There are meetings coming up for these issues to be discussed and communicated further (e.g., the Union conference, the TPMAT meeting, the Global Fund Board Meeting).

3: Safeguards for Sustaining Supply, Quality and Affordability while Shifting to National Procurement - Presenter: Sharonann Lynch

Co-financing of TB medicines has created a number of challenges to procurement of quality-assured TB medicines, especially related to country rules and regulations around national procurement with domestic financing. There are many benefits to pooled procurement (e.g., via GDF) including guarantees of quality assurance and the creation of healthy TB medicines markets with multiple generic suppliers which have led to more consistent supply and subsequent price reductions. Countries may not continue to procure internationally recognized quality-assured medicines when procuring domestically, either because they opt out of doing so or face legal restrictions affecting how and/or what they procure. Co-financing may remove a number of levers that both national TB programs (NTPs) and partners can use to maintain quality, avert stockouts, and potentially delay development of resistance to newer regimens such as bedaquiline. Questions remain as to the impact of the removal of such safeguards, and discussions are needed around the steps that national and global stakeholders might take to ensure that access to quality-assured medicines is not affected. It is also important to monitor, document, and measure the risks associated with co-financing versus pooled procurement.



SUPPLEMENTARY SLIDES: Assessment of Domestic Procurement of Child-Friendly DS-TB Medicines and Impact of National Procurement - Presenter: Brenda Waning

Graphs were presented describing procurement for pediatric FDCs for drug-sensitive TB (DS-TB) procured through GDF with trends related to the annual numbers of treatment courses procured. The volume of paediatric FDCs procured through GDF has been trending down over time. While the number of countries procuring from GDF since 2017 may appear stable in terms of overall numbers, these numbers mask the fact that GDF has started supplying to some high-income countries which are replacing low- and middle-income countries (LMICs) opting out of pooled procurement. GDF data also show that, out of 53 GDF priority countries, 32 used domestic financing to procure pediatric DS-TB medications. Of these 32 countries, only 9 procured from GDF. Twenty-three procured from local suppliers and, of these, 7 procured a mix of quality assured medicines and medicines of unknown quality, while 13 only procured medicines of unknown quality, including non-optimized formulations. More analyses are needed around the impact of domestic procurement on stock outs, price, and procurement of WHO-recommended medicines.

FACILITATED DISCUSSION - Facilitators: Sharonann Lynch and Denis Godlevskiy

KEY POINTS

Evidence on the Loss of Levers that Follow from Co-Financing Requirements

Participants gave examples from both projects and countries of the impact of loss of safeguards, including the difficulty in confirming procurement timelines or guaranteeing procurement forecasts to manufacturers, the need to adjust guidelines to take into account potential issues around non-optimized formulations and medicines of unknown quality, the existence of non-competitive bids when only a single manufacturer is registered in a country, and the increased likelihood of drugs of unknown quality being the only drugs qualified for procurement under national procurement rules. Evidence on and analysis of the impact of the loss of such safeguards could be a focus of future TPMAT meetings.

The Impact of Co-Financing on TB Medicines Quality

It is important to speak up collectively for TB medicines quality assurance continually. Many important mechanisms exist to help protect quality standards (ERP, WHO PQ, pooled procurement, etc.). Quality is especially important to avoid anti-microbial resistance (AMR) and, without mechanisms like GDF, addressing the AMR issue can add additional work for NTPs, such as monitoring quality at country and facility level. The Global Fund and partners are looking closely at how quality is measured.

TB Medicines Markets Need Engaged and Incentivized Manufacturers

There should be a priority around ensuring evidence-based products continue to be available and supporting manufacturers—especially those for DR and paediatric TB which have small markets. An important message to manufacturers and developers is that there is a market, even if it is small. Through pooled procurement and market consolidation, GDF is an important mechanism to stimulate product development and supply security.



SESSION 2: Global Fund Strategic Initiative - Facilitator: Stijn Deborggraeve (MSF)

4: Update on the Global Fund Strategic Initiative: Next Generation Market Shaping and How It Pertains to TB Diagnostics - Presenter: Melanie Kitongo (Global Fund)

The Global Fund has launched its new 3-year Next Generation Market Shaping strategic initiative (SI) that aims to support the new Global Fund Strategy (2023–2028) and catalyze impact of new health product introductions across HIV, TB, and malaria programs. Of relevance to TB is the SI workstream "Accelerate Health Product Introductions at Scale" which will invest \$35 million across all three diseases to address barriers that affect the scale up of new products. This workstream includes support for country readiness to ensure that communities have tools and systems in place to introduce new health products. The focus of the SI for TB will be primarily on diagnostics. The amount of funding for this workstream is not large. Prioritization will be given to interventions that provide technical assistance to translate guidance into national strategies and planning, facilitate regional engagement to support demand for the introduction of new tools, and provide implementation support to drive and scale introduction of these tools. Global Fund will target the 20 TB priority countries (plus five countries in Western and Central Africa), but there will be a list of criteria leading to the selection of these countries, followed by further consultation with partners to develop a final list.

FACILITATED DISCUSSION - Facilitator: Stijn Deborggraeve

KEY POINTS

Support for the Introduction and Scale Up of New Diagnostics

Participants agreed on the need for such an SI as there are a number of new diagnostics coming to market in the coming years. Participants emphasized that advocacy, demand generation, and technical assistance support are key to facilitating access to new diagnostics. It was also raised that countries presently have concerns about platform proliferation and sustainability.

The Importance of Partner Coordination

This is the only Global Fund SI that has a TB component and the budget is relatively small, so avoiding duplication, amplifying existing work, and filling programmatic gaps are priorities. The Global Fund and its partners are working together closely on this initiative to ensure alignment and synergy and avoid duplication. Efforts by existing diagnostic consortiums on building country readiness and capacity can be leveraged. A significant amount of work for the SI will be in partner coordination and this is where the involvement of TPMAT can add value.

Community-Level Inputs

There is interest and advocacy within civil society for new diagnostic introduction, with the civil society space having taken time to learn about diagnostics across different diseases. Global Fund is thinking about engaging communities in countries where there are already diagnostic trials going on to see how demand can be built and to get more countries excited about the new products in the pipeline. UNITAID has also issued a call for proposals on community-led demand creation which would support work for diagnostic and treatment literacy and uptake.



Wrap-Up

Brenda Waning thanked everyone for participating. GDF will follow up with a meeting report. TPMAT participants will soon get an invite for an in-person meeting on the 13-14 December in Washington DC. The themes of this virtual meeting will be discussed in more detail, as well as the implications of the new Global Fund Quality Assurance Policy for Health Products.

Consolidated Action Points

- Partners to consider how to track savings from price reductions and how this translates into more commodities and better access—as well as how the opportunities presented from these savings might be messaged—for inclusion in discussions at upcoming meetings.
- Global Fund will continue to actively monitor essential commodities gaps, which it presently
 does for the highest burden countries.
- USAID has technical assistance available. Countries can email USAIDTBTA@usaid.gov to discuss further.
- Continue to monitor issues around the shift to domestic procurement/national financing: what levers/safeguards might be available to partners, what actions might be taken at national and global level to address the loss of safeguards, and which stakeholders should be included?
- WHO will continue to flag the issue of the loss of levers/safeguards during review of TB
 national strategic plans and funding applications and will bring the issue up during the annual
 meeting of the Child and Adolescent TB Working Group in November.
- Global Fund along with TPMAT will continue to focus on maintaining and strengthening coordination across various strategic initiatives.

Annex 1: Agenda

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

October 23, 2023, 8:00-10:00am New York / 2:00-4:00pm 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:

- Summarize recent TB product price decreases, and identify next steps to optimize use of savings from these price decreases
- Provide stakeholder input on current Global Fund initiatives: A strategic initiative on country readiness, and a process for establishing KPIs on new product uptake

Chair: Brenda Waning

14:00-14:05	Welcome, Opening	Brenda Waning, GDF
Session 1. Pricing of TB commodities, progress and goals		
Facilitators: Sharonann Lynch (O'Neil Center) and Denis Godlevskiy (ITPC-EECA)		
14:05-14:20	 Updates on recent changes in pricing of TB commodities 	Brenda Waning, GDF
	Respondent	Grania Bragden, Global Fund
14:20-14:50	 Q&A, discussion, action steps (e.g., to ensure savings from price reductions equates to more people diagnosed and treated) 	Sharonann Lynch, Denis Godlevskiy
14:50-15:05	 Safeguards for Sustaining Supply, Quality and Affordability while Shifting to National Procurement 	Sharonann Lynch
15:05-15:20	Q&A, discussion, action steps	Sharonann Lynch, Denis Godlevskiy
Session 2. Global Fund Strategic Initiative		
Facilitator: Stijn Deborggraeve (MSF)		
15:20 – 15:35	 Update on the Global Fund Strategic Initiative: Next Generation Market Shaping and how it pertains to TB diagnostics 	Melanie Kitongo, Global Fund
15:35 – 15:50	Q&A, discussion, action steps	Stijn Deborggraeve
Meeting Closure		
15:50 – 16:00	Meeting closure and wrap up	Brenda Waning, GDF

Annex 2: List of Participants

1 Brenda Waning (Chair)

GDF Chief Stop TB Partnership Geneva, Switzerland

2 Cheri Vincent

Chief Infectious Diseases Division USAID Washington DC, USA

3 Thomas Chiang

Senior TB Technical Advisor USAID Washington DC, USA

4 Brian Kaiser

Technical Officer, GDF Stop TB Partnership Geneva, Switzerland

5 Wayne Van Gemert

Technical Officer, TB Diagnostics Stop TB Partnership Geneva, Switzerland

6 Lindsay McKenna

TB Project Co-Director Treatment Action Group New York, USA

7 Sharonann Lynch

Senior Scholar, Global Health Policy & Politics Initiative, O'Neill Institute, Georgetown University Washington DC, USA

8 Agrata Sharma

Fellow, Global Health Policy & Politics Initiative, O'Neill Institute, Georgetown University Washington DC, USA

Fabienne Jouberton

Pharmacist for TB and NTDs MSF Geneva, Switzerland

10 Stijn Deborggraeve

Diagnostics Advisor, Infectious Disease MSF Amsterdam, Netherlands

11 Yulia Kalancha

Executive Director TB Europe Coalition Kyiv, Ukraine

12 Lesya Tonkonog

Project Coordinator TB Europe Coalition Kyiv, Ukraine

13 Olesia Murha

Administrative Officer TB Europe Coalition Kyiv, Ukraine

14 Denis Godlevsky

Regional Head ITPC Eastern Europe and Central Asia; ECAT Munstertal, Germany

15 Martina Casenghi

Technical Director, CaP TB Project Elizabeth Glaser Pediatric AIDS Foundation Geneva, Switzerland

16 Agnes Gebhard

Technical Director KNCV TB Foundation The Hague, Netherlands

17 Mansa Mbenga

Team Lead

KNCV TB Foundation

The Hague, Netherlands

18 Fuad Mirzayev

Team Lead, Global TB Programme

WHO

Geneva, Switzerland

19 Kerri Viney

Technical Officer, Global TB Programme

WHO

Geneva, Switzerland

20 Sabine Verkuijl

Medical Officer, Global TB Programme

WHO

Geneva, Switzerland

21 Deus Mubangizi

Coordinator, Prequalification Team

WHO

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22 Tiziana Masini

Technical Officer, Global TB Programme

WHO

Geneva, Switzerland

23 Annemieke Brands

Technical Officer, Global TB Programme

WHO

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24 Jordi Balleste

Unit Chief, Strategic Fund

Pan American Health Organization

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25 Martha Maria Suazo

Procurement Specialist

Pan American Health Organization

Washington DC, USA

26 Marcos Chapparo

Procurement Specialist

Pan American Health Organization

Washington DC, USA

27 Janet Ginnard

Director, Strategy

UNITAID

Geneva, Switzerland

28 Cherise Scott

Technical Manager, Strategy

UNITAID

Geneva, Switzerland

29 Luca Occhini

Team Lead, Programme Division

UNITAID

Geneva, Switzerland

30 Grania Brigden

Senior TB Advisor

The Global Fund

Geneva, Switzerland

31 Melanie Kitongo

TB Technical Analyst, Technical Advice &

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Geneva, Switzerland

32 Aziz Jafarov

Manager, Global Sourcing Health

Technologies

The Global Fund

Geneva, Switzerland

34 Clarisse Morris

Manager, Market Shaping & Partnerships

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Geneva, Switzerland

35 Erica Lessem

Director of Community Engagement

SMART4TB

New York, USA

36 Gillian Leith

Health Markets Executive MedAccess London, England

37 Evans Mburu

Implementation Executive MedAccess
London, England

38 Michael Campbell

Director, New Market Opportunities Team Clinton Health Access Initiative Manchester, England

39 Claire Albert Watkins

Global Markets Team Clinton Health Access Initiative Massachussetts, USA

40 Vanessa Rouzier

Chair, Pediatrics Department GHESKIO Port-au-Prince, Haiti

41 Patrick Migambi

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42 Rita Patricia

Deputy Programme Manager National TB Programme Accra, Ghana

43 Lim Sheng Teng

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44 Olena lakovenko

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45 **Beth Anne Pratt**

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