TUBERCULOSIS PROCUREMENT AND MARKET-SHAPING ACTION TEAM (TPMAT)

SUMMARY MEETING REPORT

June 20 – 21, 2024

Virtual

Background and Introduction

The Tuberculosis Procurement and Market-Shaping Action Team (TPMAT)—established in July 2016—is the key global forum bringing stakeholders together 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 with TB and the NTPs that serve them. TPMAT uses a number of tools including the Global Drug Facility (GDF)-managed TB medicines dashboard which shows the status of all TB medicines in relation to different institutional guidance documents.

Day 1

Session 1. Updates from Partners - Facilitator: Lindsay McKenna (TAG)

1. Updates from Unitaid – Presenter: Cherise Scott (UNITAID)

Unitaid is in the process of identifying its priorities for market intervention across the TB care cascade and aiming to fill any identified gaps in concert and in collaboration with partners also doing the same. This priority setting and collaboration with partners will be facilitated by the Unitaid-funded ASCENT project over the next year and half. To complement this work and drive further impact, a call for proposals closed in January with anticipated projects to begin early 2025 that will emphasize community-led demand creation and innovative case finding and surveillance to support global efforts on antimicrobial resistance (AMR). Unitaid and TPMAT are hosting an Access Workshop from June 24-25, with the ASCENT project as one focus area.

2. IMPAACT4TB Consortium – Presenter: Makaita Gombe (Aurum Institute)

Due to collective work by USAID and GDF, the price for 3HP fixed-dose combination (FDC) has now dropped to $9.99, global procurement is increasing, and global manufacturing capacity for rifapentine is strong. Child-friendly formulations of rifapentine are also more affordable ($6.53 for a 15kg child), and prices are expected to decrease further with a new supplier of isoniazid 100mg dispersible tablets (DT) coming to market. In IMPAACT4TB project countries, programmes need to have both rifapentine and isoniazid DT available at the same time for 3HP. WHO has agreed to include a bulk paediatric rifapentine and isoniazid co-pack in the WHO Prequalification (PQ) Expression of Interest (EOI) to help with this challenge. In some countries, practitioners want options to give either 3HP or 1HP for adults. MPAACT4TB asks if it is possible to develop an all-purpose pack that can cater to either 3HP or 1HP.

3. GDF Catalog Diagnostics Updates – Presenter: Brian Kaiser (GDF)

There have been updates to the GDF Diagnostics Catalog, notably a bedaquiline drug-sensitivity testing (DST) test for Mycobacteria growth indicator tube (MGIT) test liquid cultures. Bedaquiline pure drug

substance (PDS) is still available for free from the US National Institutes of Health (NIH); however, GDF is offering the product in its catalog to allow clients to order at the same time as they do other diagnostic orders. GDF is now offering a moxifloxacin vial for MGIT and has updated its agreement with Cepheid to cater for tiered service level agreements and trade-in of the older GeneXpert R1 machines. GDF currently has an open tender for digital chest X-Ray (DXR) and computer-aided diagnostics/artificial intelligence (CAD/AI), as well as upcoming tenders for infection control products and interferon gamma release assays (IGRA). GDF is also expecting a new TB skin test will receive quality assurance in the next few months.

NOTE:

Pure Drug Substances

USAID has been working with countries to access bedaquiline, delamanid, and pretomanid PDS for DST testing and encourages any country or TPMAT partner struggling to obtain PDS to contact them.

4. Global Fund Updates – Presenter: Melanie Kitongo (Global Fund)

Global Fund shared updates on its Next Generation Market Shaping Strategic Initiative (SI) focused on TB diagnostics. Global Fund anticipates that, by the end of 2024, market estimates for new point-of-care (POC) and low complexity nucleic acid amplification tests (NAATs) will become available for Global Fund's 20 priority countries and 5 additional target countries in West and Central Africa. Global Fund will also carry out mapping of chest X-rays in these countries and support the participation of NTPs, lab directorates, and civil society organizations (CSOs) in regional engagements to promote demand generation. Global Fund requests that partners share any planned regional engagements so that they can see how to support participation. Global Fund will continue to scope new products that might be leveraged with tools coming up under the SI (e.g., its revolving facility and access fund).

5. SMART4TB Consortium – Presenter: Erica Lessem (JHU)

SMART4TB presented a number of upcoming studies including PRISM-TB (stratified medicine for further shortening treatment for some people with drug-resistant TB or DR-TB), BREACH-TB (one month of bedaquiline as pan-TPT), and SMILE-TB (paediatric drug-sensitive TB or DS-TB shortening). A PRISM study on paediatrics, PRISM-Kids, is also being designed and will be shared soon. SMART4TB is proactively considering access around these studies in the event the trial results are positive. As SMART4TB studies involve existing drugs, for the most part, there are not many specific access barriers expected, though there are products for which price and other access considerations could be improved (e.g., pretomanid and paediatric delamanid pricing, and potential dose optimization work / fixed-dose combinations to minimize pill burden). SMART4TB's diagnostics work includes technical support and modest financial support for early-stage products such as tongue swab-based molecular diagnostics that could work closer to the POC. SMART4TB hopes to work with manufacturers on access plans and notes that manufacturers are not all at the same stage of familiarity with global health markets. SMART4TB hopes to work with TPMAT on aligning access considerations, conditionalities, and research, and to create synergies with TPMAT partners so that support can be continued and access ensured after SMART4TB's role is finished.

6. Updates from WHO Global TB Programme – Presenter: Sabine Verkuijl (WHO)

The Paediatric Drug Optimization (PADO) group published its October 2023 meeting report, including its short- and longer-term priority lists, with rifapentine 150mg DT remaining a short-term priority, along with pretomanid and 100mg DTs for rifampicin and moxifloxacin. The 22nd WHO PQ EOI update was published with a number of new additions and subtractions. A rapid communication was issued on TB preventive treatment (TPT), including a new recommendation on the use of levofloxacin for contacts of people with multi-drug resistant/rifampicin-resistant TB (MDR/RR-TB) and updated 3HP dosing guidance to be issued

for children aged under 2 years; new guidelines and an operational handbook will then be issued in August. Based on new evidence on first-line drugs (FLDs) in children, WHO issued a call for proposals for contributions toward an evidence review. The review may lead to the Technical Advisory Group (TAG) on dosing advising on updating dosing guidance. WHO envisages that harmonized weight bands will be used from 3 kgs up to 70+ kgs to ensure alignment, streamlining, and simplification of dosing recommendations for children. Based on updated dosing guidance, the exact formulation and strength of rifampicin may need to be prioritized by PADO-TB and potentially added to future WHO PQ EOIs and Global Fund Expert Review Panel (ERP) updates.

The Guideline Development Group (GDG) for diagnostics met in May with the objectives to consolidate product-specific recommendations into class-based recommendations, update recommendations for technologies falling into low-complexity NAAT classes and evaluate concurrent use of WHO rapid diagnostic tests for the diagnosis of TB in both children and people living with HIV (PLHIV). A rapid communication will be issued with implications for the number of tests needed. A GDG meeting on DR-TB treatment will be held from June 24-27 to review evidence from the BEAT-TB and endTB trials. This meeting is also likely to result in a rapid communication. The WHO TB in Children and Adolescents Workstream has launched the 3rd edition of its Roadmap Towards Ending TB in Children and Adolescents which defines actions to be prioritized and implemented over the next five years to reduce TB-related morbidity and mortality in children and adolescents. WHO is also offering e-courses on TB in children and adolescents for health care workers and on programmatic considerations.

7. Debrief on Potential BPa FDC Informal Consultation – Presenter: Sharonann Lynch (O'Neil Institute)

An informal consultation regarding the BPaLM regimen and whether it would benefit from a bedaquiline/pretomanid (BPa) fixed-dose combination (FDC) or a co-package took place on June 6th. Pros and cons were discussed from the clinical, programme, global market and procurement, supply chain management, and affected community perspectives. The consultation found that a simplified, standardized regimen might facilitate implementation for those eligible for BPa-based regimens. It was suggested that more evidence be obtained on community preferences on pill burden and its impact on adherence. A number of disadvantages remain, including different dosing guidance for bedaquiline-containing regimens, potential restrictions of clinical options for those on BPaLM, and the difficulty that FDCs create in managing adverse events (AEs). Additionally, as regimens and recommendations continually evolve, greater flexibility around component medicines is required. Lastly, an FDC or co-park might also lead to further market segmentation, higher prices, and unstable supply, particularly for those people ineligible for BPa-based regimens. A summary report of the consultation will be made available.

FACILITATED DISCUSSION – Facilitator: Lyndsay McKenna (TAG)

KEY POINTS

Current Challenges with a BPa FDC

TPMAT members noted a number of challenges besides finding a willing manufacturer. There is currently only one supplier that is quality-assured for both bedaquiline and pretomanid, thus risking single sourcing and monopolistic approaches to pricing and availability. There are questions around how to manage production capacity for multiple medicines and how to deal with differing shelf-lives of component medicines within both an FDC and a co-pack. There are additional costs associated with pack development and many people interrupt linezolid, creating the potential for wastage within co-packs. There was also concern about challenges around availability of single formulations of bedaquiline at the global and country level for people ineligible for pretomanid-based regimens.

Next Steps after the BPa FDC Informal Consultation

WHO is working with GDF on a meeting summary that will come out soon. There might also be another consultation should the supply situation change, if more data on implementation approaches or on preferences from affected communities become available, or if other regimens for DR-TB are recommended.

Co-Packaged Rifapentine 150mg DT/Isoniazid 100mg DT Paediatric 3HP, 1HP

There is no single supplier of both products. One manufacture has an isoniazid DT, but has not yet received approval for a rifapentine DT. The other manufacturer has a rifapentine DT but is not yet received approval for an isoniazid DT. An expected update to WHO guidance on dosing should inform decisions around co-packaging of paediatric 3HP or 1HP. It was also noted that partners have not seen significant country uptake of rifapentine 150mg DT.

8. Impact of Domestic Procurement on Global Supply of Quality-Assured Medicines – Presenter: Brenda Waning (GDF)

TB medicine markets are extremely fragile and fragmented. In the past, the market was dominated by countries using donor and multilateral funding and procurement, including for first-line drugs (FLDs). There are now more non-PQ products being purchased than PQ, and GDF procurement represents a smaller percentage of PQ products procured. Of the 53 GDF priority countries—which represent 80% of the global TB medicines market—32 (62%) use domestic funds, 23 (72%) procure locally, and 13 (57%) procure non-PQ products. The trend toward domestic financing and procurement has led to an increase in potential and actual stockouts due to delayed or failed tenders. GDF has warned stakeholders about this trend since 2018. Countries procuring domestically do not generally provide GDF with quantification data, preventing early warning of possible emergencies and making it difficult for GDF to respond.

In recent years, a country with one of the largest TB burdens—and, thus, greatest demand for medicines—has had major challenges with tenders. The country procures and finances domestically. Tender awards are often delayed. Suppliers are not required to have WHO PQ, are late in delivering products, and deliver insufficient quantities. Due to several delayed and failed tenders for adult FLDs, GDF was approached by this country with emergency orders in December 2023, March 2024, and June 2024, with the expectation of extremely rapid delivery. Due to the size of the demand, the March emergency order alone consumed two months of GDF's suppliers' production capacity. Additionally, suppliers in the country have been instructed to prioritize domestic production over export, including to GDF. This has resulted in a massive strain on the global supply of FLDs and led to other GDF countries experiencing stockout. The issue has overtaken much of GDF's work for the last several months.

GDF is carrying out a number of mitigation measures. Communications have been created to brief partners on these supply shortages and encourage countries procuring from GDF to place orders far in advance. GDF is carrying out weekly production planning and prioritization exercises, as well as country situation assessments. Additional measures include splitting and expediting shipments, exploring supplier and procurement agent warehousing options, looking at how to expand and expedite API sources and production capacities, and exploring alternative suppliers. It is not anticipated that clinical research projects will be affected, as these projects constitute tiny volumes, and their needs are clear in advance.

FACILITATED DISCUSSION – Facilitator: Lyndsey McKenna (TAG)

KEY POINTS

Impact on Countries

Emergency orders have consumed four months of production capacity granted to GDF by its suppliers. The short turnaround time on the emergency orders also means that other countries are having orders postponed. The country has also placed its own direct orders with GDF-contracted suppliers, and these have taken over additional production capacity, the percentage of which is unknown.

Some countries in Africa are facing stockouts. PAHO has been facing delays and, over the last six to eight weeks, has seen suppliers turn away its orders. PAHO also notes that suppliers will often give priority to the local market instead of exports. PAHO is informing countries, as GDF has done, to make sure they share their needs with PAHO well in advance. GDF has posted about the supply challenges on its website.

Outreach to WHO PQ

There is presently one supplier with a dossier under review at WHO PQ which could help alleviate supply challenges. Both PAHO and GDF have approached WHO PQ to see if the supplier's dossier review might be expedited. Outreach to WHO PQ has come from the highest levels of Stop TB Partnership and WHO. WHO PQ expects to approve an unspecified product in June, but GDF does not know for which product or supplier.

Outreach to Global Fund

Some participants asked if Global Fund might provide a special exception to its policy on PQ products. The problem has been discussed at the Global Fund TB Situation Room and internal conversations are ongoing. There may need to be a dedicated Working Group within Global Fund on the problem. Global Fund members of TPMAT promised to continue to bring the issue to the attention of various teams of relevance within Global Fund as the issue is cross-cutting beyond the TB team.

HPMZ

HPMZ was brought up as a DS-TB alternative to the current HRZE FDCs, but countries are at a very early stage of planning for this regimen. Due to the cost of the regimen and the time that is required for countries to change regimens, HPMZ may not be something that could be implemented immediately to address an emergency unfolding over the next six months.

Opinion on Procurement of Non-Prequalified FLD FDCs

There is presently not sufficient PQ product to meet the global demand for PQ FDCs. The loss of one of two main PQ rifampicin API suppliers coupled with a massive increase of donor-funded emergency orders for PQ FDCs from NTPs that usually do not procure PQ FDCs using domestic funding means there is an insufficient supply of PQ FDCs and countries are facing stockouts. A question was raised on the potential of GDF to procure non-PQ FDCs for countries that would have normally procured non-PQ FDCs in order to avert stockouts. Many TPMAT participants supported this idea, with the caveat that consultations are needed with quality assurance experts around risk mitigation for non-PQ products. TPMAT would like feedback from donors about whether an exception could be made to allow non-PQ FDCs to be procured with donor funds as an interim measure over the next 6 months.

Mitigating Risk for an Interim Shift to Non-PQ Medicines

Participants agreed that there is a need for risk mitigation in the context of the procurement of non-PQ products. Experts on quality assurance should be consulted and criteria developed around 1) how

suppliers should be selected and 2) which countries should get a stopgap supply of non-PQ medicines. GDF has mapped non-PQ suppliers and is receiving advice as to their capacity and the quality of their products. MSF noted that when it receives requests for medicines that are not available through PQ, it mitigates risk through information gathering, technical visits to manufacturing sites, having extra safety checks around pharmacovigilance, and other steps. One country representative from a country procuring non-PQ FLDs noted that if there is high quality and robust quality control (QC) testing at both national laboratories and points of medicine receipt and distribution, quality of non-PQ medicines can be assured. The country representative also indicated that strong pharmacovigilance is needed to assess for side effects and treatment outcomes.

Session 2. UNITAID ASCENT Project: New Market-Shaping Activities - Facilitator: Sharonann Lynch (O'Neil Institute)

9. Overview of the Activities and Focus Areas - Presenter: Claire Watkins (CHAI)

The Adherence Support Coalition to End TB (ASCENT), funded by Unitaid, involves a partnership with KNCV, CHAI, Aurum Institute, and others. ASCENT's original core grant (2019-2023) was focused on digital adherence technology. ASCENT has been extended for two years. The project is now focused on access to new TB products and includes market barriers for relevant products. CHAI and Aurum Institute will lead this market shaping work. Their aim is to identify, design, and execute interventions to address availability, affordability, and sustainability around several priority TB products. Activities include 1) articulating key access gaps and identifying opportunities for intervention; 2) performing in-depth market analysis at country and global level for identified priority products; 3) developing priority product access plans and access strategies; 4) designing priority product implementation plans; 5) executing market interventions/access strategies in collaboration with other partners. ASCENT's scope will consider diagnostics, therapeutics, and supportive tools for DR-TB scale-up, aligned to Unitaid's broad portfolio of TB work. CHAI and Aurum Institute are developing a shortlist of 5-6 priority products over the next 3-4 months, consulting with partners to refine selection criteria. Consultation fora include TPMAT and the Unitaid Access Workshop (June 24-25). Product access plans and market strategies for each priority product will be developed by the end of 2024, with an implementation phase running through September 2025. CHAI and Aurum Institute will ensure collaboration, transparency and joint learning throughout.

Day 2

Session 1. Deep Dive on Initial Priorities under KNCV ASCENT Market Shaping Activities - Facilitator: Sharonann Lynch (O'Neil Institute)

10. Initial Priority Areas for Market Shaping Activities: Key Gaps and Access Challenges in the Patient Pathway – Presenter: Makaita Gombe (Aurum Institute), Claire Watkins (CHAI)

ASCENT is seeking to prioritize products based on an assessment of what elements make up a fully functioning TB care cascade. Gaps on the cascade exist at multiple points. Focusing on five categories—prevention, screening, diagnosis, drug susceptibility, and treatment and support—ASCENT will identify top-level critical gaps, key access areas, and possible products associated with each step. It will also consider some products in the pipeline close to market. ASCENT seeks to engage stakeholders as to which products are most relevant and where they see existing gaps in access. A short list of products will then be prioritized based on four dimensions of criteria: impact, suitability, economics, and opportunities. The criteria are not meant definitively, but rather to help CHAI and Aurum Institute organize their thinking systematically. Priority products must align with Unitaid's TB portfolio and strategy.

FACILITATED DISCUSSION – Facilitator: Sharonann Lynch (O'Neil Institute)

KEY POINTS

Short Timeline

ASCENT has an extremely short (i.e., 3-4 month) timeline to implement agreed upon activities. ASCENT confirmed that—if the timeline proves too restrictive—it will finalize prioritized product action plans and market strategies, and then reach out to other partners and projects within Unitaid to possibly take up interventions. Participants suggested a number of strategies to improve time efficiency such as:

- Shifting to prioritizing potential gaps for products presently in the pipeline.
- Focusing on pre-approval access for innovative drugs for people with few treatment options.
- Providing groundwork for market action plans that other partners might then create.
- Developing a continuity plan as to what will happen with products after the project wraps.

Scope

Participants questioned ASCENT's broad scope of products. ASCENT will focus on products already on, or close to, market and what can be done in the short term to facilitate access. ASCENT hopes to finetune the selection process for products with the support of TPMAT and others over the coming months. Participants emphasized the need to prioritize paediatric products and supportive tools.

The Need for Close Coordination and Partnership

Participants noted that a number of partners are also doing market strategies and interventions and had questions as to how coordination, alignment, and collaboration would work. Suggestions include:

- Creating of a more structured and formalized coordination process.
- Carrying out a stakeholder or gap analysis of partners working in the area of market access.
- Allowing partners to take up interventions ASCENT will not manage due to time constraints.
- Learning from other successful collaborations around market access (e.g., rifapentine, etc.).

ASCENT is committed to collaborating with partners both via TPMAT and through other fora and seeks to share market intelligence and implementation lessons widely. Global Fund emphasized that it was communicating with Unitaid about ASCENT on alignment with its Next Generation Market Shaping SI.

Importance of Understanding Partner Positions

Several WHO GDGs (e.g., on dosing, diagnostics, nutrition) are meeting and releasing rapid communications. Prioritization of products should ensure that GDG findings are incorporated. Several products on ASCENT's list for prioritization have not yet been recommended by WHO. There needs to be alignment on language and messaging.

Opportunities for Partner Engagement

Unitaid's Access Workshop (June 24-25) will bring together stakeholders to discuss Unitaid's DR-TB investments and help develop a comprehensive approach to investments across the TB cascade. The meeting will provide an opportunity to coordinate on ASCENT's product prioritization, but products will not be selected at that time. Other opportunities for coordination exist (e.g., KNCV is organizing a WHO/Unitaid meeting of African countries in Dar es Salaam to introduce people-based regimens and other innovations in DR-TB management. CHAI will attend to discuss market access interventions).

Need for Country and Community Consultation

Participants felt country and community consultation on gap analysis and product prioritization is essential. TAG is doing the civil society and community engagement work for ASCENT but is limited to the

8 countries targeted in the technical assistance arm of ASCENT. Gap analysis needs to involve a wider set of community groups. TAG might be able to facilitate formal community and country consultations on behalf of ASCENT, and Global Fund also has a number of existing platforms to engage CSOs, NTPs, and laboratory departments at country level.

Measuring Impact

Several participants noted the need to better measure and assess the effectiveness and impact of various market interventions, as well as the synergistic impact of multiple interventions, to have a better understanding of which tools work, which do not, and which may cause harm.

Identified Gaps

The importance of focusing on diagnostics was emphasized. Participants highlighted gaps in specimen method technologies and the need to have more non-sputum-based tests to support diagnosis in children who cannot produce sputum. Paediatric CAD/AI was also highlighted as a gap, as CAD software versions are not well-adapted to the paediatric population. There are also gaps in DST and technologies to cut down on DST turn-around-time (TAT). Other gaps highlighted include improving systems such as those for contact tracing, decentralized diagnostics, and treatment monitoring, as well as gaps in support for nutrition interventions.

Key Criteria for Prioritization

Key criteria for prioritization of products should include type of procurement mechanism, as these often restrict the ability of countries to use certain tools. Other criteria might include overall market health for the product and what might be needed to make the market for the product sustainable. Additionally, the need to prioritize products for children was emphasized, especially diagnostics. ASCENT may need to rethink its prioritization criteria to create a more central focus on TB diagnostics and other products aimed at children with TB.

11. COGs Analysis and Compound Selection – Presenter: Claire Watkins and Fred Nytko

CHAI's Cost of Goods analysis (COGs) activity is a separate workstream within ASCENT but feeds into ASCENT's product prioritization processes. COGs are estimates of the total direct production costs for manufacturing a product. COGs consider input and manufacturing process costs, as well as costs around formulation and packaging, and include consideration of economies of scale. CHAI's COGs assume that manufacturing is done in a low-cost setting, based on the example of a generic manufacturer in India. COGs cannot estimate the price for which a product will be sold but can inform pricing discussions with manufacturers. Each COGs analysis utilizes a different set of assumptions, so it is important to bring together as much information as possible, from the widest range of sources, and to closely engage partners. The intended outcomes of CHAI's COGs workstream are to 1) create vetted, reliable, consolidated COGs estimates for key TB medicines; 2) publicize analyses to provide transparency and market intelligence to a broad range of stakeholders; 3) provide guidance on how to interpret and utilize COGs; 4) provide insight into target pricing and the scale up required to achieve pricing goals. CHAI's prioritization exercise resulted in a shortlist of four products targeted for COGs: bedaquiline, delamanid, pretomanid and, possibly, rifapentine.

DISCUSSANT – BRUCE THOMAS (ARCADY GROUP)

CHAI's call for a vetted, widely accepted, and regularly used COGs model is welcome, as COGs models can be used for a range of purposes, including to inform target pricing and model different interventions. His own review aligns with CHAI on bedaquiline and pretomanid, but also highlights sutezolid and TBAJ 876 as products for which the manufacturing routes have already been described, fully costed, and are

presently or soon-to-be available within ChemRxiv. COGs models should be built collaboratively as there is a lot of work already done on low cost/alternative manufacturing processes by Gates Foundation grantees. Gates Foundation work by M4All is open access and can be a source of data for CHAI.

FACILITATED DISCUSSION – Facilitator: Sharonann Lynch (O'Neil Institute)

KEY POINTS

CHAI's COGs Work vs. the 2017 Target Regimen Research

COGs research from 2016-2017 helped establish the $500 target DR-TB regimen price which GDF used in its tenders and successfully contributed to lower medicine prices over time. This earlier research, however, used a higher-level approach and was mostly sourced through open access data. Since then, COGs analyses for CHAI have become more advanced and specific, taking into consideration, for example, utilization factors. There is also more historic and detailed data on imports, exports, and other aspects of the COGs process so CHAI has a better sense of how the market is moving.

Low Volume of DR-TB Medicines

TPMAT participants were interested in how COGs analyses take into consideration extremely low volume DR-TB medicines, the fact that many people will not be treated with generic products, and the issue of multiple suppliers. CHAI responded that input costs were scaled based on the amount required for the desired final product output. The main cost driver for products at low volumes will be not reaching economies of scale for starting material purchases. Manufacturers of low volume products will also be more likely to implement higher mark-ups to arrive at a final price.

Pipeline Drugs and COGs

CHAI did not prioritize pipeline drugs for its COGs work because it was difficult to narrow down the list of these products. Additionally, there is less evidence on pipeline products, as well as sensitivities around picking one company's pipeline product over that of another. CHAI felt that it might be worth doing COGs for pipeline drugs separately from the COGs for drugs currently on the market. TPMAT participants concurred, as it would be useful to have preliminary COGs on target prices for promising drugs to start access discussions. Drug trials give a clear sense of promising pipeline products, so it may be feasible to pare down the pipeline product list. CHAI could start with drugs that have the potential to replace compounds on the M4All shortlist (e.g., sutezolid, TBAJ) so that information could be more easily inferred. There was a suggestion to have other TPMAT partners prioritize COGs for pipeline drugs, so the onus is not all on CHAI.

Session 2. Target Prices for Selected TB Products - Facilitator: Grania Brigden (Global Fund)

12. Target Prices for Select TB Medicines – Presenter: Christophe Perrin (MSF)

To help inform upcoming GDF tenders, an overview of current and target prices for four TB medicines and one TB skin test was given. Target prices are based on the estimated costs of active and inactive pharmaceutical ingredients, formulation, and packaging. They use a cost-plus model, including a reasonable profit margin, with the assumption of adequate market competition and transparency. Target prices align pretomanid prices to bedaquiline prices and would bring down the price of the BPaLM regimen from $416 to $296 in the medium-term and $246 in the long-term.

Medicine	Manufacturer[1]	GDF Price (June 2024	Cost-Based Target Generic Price	Target Price Medium-Term	Target Price Long-Term
Bedaquiline 100mg tablet	1	$130	$48-102	**$120**	$100
	2	$159			
	3	$192			
Pretomanid 200mg tablet	1	$240	$66-210	**$130**	$100
	2	$238			
Delamanid 50mg tablet	1	$1190	$30-96	**$800**	$400
	2	$1242			
Rfp/Inh FDC (3HP) 300/300	1	$9.99	n/a	**$9**	n/a
Cy-TB Skin Test	1	$4.45 (India price in 2022; not in GDF catalog)		**$1**	n/a

[1]Names of manufacturers have been excluded.

FACILITATED DISCUSSION – Facilitator: Grania Brigden (Global Fund)

KEY POINTS

Upcoming GDF Tenders

GDF will go to tender in Q3 2024. New contracts will go in place on 1 January 2025, with contract duration for a minimum of 1 year, renewable up to 2 years. Target prices are meant to help guide suppliers on expectations during the GDF tender.

Bedaquiline/Pretomanid/BPaLM Target Prices

Participants indicated that a $120 target price for bedaquiline was feasible, especially with countries rapidly scaling up BPaLM in their new Global Fund grants. It was noted that new bedaquiline-based trial regimens are using more frequent or higher dosing, as well as using bedaquiline in TPT. Over the long-term, this might lead to increased demand for bedaquiline and further justify a decrease in price. The medium-term target price for pretomanid ($130) was seen as ambitious, but evidence based. There was support for parity between bedaquiline and pretomanid prices, especially with the scale up of BPaLM. However, there are issues with the pretomanid market, including a proliferation of licensed suppliers and the fact that many suppliers have not received significant volumes to date. The pretomanid target price should consider the context of suppliers' requirements for market entry.

Delamanid Prices

There was strong consensus the current price of delamanid—though recently reduced from $1700 to $1190—is still far too expensive for programmes. Many participants pointed out that the GDG on dosing will be meeting within a week, and there is the possibility that it will issue a rapid communication on the BEAT-TB and/or 9-month endTB regimens within which delamanid plays an important role. If these regimens are recommended, they would be important for an $800 target price. Participants discussed whether the GDG could speed up the development of a rapid communication, or if GDF could delay the tender until a communication is developed. GDF, however, wished to issue the tender quickly because quality assurance for the licensed generic product has been long delayed. GDF also explained that a rapid communication, while a helpful signal, does not usually result in significant changes to demand which are

typically tied to the release of formal WHO guidance. The delamanid tender is for one year so, if WHO guidance comes out and volumes subsequently go up, GDF can retender quite quickly. Participants emphasized that paediatric delamanid, while representing a small market, is an extremely important medicine for children. The formulation's high price, however, is being driven by a single manufacturing step and this step is almost impossible to avoid.

Rifapentine Prices

There was no objection to the suggested medium-term target price for rifapentine. Some participants, however, thought a $9.00 target price might not be bold enough given work being done in South Africa creating a locally manufactured rifapentine product. If regional manufacturing initiatives are launched, and if the HPMZ regimen scales up, the target price for rifapentine might decrease much further.

Next Generation Skin Tests

Next generation skin tests might play a role in supporting TPT scale up, but at present the price seems high. There has not been much feedback from NTPs as to their interest in such tests, and it is unclear what the market for the tests might look like in the context of TPT scale up. Recipients of the tests would still need to return for their results, so the extent to which they can contribute to case finding is unclear. The manufacturer's price may also be a disincentive to uptake. The price of the old tuberculin skin tests might serve as a reference for target prices.

Consolidated Action Points

- GDF will use the discussion around target prices in its upcoming tenders.
- The organizers of the BPa FDC Informal Consultation will make a report of the meeting available.
- TPMAT partners will continue to bring the issue of global PQ FLD shortages to the attention of relevant decision makers (i.e., Global Fund teams, WHO PQ, etc.).
- TPMAT members recognized that the use of non-PQ FDCs may support the objective of preventing stockouts and potential treatment interruptions in country programmes. Risk assessment, consultation with quality experts, and development of in-country risk mitigation actions should be prioritized if the use of non-PQ FDCs is required.
- UNITAID and ASCENT will coordinate with partners to align with existing market access projects, including on market mapping and product prioritization, and information will be shared.
- TAG will discuss with ASCENT a possible collaboration to conduct formal community and country consultations around gap analysis and product prioritization.

Annex 1: Agenda

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

20 – 21 June 2024, 13:00/14:00 – 17:00/17:00

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.

Day 1

Chair: Brenda Waning

13:00 – 13:10	Welcome, opening	Brenda Waning, GDF
Session 1. Updates from Partners Facilitator: Lindsay McKenna, TAG		
13:10 – 13:35	2.1. Updates from Unitaid 2.2. IMPAACT4TB consortium 2.3. GDF catalog diagnostics updates 2.4. GF updates 2.5 SMART4TB consortium	2.1. Cherise Scott, Unitaid 2.2. Maka Gomba, Aurum 2.3. Brian Kaiser, GDF 2.4. Melanie Kitongo, GF 2.5. Erica Lessem, JHU
13:35 – 13:55	Updates From WHO GTB	Sabine Verkujl, WHO GTB
13:55 – 14:15	Debrief on Potential BPa FDC Informal Consultation	Sharonann Lynch, O'Neil Institute
14:15 - 14:35	Impact of Domestic Procurement on Global Supply of Quality-Assured Medicines	Brenda Waning, GDF
14:35 - 15:00	Discussion, action steps	Facilitator
15:00 – 15:10	*Break*	
Session 2. UNITAID ASCENT Project – New Market-Shaping Activities Facilitator: Sharonann Lynch, O'Neil Institute		
15:10 – 16:10	Overview of the activities and focus areas	Claire Watkins
16:10 - 16:50	Discussion, action steps	Facilitator
16.50 - 17.00	Wrap up and closure of Day 1	Brenda Waning

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Day 2

14:00 – 14:05	Opening	Brenda Waning, GDF
Session 1. Deep Dive on Initial Priorities under KNCV ASCENT Market Shaping Activities Facilitator: Sharonann Lynch, O'Neil Institute		
14:05 – 14:50	Initial priority areas for Market Shaping Activities	Claire Watkins
14:50 - 15:20	Q&A, discussions, action steps	Facilitator
15:20 – 15:35	COGs analysis and compound selection	Claire Watkins, Fred Nytko
15:05 – 15:15	Discussant	Bruce/MEDS4ALL (TBC)
15:45 - 15:50	*Break*	
Session 2. Target Prices for Selected TB Products Facilitator: Grania Brigden, GF		
15:50-16:00	Target Prices for Select TB Medicines	Christophe Perrin, MSF
16:00-16:10	Target Prices for TB Skin Tests	(TBD)
16:10 – 16:20	Discussant	Grania Brigden, GF
16:10-16:45	Discussion, action steps	Facilitator
Meeting Closure		
16:45 – 17:00	Meeting Closure and wrap up	Brenda Waning, GDF

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Annex 2: List of Participants

1.	**Balleste**	Jordi	Unit Chief, Strategic Fund Pan American Health Organization Washington DC, USA	**11.**	**Gombe**	Makaita	Senior Program Manager Aurum Institute Johannesburg, South Africa
2.	**Brands**	Annemieke	Technical Officer, Global TB Programme WHO Geneva, Switzerland	**12.**	**Iakovenko**	Olena	Programme Assistant, GDF Stop TB Partnership Geneva, Switzerland
3.	**Brigden**	Grania	Senior TB Advisor The Global Fund Geneva, Switzerland	**13.**	**Jouberton**	Fabienne	Pharmacist for TB and NTDs MSF Geneva, Switzerland
4.	**Campbell**	Michael	Director, New Market Opportunities Team Clinton Health Access Initiative Manchester, England	**14.**	**Kaiser**	Brian	Technical Officer, Market Strategies, GDF Stop TB Partnership Geneva, Switzerland
5.	**Casenghi**	Martina	Technical Director, CaP TB Project Elizabeth Glaser Pediatric AIDS Foundation Geneva, Switzerland	**15.**	**Kalancha**	Yulia	Executive Director TB Europe Coalition Kyiv, Ukraine
6.	**Chiang**	Thomas	Senior TB Technical Advisor USAID Washington DC, USA	**16.**	**Kavartadze**	Maya	Demand, Technical Assistance and Capacity Building Team Leader, GDF Stop TB Partnership Geneva, Switzerland
7.	**Chikwanha**	Isaac	Senior Director, Investment Strategy, Access & Delivery GHIT Fund Tokyo, Japan	**17.**	**Kawaza**	Nicole	Project Manager Aurum Institute Johannesburg, South Africa
8.	**Frick**	Mike	TB Project Co-Director Treatment Action Group New York, USA	**18.**	**Kitongo**	Melanie	TB Technical Analyst, Technical Advice & Partnerships The Global Fund Geneva, Switzerland
9.	**Garcia-Prats**	Tony	Medical Director, Paediatric TB Pharmacokinetics Research Unit University of Wisconsin Wisconsin, USA	**19.**	**Leith**	Gillian	Health Markets Executive MedAccess London, England
10.	**Gebhard**	Agnes	Technical Director KNCV TB Foundation The Hague, Netherlands	**20.**	**Lessem**	Erica	Director of Community Engagement SMART4TB New York, USA

21.	**Lynch**	Sharonann	Senior Scholar, Global Health Policy & Politics Initiative, O'Neill Institute, Georgetown University Washington DC, USA	**31.**	**Pratt**	Beth Anne	Senior Technical Writer, GDF Stop TB Partnership Nairobi, Kenya
22.	**Masini**	Tiziana	Technical Officer, Global TB Programme WHO Geneva, Switzerland	**32.**	**Scalise**	Sarah Cooke	Senior TB Technical Advisor TB Diagnostics USAID Washington DC, USA
23.	**Mbae**	Ernest	Deputy Director, Procurement National Quality Control Lab Nairobi, Kenya	**33.**	**Scott**	Cherise	Technical Manager, Strategy UNITAID Geneva, Switzerland
24.	**Mbenga**	Mansa	Senior PMDT Consultant Treatment and Care Team Lead, KNCV The Hague, Netherlands	**34.**	**Sharma**	Agrata	Fellow, Global Health Policy & Politics Initiative, O'Neill Institute Georgetown University Washington DC, USA
25.	**McKenna**	Lindsey	TB Project Co-Director Treatment Action Group New York, USA	**35.**	**Siwach**	Aman	Director Global Markets Team Clinton Health Access Initiative Mumbai, India
26.	**Ndaki**	Kanya	Director, Group Communications Aurum Institute Johannesburg, South Africa	**36.**	**Tarlton**	Dessie	Program Manager, Unitaid Geneva, Switzerland
27.	**Nytko III**	Frederick	Product Development, Quality, Costing and Regulatory Affairs CHAI	**37.**	**Tembo**	Edna	Executive Director, The Coalition of Women Living with HIV and AIDS in Malawi (COWLHA) Lilongwe, Malawi
28.	**Onasanya**	Kenny	Program Manager, Procurement and Supply Management, Unitaid Geneva, Switzerland	**38.**	**Thomas**	Bruce	Managing Director, The Arcady Group Virginia, USA
29.	**Osibegsan**	Ademola	Technical Manager Strategic Sourcing and Supply, Unitaid Geneva, Switzerland	**39.**	**Tonkonog**	Lesya	Project Coordinator TB Europe Coalition Kyiv, Ukraine
30.	**Perrin**	Christophe	TB Advocacy Pharmacist, MSF Access Campaign Paris, France	**40.**	**Verkuijl**	Sabine	Medical Officer, Global TB Programme WHO Geneva, Switzerland

41.	**Vincent**	Cheri	Chief of the Infectious Diseases Division USAID Washington DC, USA	**43.**	**Waning**	Brenda	GDF Chief Stop TB Partnership Geneva, Switzerland
42.	**Viney**	Kerri	Technical Officer, Global TB Programme WHO Geneva, Switzerland	**44.**	**Watkins**	Claire	Global Markets Team Clinton Health Access Initiative Massachusetts, USA