

TAG

Treatment Action Group

www.treatmentactiongroup.org

Demanding a Higher Standard of TB Care:

**New tools, new challenges, new
approaches to improving treatment
for drug-resistant TB**

2 September 2020

Housekeeping

- Live captioning
- 1 hour 15 minutes
- 4 presentations (8-10 min each)
- Q&A segment (20-30 min)
- Please submit questions using “questions” or “chat” feature

Captioner: Darcy Kriens from ACS Captions

Caption Link:

<https://www.streamtext.net/player?event=TAG>

*Just click the link to open live captioning alongside webinar screen.

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Question	Asker

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- ▶ Handouts: 0 of 5
- ▼ Chat

Type message here.

To: All - Entire Audience

Part One of Two-Part Series

Wednesday, Sept. 2nd @8:00 AM ET

Treatment for Drug-resistant TB

- **Introduction**, Lindsay McKenna, Treatment Action Group (TAG)
- **A Decade+ in the Making: All-oral, Short-course Regimens for DR-TB**, Dr. Jennifer Furin, Harvard Medical School
- **Mobilizing Political Will to Close Gaps and Intensify the Response to DR-TB**, Sharonann Lynch, Médecins Sans Frontières Access Campaign (MSF)
- **Gaps in the DR-TB Cascade of Care & Proposed Actions for Addressing Obstacles Faced by Affected Communities**, Paran Winarni, Pejuang Tangguh (PETA), Indonesia
- **Ensuring Access to the DR-TB Treatments of Today and Tomorrow**, Prathibha Sivasubramanian, Third World Network
- **Question and Answer Segment**, Facilitated by Lynette Mabote, Treatment Action Group (TAG)

Thursday, Sept. 3rd @8:00 AM ET

TB Diagnostic Tools

- **Introduction**, David Branigan, Treatment Action Group (TAG)
- **The Highest Standard of Care for TB: The Tools We Have and How They Should Be Used Together**, Dr. [Name], [University]
- **Access to TB Diagnostic Tools and DR-TB Treatment: Challenges and Opportunities**, [Name] Tope Adams,
- **Integrating Policy into Practice: Scaling Up Rapid Molecular Tests as the Initial TB Test for All & LAM Testing among PLWHA**, Stijn Deborggraeve, MSF Access Campaign
- **Opportunities and Challenges for TB Diagnostics Advocacy in the Context of COVID-19: Holding Actors Accountable & Mobilizing Political Will for Action**, Blessina Kumar, Global Coalition of TB Activists (GCTA)
- **Question and Answer Segment**, Facilitated by Lynette Mabote, Treatment Action Group (TAG)

Not too late to register!!
<https://attendee.gotowebinar.com/register/5279283499429692944>

TAG

Treatment Action Group

Activist Guide Series

AN ACTIVIST'S GUIDE TO TREATMENT FOR DRUG-RESISTANT TUBERCULOSIS

TAG
Treatment Action Group

July 2020

Written by: Lindsay McKenna

Reviewed by: Christophe Perrin, Diptendu Bhattacharya, Gloria Kerubo Moses, Jennifer Furin, Jimmy Galarza Castillo, Lynette Mabote, Mike Frick, Oxana Rucisneanu, Sergey Kondratyuk, and Vivian Cox

I. INTRODUCTION AND BACKGROUND

In 2020, the World Health Organization (WHO) issued updated guidelines, establishing a new global standard of care for the treatment of **drug-resistant tuberculosis (DR-TB)**.¹ The updated guidelines reinforce the use of standardized shorter regimens and move further away from the use of **injectable agents** (see box below) previously considered a cornerstone of treatment for drug-resistant TB.

The WHO first introduced guidelines supporting the use of a standardized shorter regimen for drug-resistant TB in 2016.² Over the course of several years, and in response to emerging evidence, the WHO modified the composition of the standardized shorter regimen it recommends under **program conditions**, replacing the injectable agent with bedaquiline.¹ In the latest iteration of its guidelines, the WHO also supports the use of other bedaquiline-based shorter regimens under **conditions of operational research** (i.e., the novel **Nix-TB regimen** and modifications to the standardized shorter regimen).³

The new global standard of care offers shorter, more effective, and less toxic treatment regimens. It also brings into clear focus what's at stake when people and communities affected by drug-resistant TB are unable to access the best available treatments—extended morbidity and time away from work resulting in lost income and financial instability, further development and transmission of drug-resistance, and increased risk of permanent disability and death.

We wrote this guide to help activists: unpack the latest WHO guidelines; understand the evidence behind each of the WHO-recommended regimens; identify barriers to availability, accessibility, and affordability; and hold governments and other actors accountable for ensuring all people and communities affected by drug-resistant TB can share in the benefits of scientific progress. This guide suggests actions activists can take to promote equitable access to the new global standard of care for drug-resistant TB.



Injectable agents, amikacin, kanamycin, capreomycin, and streptomycin, most of which are also referred to as aminoglycosides, were previously considered a key component of treatment for drug-resistant TB. These medicines, administered daily by injection, have toxic side effects that can cause permanent disability, including hearing loss, and kanamycin and capreomycin have been linked to increased risk of treatment failure and death. Another family of medications used to treat drug-resistant TB known as the carbapenems are also given via injection but are not routinely used and thus are considered as a separate category.

i. Nine- to 12-months of clofazimine, levofloxacin (or moxifloxacin), ethambutol, and pyrazinamide; supplemented by bedaquiline for the first six months and high dose isoniazid, ethionamide (or prothionamide) for the first four- to six-months.

AN ACTIVIST'S GUIDE TO TUBERCULOSIS DIAGNOSTIC TOOLS

TAG
Treatment Action Group

July 2020

Written by: David Branigan

Reviewed by: Patrick Agbassi, Stijn Deborggraave, Mikashmi Kohli, Blessina Kumar, Lynette Mabote, Emily MacLean, Albert Makone, Lindsay McKenna, Madhukar Pai, and Alexandra Zimmer

INTRODUCTION

Diagnosing tuberculosis (TB) is an essential step toward ensuring that all people with TB receive effective treatment and are ultimately cured of the deadly disease. While no TB diagnostic test is perfect, the technologies and tools used to diagnose TB continue to improve because of investments in TB research and development, making them more accurate, simple, and appropriate for use at the **point-of-care**. As TB diagnostic tools evolve, so do the recommendations and guidance from the World Health Organization (WHO) on how these tools should be optimally used in country programs. The following guide reviews current and forthcoming TB diagnostic tools and details the latest WHO guidance on the use of these tools.

All people at risk of TB have the right to TB diagnostic testing at the highest standard of care. In 2020, the United Nations Committee on Economic, Social, and Cultural Rights (CESCR) released a general comment on the right of all people to the benefits and applications of scientific progress. In the comment, the CESCR explained that an essential element of the right is "quality," which it defined as "the most advanced, up-to-date and generally accepted and verifiable science available at the time, according to the standards generally accepted by the scientific community."¹ The WHO is the primary body for determining the quality of TB diagnostic tools and for providing detailed policy recommendations and guidance on the optimal use and implementation of these tools. As part of this, the WHO keeps an essential diagnostics list (EDL) of WHO-recommended TB diagnostic tests that countries should prioritize and implement.² Yet, many countries have failed to fully scale up and implement TB diagnostic testing in accordance with WHO guidance and the EDL, thus failing to fulfill their human rights obligations under the **right to science** and the right to health.³

The TB diagnostic pathway is the entry point through which people with TB access the **TB cascade of care**. Under optimal circumstances, TB-affected communities are regularly offered TB screening and testing, followed by TB treatment or **TB preventive therapy (TPT)**⁴ as appropriate (see *Figure 1: The highest standard of care for TB diagnosis*). In actuality, however, many people seek care only after developing symptoms of active TB, and they often face stigma when doing so.^{5,6,7} Of those who are diagnosed, many do not receive the drug-susceptibility testing necessary to inform optimal treatment regimens. Meanwhile, low rates of TB preventive therapy (TPT) initiation persist among high-risk people, leaving them at risk of developing active TB disease.⁸

POINT-OF-CARE: the location where a person presents to care for a disease or condition

RIGHT TO SCIENCE: the right of all people to enjoy the benefits of scientific progress and its applications enshrined in Article 15 of the International Convention on Economic, Social and Cultural Rights

TB CASCADE OF CARE: the entire pathway of TB care, including diagnosis, treatment, and cure

TB PREVENTIVE THERAPY (TPT): treatment taken by people with TB infection to prevent progression from infection to active TB disease; TPT is also sometimes given to protect people who are uninfected but at risk of TB exposure and infection

An Activist's Guide to Treatment for Drug-Resistant Tuberculosis

1. Unpacks 2020 updates to the World Health Organization (WHO) guidelines, including recommended regimens + important factors that determine eligibility (e.g., type and severity of TB disease, age, etc.)
2. Highlights existing evidence supporting each of the recommended regimens + related ongoing and planned clinical trials / further research (*“Knowing your evidence base”*)
3. Discusses access barriers (e.g., data gaps, registration, intellectual property, pricing)*
4. Suggests actions activists can take to help overcome barriers and promote equitable access to treatment for drug-resistant TB
5. Includes responses to common excuses (*“Overcoming resistance to implementing new regimens”*)

*Access to TB diagnosis + drug-susceptibility testing is a huge barrier; covered in depth in *An Activist's Guide to TB Diagnostic Tools*.

Regimens for treatment of drug-resistant TB include:

- 1 under routine program conditions, and only for RR-/MDR-TB, the nine- to 12-month standardized shorter regimen with bedaquiline given in place of the injectable agent;ⁱⁱ
- 2 under routine program conditions, an 18- to 20-month individualized all-oral regimen composed of four to five medicines selected according to the priority grouping of medicines recommended by the WHO in 2018/2019 (see Table 1);
- 3 under operational research conditions, modifications to the nine- to 12-month standardized shorter regimen with bedaquiline given in place of the injectable agent. Modifications may include, for example, linezolid given in place of ethionamide/prothionamide; and
- 4 under operational research conditions, and only for MDR-TB with additional fluoroquinolone resistance (FQ-R-MDR-TB), the six- to nine-month BPaL or Nix-TB regimen, composed of bedaquiline, pretomanid, and linezolid.

Access the full guide here:

<https://www.treatmentactiongroup.org/publication/an-activists-guide-to-treatment-for-drug-resistant-tuberculosis/>

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Treatment Action Group

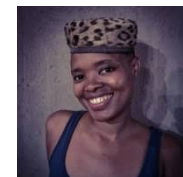
Agenda Overview



Wednesday, Sept. 2nd @8:00 AM ET

Treatment for Drug-resistant TB

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A Decade+ in the Making: All-Oral, Shorter Regimens for Drug-Resistant Tuberculosis

Jennifer Furin, MD., PhD
Harvard Medical School

Well-intentioned “1995 advice” to people living with DR-TB



- “A short time in a long life” mantra;
- But was this true?
- 24 months, not taking into account pre-treatment delays;
- Miserable side effects (“felt like an eternity”), some permanent (“ruined my life”);
- Treatment success in just about half of patients;
- Evidence base supporting DR-TB treatment regimens was virtually non-existent;
- WHO recommendations: focus on DS-TB to prevent DR-TB (i.e. “don’t treat”)

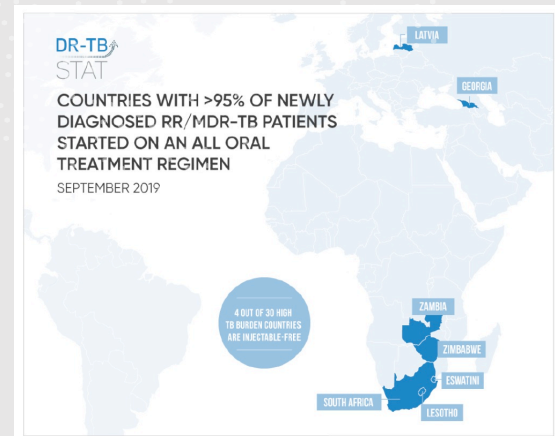
2010s: Glimmers of Hope

- Repurposed drugs: linezolid, clofazimine
- Newer agents: bedaquiline, delamanid, pretomanid
- Shorter regimens: “Bangladesh”;
- Clinical trials: STREAM, pharmaceutical company-led, NGO-led, vulnerable populations started to be included;
- WHO guidelines based on more robust evidence—still emphasized “feasibility”, “costs” and lacked affected transparency, affected community participation

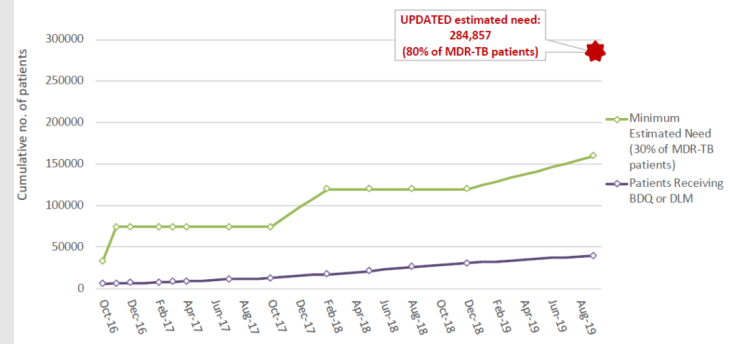


2020: All-Oral, Shorter Regimens but Access is a Major Issue

- Results from phase III studies support shorter regimens;
- Results from program experience/operational research support all-oral shorter regimens;
- Multiple phase III trial results expected in this decade;
- WHO recommends all-oral shorter regimens in most transparently crafted, community inclusive guidelines yet;
- Fewer than 20% of patients receive these globally as programs and providers still focus on “protecting drugs” instead of “protecting people”



Global progress on access to bedaquiline and delamanid versus *minimum* estimated global need



Older DR-TB treatment regimens are an abomination

- Their continued use is medical malpractice and a violation of human rights;
- The TAG Activist Guides are one of the best tools to ensure people know what they deserve and can serve as an important accountability tool

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TREATMENT
FOR DRUG-RESISTANT TUBERCULOSIS

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The WHO first introduced guidelines supporting the use of a standardized shorter regimen for drug-resistant TB in 2016.² Over the course of several years, and in response to emerging evidence, the WHO modified the composition of the standardized shorter regimen it

KEY TERMS

DRUG-RESISTANT TUBERCULOSIS
encompasses forms of TB resistant to key medicines (see section II).

PROGRAM CONDITIONS
are the routine conditions under which National TB Programs operate and treat TB.

CONDITIONS OF OPERATIONAL

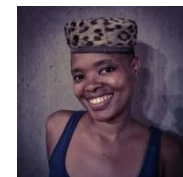
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Mobilizing Political Will to Close Gaps and Intensify the Response to DR- TB:

Access to new DR-TB regimens

Sharonann Lynch
MSF Access Campaign
TAG Webinar

2 September 2020

Acknowledgements:

Christophe Perrin, Roshan
Joseph, Pilurca Ustero, Felipe
Carvalho, Leena Menghaney

MSF Access Campaign Technical Brief

SEPTEMBER 2019
(UPDATED OCTOBER 2019)



MAKING THE SWITCH

Saving More Lives with Optimal Treatment for Drug-Resistant TB

INTRODUCTION

Multidrug-resistant tuberculosis (MDR-TB) is defined as TB that is resistant to isoniazid and rifampicin, with or without resistance to other first-line drugs.¹ Pre-extensively drug-resistant TB (pre-XDR-TB) is defined as resistance to at least isoniazid and rifampicin as well as either second-line injectables or fluoroquinolones (levofloxacin or moxifloxacin) but not both. Extensively drug-resistant TB (XDR-TB) is defined as resistance to at least isoniazid and rifampicin, any fluoroquinolone and any of the three second-line injectable agents (amikacin, capreomycin or kanamycin).² XDR-TB is more difficult to treat, and cure, than MDR-TB.

Drug-resistant tuberculosis (DR-TB) requires use of second-line treatment regimens, which may include repurposed or newer TB drugs. The previously recommended DR-TB treatment regimens used by most countries had a high pill burden, long treatment duration (of up to two years), painful daily injections (for up to eight months), severe side effects (due to toxic drugs) and poor treatment outcomes. These suboptimal regimens achieved treatment success rates of only 55% for people with multidrug-resistant/rifampicin-resistant tuberculosis (MDR/RR-TB) and 34% for people with XDR-TB.³

The World Health Organization (WHO) issued new MDR/RR-TB treatment guidelines⁴ in March 2019. This technical brief provides a summary of the treatment regimens now recommended by WHO, which represent hope for people with DR-TB and their caregivers because they offer better cure rates and fewer side effects using safer all-oral treatment. Médecins Sans Frontières (MSF) urges countries to make a timely switch to these regimens given the clear benefits of providing bedaquiline for all people with MDR-TB and the urgent need to discontinue use of harmful injectable agents.

In July 2019, WHO Director-General Dr Tedros Adhanom Ghebreyesus called for countries to transition to the all-oral regimens to treat DR-TB by World TB Day, 24 March 2020. By this time 100% of people newly enrolled on treatment should be offered the optimal regimen.⁵

BACKGROUND: NEW WHO TREATMENT GUIDELINES

In August 2018, WHO released the Rapid Communication “Key changes to treatment of multidrug- and rifampicin-



© Oksana Parafeniuk
Natalia began treatment at MSF's DR-TB treatment project in Zhytomyr Oblast, Ukraine in October 2018.

resistant tuberculosis,” which for the first time recommended all-oral regimens as the standard to treat MDR-TB.⁶ Following this communication, WHO released a pre-final text of the “WHO treatment guidelines for multidrug- and rifampicin-resistant tuberculosis” in December 2018, and released the “Consolidated guidelines on drug-resistant tuberculosis treatment” in early 2019.^{4,7} These guidelines replace all other previous WHO recommendations on DR-TB treatment.

The new WHO recommendations are based on reviews of evidence available from:

- A multi-country meta-analysis of individual patient data
- Phase III trials on delamanid and shorter MDR-TB regimens
- Bedaquiline and delamanid trials in patients under 18 years of age
- Programmatic data using bedaquiline, delamanid and other novel regimens

The multi-country meta-analysis assessed:

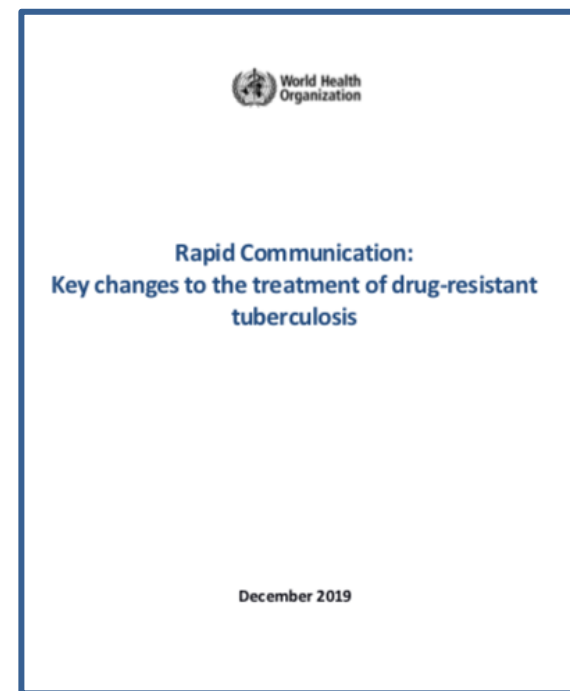
- Newer all-oral long regimen: number of drugs that should be used and duration of treatment in order to achieve better treatment outcomes
- Short-course regimen: efficacy and safety compared with the older long regimen (using injectable agents)
- Monitoring: benefit of monthly culture over smear microscopy monitoring

<https://msfaccess.org/making-the-switch>

WHO recommendations

<https://msfaccess.org/making-the-switch>

- All people with MDR-TB should benefit from a shorter or longer **all-oral** regimen
- MDR-TB: Most can receive **bedaquiline-based, all-oral, shorter regimen**, consisting of the 2016 WHO standardised shorter regimen with bedaquiline substituted for the injectable agent
- Pre-XDR and XDR and complicated MDR-TB:
 - Individualised longer regimen based on 2018 WHO drug groups
 - A regimen consisting of bedaquiline, pretomanid and linezolid (BPaL) may be used under operational research conditions for people with XDR-TB



11 December 2019

WHO recommendations

Year	WHO Guidance Updates
2013	Interim policy guidance recommends bedaquiline for DR-TB treatment.
2014	Interim policy guidance recommends delamanid for DR-TB treatment.
2015	Companion DR-TB treatment handbook includes the use of bedaquiline and delamanid.
2016	Guidance recommends short, standardised regimen to treat DR-TB (the injectable-containing 'Bangladesh regimen'). Guidance extends recommendation on delamanid to children and adolescents.
2017	Guidance recommends conditions for expanded combined and extended use of bedaquiline and delamanid.
2018	Rapid communication changes drug groupings, recommends against the use of injectables due to worse outcomes, and recommends first-ever longer all-oral DR-TB treatment regimen. Further guidance issued on isoniazid-resistant TB.
2019	Consolidated guidelines on DR-TB treatment issued. Rapid communication recommends shorter all-oral bedaquiline-containing regimen for those eligible and new BPaL regimen under operational research conditions.
2020	Consolidated guidelines on DR-TB summarises previous updates, confirms safety of extended bedaquiline use and bedaquiline-delamanid combination, and recommends more decentralised models of care.

Part 1

NATIONAL POLICIES

Marking the fault lines

- What % of TB diagnosis is from smear microscopy?
- What % of PHC have TB LAM?
- What % of hospitals have GeneXpert MTB/RIF and TB LAM?
- What % of people starting DRTB are on all-oral?
- What % of PHC and district facilities can provide ambulatory DRTB treatment?

Opportunities for policy change

- When is the next National Strategy Plan being reviewed for developed?
- When are the national TB/DRTB treatment guidelines being developed?
- When is the committee convening? Circulars or memoranda possible?
- What is in the GFATM proposal?
- When is the next opportunity for funding or reprogramming?

****Check out:**

Gobal Fund 2020-2022 Funding Request Tracker

1 September 2020

[funding request tracker](https://www.theglobalfund.org/media/9261/fundingmodel_2020-2022fundingrequeststatus_tracker_en.xlsx)

https://www.theglobalfund.org/media/9261/fundingmodel_2020-2022fundingrequeststatus_tracker_en.xlsx

Global Fund

- Countries submit a **Prioritized Above Allocation Request (PAAR)** with their applications (now mandatory), which is where unspent funds will be reallocated
- Once the proposal is approved and during the implementation period, countries can request reprogramming, or “**program revision**” as it’s now called.
- This is a request to change the scale (**targets**) and/or scope (**objectives, interventions**) of a program within an already approved budget ceiling.
- The triggers are changed circumstances or arrangements such as emerging new scientific evidence or normative guidance, change in national context, risk mitigation etc.
- Depending on which “**portfolio**” category the country belongs to (focused, core or high impact) the revision can happen once per year (focused) or at any time (core or high impact).

DRTB treatment regimens

New paediatric TB FDCs are the standard of care

National policy reflects WHO guidance on bedaquiline use for adults

National policy reflects WHO guidance on delamanid use for adults and children

National policy includes the WHO-recommended, 9-month (shorter) MDR-TB treatment regimen



TB Policies in 29 Countries

A survey of prevention, testing and treatment policies and practices



Stop TB Partnership

2017 Out of Step report

- Paediatric TB fixed-dose combinations (FDCs) are the standard of care in 50% (14/28) of countries, but only 29% (4/14) of them have widely implemented them;
- Bedaquiline is included in the national guidelines for DR-TB treatment in 79% (23) of countries
- Delamanid is included in the national guidelines for DR-TB treatment in 62% (18) of countries
- 9-month (shorter) MDR-TB treatment regimen is included in the guidelines in 45% (13) of countries

2020 #stepupforTB report we report on policy objectives:

- Paediatric injectable-free regimens
- Minimum age for Bdq and Dlm
- Longer all-oral regimen for adults
- Modified all-oral shorter regimen for adults
- Combination and extension of Bdq and Dlm

Models of care

decentralised & ambulatory care

DS-TB treatment is started at the primary health care level*

DR-TB treatment is started at the district level*

Hospitalisation is NOT required for DS-TB treatment*, ♦

Hospitalisation is NOT required for DR-TB treatment*, ♦

2017 Out of Step report

- DS-TB treatment
 - Can be started at the PHC in 83% (24) of countries
 - and in all of African countries surveyed for the report;
 - Routine hospitalisation is required in 21% (6) of countries
- DR-TB treatment
 - Can be started at the district level in 66% (19) of countries
 - But should be at the PHC for initiation & follow up
 - Routine hospitalisation is required in 35% (10) of countries



Models of care

patient-centred & supported care

2020 #stepupforTB report, we also report on policy objectives:

DR-TB treatment follow-up can be done at a PHC facility

Daily DR-TB medicines, including injections, can be taken at home

People with DS-TB can take their daily TB medicines as self-administered therapy (SAT)

People with DR-TB can take their daily TB medicines as self-administered therapy (SAT)

Food and transport support is provided to all people on DR-TB treatment

TB and Covid-19



World Health Organization (WHO) Information Note

Tuberculosis and COVID-19

Date: 12 May 2020

COVID-19: Considerations for tuberculosis (TB) care

- “People-centred outpatient and community-based care should be strongly preferred over hospital treatment for TB patients ... to reduce opportunities for transmission.”
- “[t]he rapid roll-out of measures that reduce the need for daily encounters with healthcare staff becomes more critical. These include WHO recommended, all-oral TB treatments for multidrug-resistant TB and extensively drug-resistant TB”

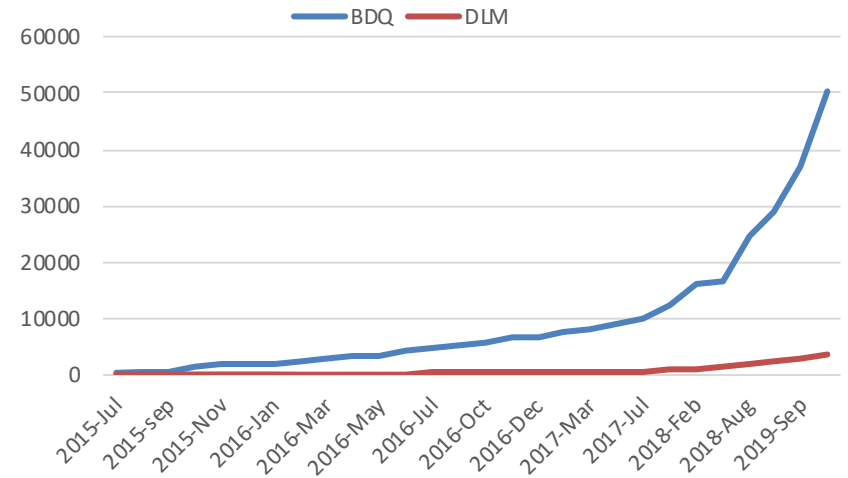
We need more self-administered therapy (SAT), as opposed to DOT and more treatment literacy

Part 2

DRUG ACCESS ISSUES

High prices and restrictive patents

Cumulative Use of BDQ and DLM Over Time



Medicine	Purchasing mechanism	Manufacturer	Price per person (monthly)	Target generic price (monthly)
Bedaquiline 100mg tablet	GDF	J&J (Janssen)	\$45	
	Russian Federation – government tender	Pharmstandard	\$246	\$8-17
Delamanid 50mg filmed coated tablet	GDF	Otsuka	\$283	
	South Africa - government tender	Mylan	\$157	\$5-16
	CIS and Georgia – government tender	R-Pharm	N/A	
Pretomanid 200mg tablet	GDF	Mylan	\$61	\$11-35

Bedaquiline

- From 2015 to 2019, **only 51,000 people**, 11% of those who need it had access
- **J&J July 2020 price dropped to US\$1.50 per day, US\$272 for 6 months**
 - Highly complicated price reduction and ‘free goods’ (20%) tied to volume commitments (125,000 treatments in 2020)
 - 32% lower than the previous lowest price of \$400 for a 6-month treatment course
 - 70% & 91% lower than 2014 introductory prices for LICs (\$900) and MICs (\$3,000) for 6 months
 - 139 countries eligible IF made through the Stop TB Partnership’s Global Drug Facility (GDF)
 - South Africa and Russia (pays \$8 a day) left out, unless they go through GDF.
- **Meanwhile the paediatric formulation is more expensive**
- **Bedaquiline should be priced even lower and made available to more countries,** given the considerable public funding and research that went into its development

Purchasing mechanism	Producer	Price per person per month, US\$*	Target price for generic versions (per month)†
GDF	J&J (Janssen)	\$45	\$8-17
Russian Federation – government tender	Pharmstandard	\$246	

Bedaquiline: patent & licensing issues

Patents

- Janssen primary patent expires in July 2023
- A number of manufacturers are expected to file for WHO PQ of their generic versions in anticipation of the patent expiry
- Several evergreening patents & secondary patent applications, on the fumarate salt form, which could extend monopoly until 2027
- Challenges: India, Brazil, Thailand and Ukraine on EECA paediatric formulation patent

Licensing issues

- J&J has not licensed to the Medicines Patent Pool (MPP)
- License to Pharmstandard for Russia and CIS countries+Georgia
- License to TB Alliance for drug-sensitive TB and in the BPaL regimen for DR-TB

Delamanid

- From 2015 to 2019, only 3,750 people accessed delamanid
 - \$1,700 for 6-month treatment
 - Low registration (only 9 out of 30 high-burden DR-TB countries)
 - WHO classification as a Group C drug
- 2017 license for Mylan to distribute tablets using Otsuka's API in India, South Africa, and elsewhere where Otsuka has no commercial presence
 - Mylan can use its own API by late 2021
- 2017 R-Pharm licensee for CIS countries+Georgia
- Basic compound patent expires 2023
- Generic manufacturers **not gearing up**
 - instead, waiting to see whether usage indications will be expanded for a larger market outside of XDR/pre-XDR

Purchasing mechanism	Producer	Price per person per month, US\$*
GDF	Otsuka	\$283
South Africa - government tenders	Mylan	\$157
CIS and Georgia – government tender	R-Pharm	N/A

Pretomanid

- BPaL (bedaquiline, pretomanid, linezolid): first all-oral 6-month treatment for extensively drug-resistant TB (XDR-TB) or treatment-intolerant or non-responsive pulmonary MDR-TB under operational research conditions
- Pta: \$364 for 6 months treatment; BPaL: \$905 for 6 months
- Developed by TBA, manufactured by Mylan
- However, given the public and philanthropic resources that went into pretomanid's development, **its high price is unjustified.**
- BPaL registration: India in July 2020, EU in August 2020, applications in 8 additional countries
 - *Mylan launched Named Patient Access Program (NPAP) for where pretomanid is not registered. Unlike similar patient-access programmes for bedaquiline and delamanid however, NPAP does not provide pretomanid free of charge*

Pretomanid: patent & licensing issues

Patents

- Patent on pretomanid expired in 2016
- TBA filed for patents on the **BPaL formulation** in many countries
- In July 2020, a patent opposition for BPaL was filed in India

Licensing

- April 2019: TBA license to Mylan for manufacturing, WHO PQ submission, national regulatory approvals, distribution, pricing negotiations, tenders
- Unknown - which countries does Mylan have exclusive rights to market the drug?
- BPaL procurement is complex giving different suppliers
- October 2019: non-exclusive license agreement with Macleods to manufacture pretomanid as part of BPaL and to supply it in 143 countries. Macleods could be ready with a pretomanid tablet supply by 2022 with WHO PQ by 2023
- TBA also has not licensed pretomanid to the MPP

Regimen prices

- Shorter all-oral bedaquiline-containing regimen: **\$460**
- Longer DR-TB regimens for people requiring 6-18 months of bedaquiline: **\$800-1,500**
- Longer fluoroquinolone-resistant regimens requiring bedaquiline and delamanid for 20 months: **\$7,500**
 - as high as \$11,000 with imipenem-cilastatin

Paediatric formulations

- **Bedaquiline**

- WHO recommends for age 6 and older
- August 2019: bedaquiline FDA-approved for 12-18 years old; treatment based on the adult Bdq 100mg tablet
- May 2020: USFDA approved Bdq 20mg dispersible tablets for children 5 years or older and weighing at least 15 kg; \$200 for a 6-month treatment for children 5-12 years old

- **Delamanid**

- WHO recommends for children 3 years and older
- 50mg adult formulation for children 6 years or older
- Dispersible tablets of 25mg only available through compassionate use from Otsuka for children older than 3 years of age

- **Pretomanid**

- Mylan has developed dispersible formulations of 10mg and 50mg of pretomanid, though their evaluation in clinical trials is pending additional safety data requested by the FDA.

Resources

#stepupforTB report *Coming in early October!!*

Step Up for TB 2020: Tuberculosis policies in 37 countries

A survey of prevention, testing and treatment policies and practices

www.msfacecess.org/stepupfortb and www.stoptb.org

DR-TB Drugs Under the Microscope, 7th Edition *Coming in early October!!*

Pricing and patent issues for drug-resistant tuberculosis medicines

www.msfacecess.org/utm2020

MSF Issue brief

Making the switch (updated March 2020)

Saving More Lives with Optimal Treatment for Drug-Resistant TB

<https://msfacecess.org/making-the-switch>

Patent oppositions database

<https://www.patentoppositions.org/>

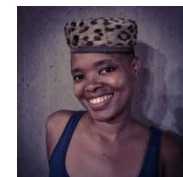
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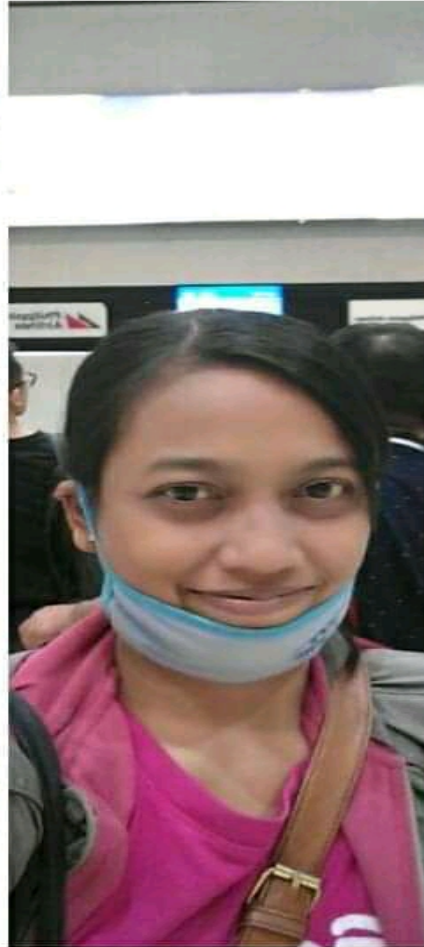
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- **Question and Answer Segment**, Facilitated by Lynette Mabote, Treatment Action Group (TAG)



Gaps in the DR-TB Cascade of Care & Proposed Actions for Addressing Obstacles Faced by Affected Communities



Paran Sarimita Winarni
2 September 2020

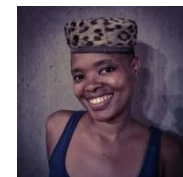
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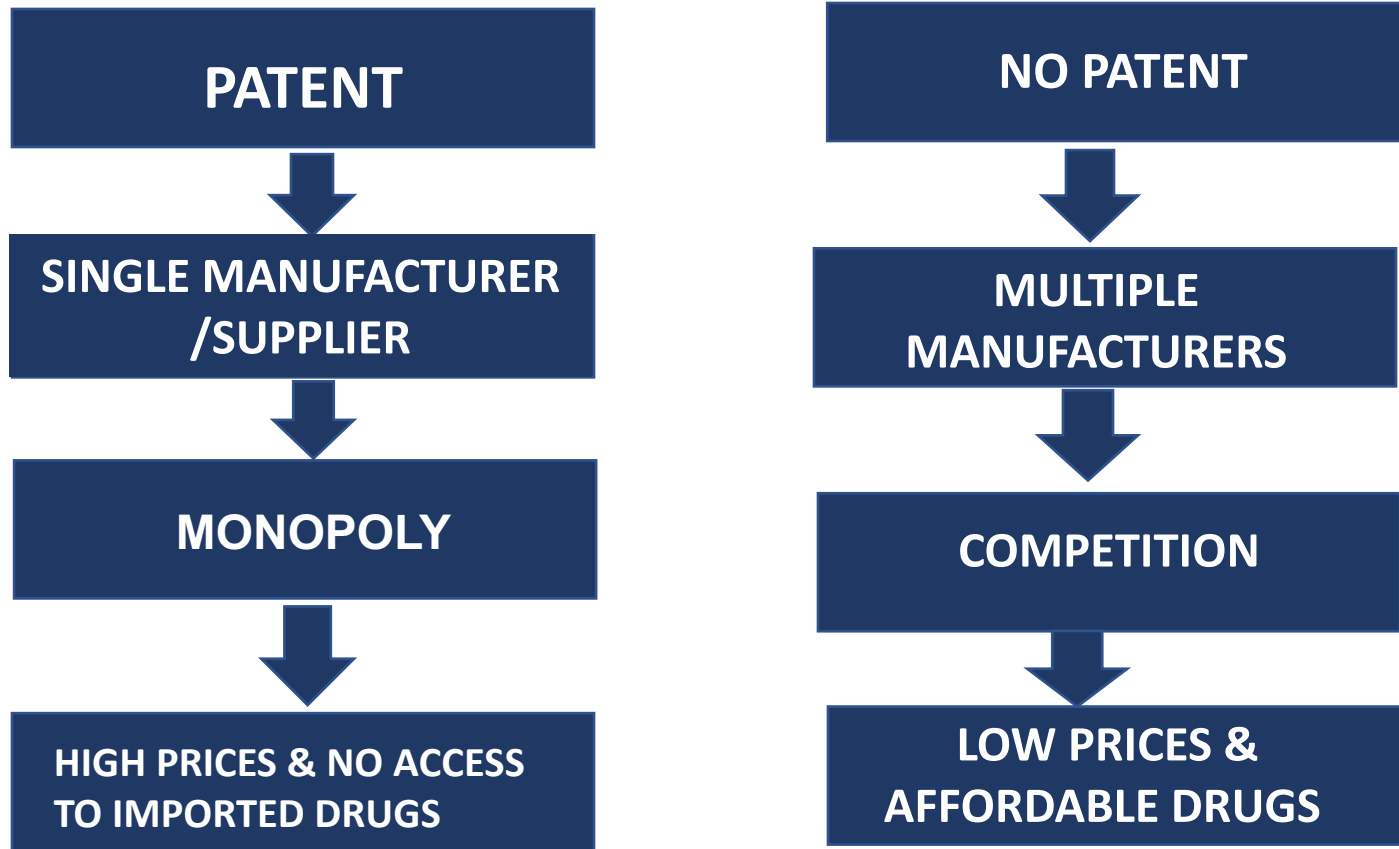
Ensuring Access to the DR-TB Treatments of Today and Tomorrow

**Activist Guide Webinar: Demanding a Higher Standard of TB
Care: New Tools, New Challenges, New Approaches to
Improving Treatment for DR-TB**

Prathibha Sivasubramanian, Third World Network

02 September, 2020

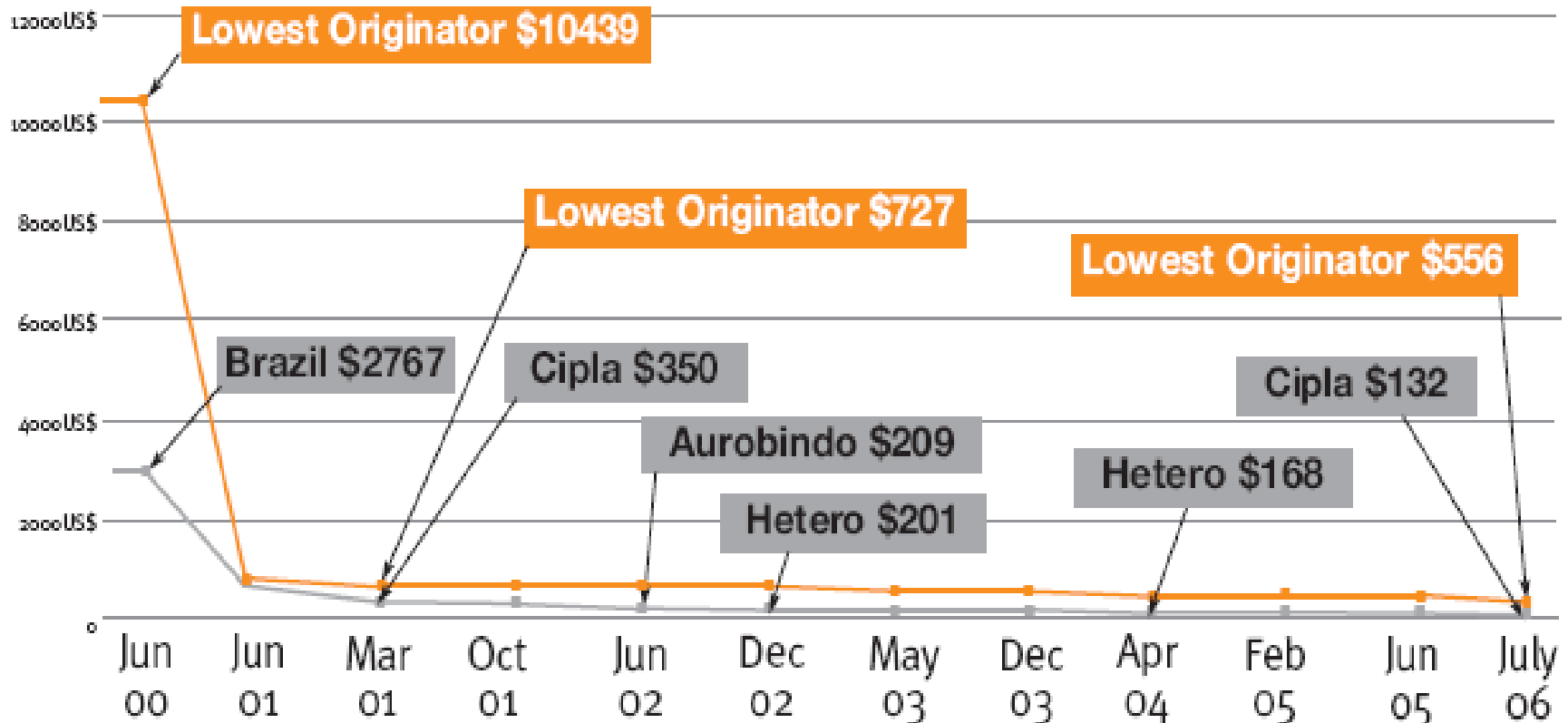
PATENTS=>MONOPOLY => HIGH PRICES => NO ACCESS



EFFECT OF COMPETITION ON PRICES

Graph 1: Sample of ARV triple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP). Lowest world prices per patient per year.

The Effects of Generic Competition June 2000-June 2006



Generic competition has shown to be the most effective means of lowering drug prices.

Courtesy : Médecins Sans Frontières

PATENTS AND INNOVATION

- Often argued that: Patent promote innovation and stimulates new technologies, industries, inventions.
- However this view ignores that: Patent do not have same impact in:
 - Countries with different industrial base, R&D capacities and availability of capital to finance innovation
- However, now patents are used to secure markets in developing countries and LDCs.
- As well as to oust competitors (new domestic and foreign market entrants) from developing countries.
- **Key issues in Patents and Access:** Reduction in innovation, high prices of patented drugs, lack of transparency in R&D spending and price fixing and proliferation of patents

EVERGREENING ...

1985 + 20 years:
Tenofovir *

1997 + 20 years:
Tenofovir
disoproxil
(prodrug) *

1998 + 20:
Tenofovir
disoproxil
fumarate salt *

2001 + 20 years:
Tenofovir
alafenamide
(prodrug) *

2012 + 20 years:
Tenofovir
alafenamide
hemifumarate **

2018 + 20:
Tenofovir
alafenamide salts
+ crystalline forms

Source:

* UNITAID and MPP, "Patents and licences on antiretrovirals: A snapshot" (2014),
<http://apps.who.int/medicinedocs/documents/s21437en/s21437en.pdf>

** <https://www.medspal.org/?page=1>

TRIPS, DOHA AND FLEXIBILITIES

- TRIPS Agreement- Minimum Standards of IP protection, 20 year term
- **What is Patentable:**
 - Inventions on or after 1 January 1995
 - All fields of technology [Art 27]
 - Both products and processes
- **Patentability Criteria for granting patents [Art 27]**
 - New
 - Involves inventive step
 - Capable of industrial application
- **These terms are not defined. It's a flexibility!**
- **TRIPS allows to establish patent opposition systems.**
- **Compulsory License (CL)[Art 31]** –if the drug is highly price,unaffordable, inaccessible-CL can be granted.
- ***Doha Declaration on TRIPS Agreement and Public Health, 2001:***
 - Reaffirms the right of WTO Members to use the flexibilities under TRIPS
 - TRIPS to be interpreted as per objectives (Article 7) and principles (Article 8)
 - **TRIPS does not and should not prevent countries from taking measures to protect public health.**

DR-TB TREATMENT...

- Have high pill burden
- Long treatment duration (upto 2 years)
- Painful and terrible side effects-daily injections
- Severe side effects and poor treatment outcomes
- Painful, long and high rates of adverse effects
- Treatment success rate among MDR-TB patients in India: 46%
Death rate: around 20%*
- Need for new DR-TB treatment- less painful, effective and shorter regiments
- **Bedaquilin, Delamanid, Pretomanid**-Three New Medicines after 50 years
- **Promising new medicines: Telacebec and OPC 167832**
- Novel classes of medicines for which the TB mycobacterium has not yet developed resistance will be needed
- Only a healthy pipeline of new compounds can allow this aspiration to become true

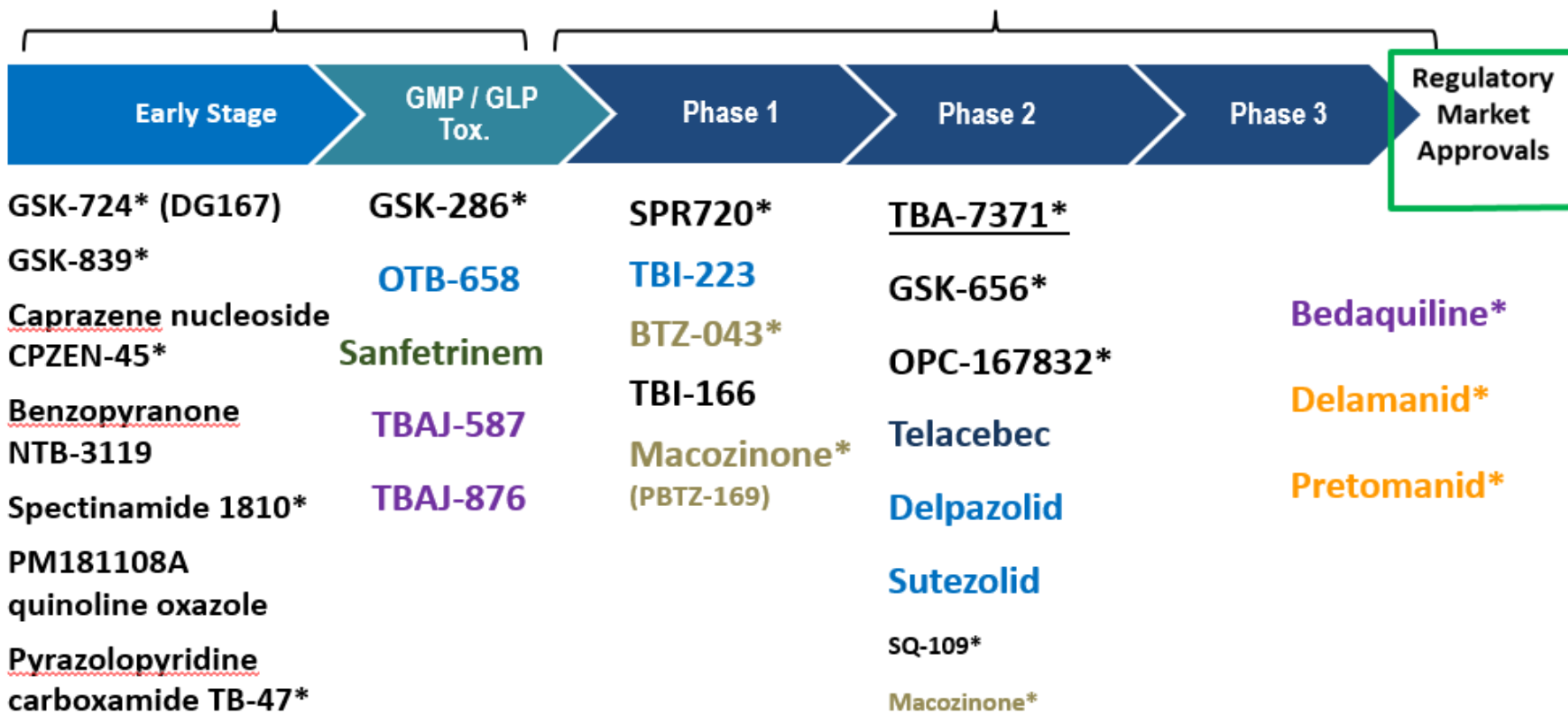
Source: MSF

* MSF Issue brief, DR-TB drugs under the microscope, 6th edn. https://www.msfacecess.org/sites/default/files/2019-10/IssueBrief_UTM_6th_Ed_FINAL_web.pdf

2020 Global New TB Drug Pipeline ¹

Preclinical Development

Clinical Development



New chemical class* Known chemical classes for any indication are color coded: fluoroquinolone, rifamycin, oxazolidinone, nitroimidazole, diarylquinoline, benzothiazinone, imidazopyridine amide, beta-lactam.

¹ New Molecular Entities not yet approved, being developed for TB or only conditionally approved for TB. Showing most advanced stage reported for each. Details for projects listed can be found at <http://www.newtbdrugs.org/pipeline/clinical> Underline = new to Phase since October 2019

Ongoing projects without a lead compound series identified: <http://www.newtbdrugs.org/pipeline/discovery>

Source: https://drive.google.com/file/d/0B3BR7L--n_1AQ0c1ZjY5bzF3VnM/view



www.newtbdrugs.org

Updated: March 2020

PATENT STATUS OF EXISTING NEW DRUGS

Drug Compound	Patent Status (as of August 2019)		
	Granted*	Pending	Not filed
Bedaquiline (patent application: WO2004011436)	Azerbaijan, Belarus, China, Congo (Republic of), India, Indonesia, Kazakhstan, Kenya, Kyrgyz Republic, Moldova, Mozambique, Pakistan, Philippines, Russia, South Africa, Tajikistan, Ukraine, Vietnam, Zimbabwe	Thailand	Angola, Bangladesh, Ethiopia, North Korea, Myanmar, Nigeria, Papua New Guinea, Peru, Somalia, Uzbekistan
Bedaquiline fumarate salt (patent application: WO2008068231)	Azerbaijan, Belarus, Indonesia, Kazakhstan, Kenya, Moldova, Mozambique, Peru, Russia, South Africa, Tajikistan, Ukraine, Zimbabwe	China, India	Angola, Bangladesh, Congo (Republic of), Ethiopia, North Korea, Kyrgyz Republic, Myanmar, Nigeria, Pakistan, Papua New Guinea, Philippines, Somalia, Thailand, Uzbekistan, Vietnam
Delamanid (patent application: WO2004033463)	China, India, Russia, South Africa, Ukraine	N/A	Angola, Azerbaijan, Bangladesh, Belarus, Congo (Republic of), Ethiopia, Indonesia, Kazakhstan, Kenya, North Korea, Kyrgyz Republic, Moldova, Mozambique, Myanmar, Nigeria, Pakistan, Papua New Guinea, Peru, Philippines, Somalia, Tajikistan, Thailand, Uzbekistan, Vietnam, Zimbabwe

* Patent is set to expire in July 2023 for bedaquiline; December 2027 for bedaquiline fumarate salt; and October 2023 for delamanid. But the patent may be extended subject to patent term extensions in applicable jurisdictions. The expiry date might vary slightly depending on the how the date of filing is calculated in respective jurisdictions.

NEW DRUGS AND PATENT STATUS

- Telecebec

PCT PUBLICATION NUMBER	APPLICANT NAME	Description	Countries application filed	Expiry date*
WO2011113606	Institut Pasteur Korea & INSERM	Markush claims covers telecebec	China, ,Russia, India, Korea, Thailand, Philipines, Mexico, Israel, Canada Australia, EPO,US	22.09.2031
WO2012143796	Institut Pasteur Korea & Qurient, CO, LTD	Compound patent application	US and Korea	20.04.2032
WO2015014993	Institut Pasteur Korea; Qurient	Compound patent application	India, Philipines, Japan,Indonesia, Russia, Korea, US, EPO, Singapore	01.08.2034
WO2018158280	Janssen	Combination of PZA and telecebec/Q-203	China, Japan, Philipines, Ukraine, EPO,Korea, Eurasian Patent Office	28.02.2038

NEW DRUGS AND PATENT STATUS

- OPC167832

PCT PUBLICATION NUMBER	APPLICANT NAME	Description	Countries application filed	Expiry date*
WO2016031255	Otsuka	Compound patent application	Israel, Japan, India, Australia, Philippines, Mexico, China, Canada, US, EPO, Eurasian Patent Office	03.03.2036

PCT PUBLICATION NUMBER	APPLICANT NAME	Description	Countries application filed	Expiry date*
WO2017066053	The Global Alliance For TB Drug Development, Inc	Combination of Bedaquilin, Pretomanid, Linezolid	India, US, Australia, Canada, Korea, Japan, EPO, Eurasian Patent Office	05.10.2036

WHAT CAN BE DONE?

- To challenge patents/patent applications covering life-saving drugs:
 - If the drugs are inaccessible
 - If there are frivolous or unworthy follow-on patents which extend monopolies

TELECEBEC: PATENT OPPOSITION

- Telecebec (Q203) is a new DR-TB drug.
- It is manufactured by Qurient Co., Ltd.
- 2010: Qureint obtained an in-licensing agreement for anti-tuberculosis antibiotics programs from Institut Pasteur Korea.
- 2013 and 2015: Q' Received grant from Korea Drug Development Fund for Q203 preclinical IND enabling studies & for Q203 phase 1 study.
- INSTITUT PASTEUR KOREA has filed patents for telecebec.
- In India, 2 patents have been identified so far. One has been opposed and other a secondary patent has got granted in August 2020.

OPPOSITION

- 8533/DELNP/2012:
 - Filed by Sankalp Rehabilitation Trust
 - Covered Q 203 molecule
 - There are documents that show compounds similar to telecebec have been known in field of drug discovery
 - Opposition has been filed on following grounds:
 - Invention is not novel;
 - Does not involve inventive step- known science
 - Does not satisfy section 3 (d)-therapeutic efficacy
 - Vague and broad Markush claims

BPaL:OPPOSITION

- BPaL, a regimen that is first all-oral, a combination of bedaquiline (B), pretomanid (Pa) and linezolid (L)
- is a 6 months treatment for highly resistant form of DR-TB.
- In BPaL, each drug has potent preclinical and clinical anti-TB activity and studies show that there is minimal pre-existing resistance.
- TB Alliance however has filed a patent application for the combination of Bedaquiline, Pretomanid and Linezolid in multiple jurisdictions, including high burden countries like India.
- The Govt of India has approved the BPL regime (individual drugs in combo on 17/July/2020)

OPPOSITION

- Opposition filed by DNP and Sankalp Rehabilitation Trust
- DNP has argued:
 - Documents prove that the combination is anticipated and obvious
 - Grounds:
 - Not novel
 - Publicly known/used
 - Combination is obvious- compounds individually used together
 - Does not satisfy section 3(d) [no therapeutic efficacy] and (e) [no synergistic effect]

WAY FORWARD....

- To advocate for high quality patent examination with National Patent Office. Need to sensitize patent offices, examiners of the link between patents and a2m and the impact of examination practice.
- Advocacy with Governments to take measures to avoid multiple patenting of the same drug(or secondary patenting).
- To create international awareness of the need to limit the grant of secondary patents and to support countries that take measures to limit grant of secondary patents.
- To understand concepts of patents and access and coordinate with activists, patient groups and networks such as PLHIV, HepC in other countries in identifying patent applications, file oppositions wherever possible.
- **To advocate inclusion of higher standards of patentability and exclusions from patentability in law, policy or guidelines.**
- Examine and challenge arguments such as “patents promote R and D and innovation”. Suggest arguments to promote genuine inventions, technology transfer and local production of low-cost, good-quality medicines.
- Advocate for Compulsory License for Bedaquilin and Delamanid and ensure their availability for patients.

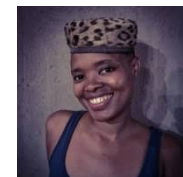
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Question & Answer Segment

Please submit your questions using “questions” or “chat” feature.

???

The screenshot displays the GoToWebinar Control Panel interface. The top navigation bar includes: Sharing, Dashboard, Attendees: 1 of 501 (max), Audio, Webcam, and Questions. The Questions section is expanded, showing a table with columns for Question and Asker, and a checkbox for 'Show Answered Questions'. Below the table is a text input field labeled 'Type answer here'. Underneath this field are buttons for 'Send Privately' and 'Send To All'. The Chat section is also expanded, showing a text input field labeled 'Type message here'. At the bottom, there is a 'To:' dropdown menu set to 'All - Entire Audience' and a 'Send' button. Two red arrows point to the 'Type answer here' and 'Type message here' input fields respectively.

VI. TAKING ACTION

There are several actions activists can take to help overcome the barriers discussed in the previous sections and to promote equitable access to treatment for drug-resistant TB.



Collect information to support appeals to national and subnational policy makers to adopt the global standard of care articulated in the 2020 update to the WHO consolidated guidelines on drug-resistant tuberculosis treatment and informed by evolving scientific evidence.

- Review your National Strategic Plan (NSP) and TB Treatment Guidelines to look for policies that are misaligned with WHO guidance;
- Request information on the number of drug-resistant TB treatment starts by regimen, and compare these figures with local incidence estimates;
- Examine the national drug-resistant TB donor landscape (i.e., the overall program budget, the percent funded, and the proportion that is domestic vs. donor funding);
- Understand the mechanisms and sources of funding used to procure medicines for drug-resistant TB and how corresponding government tenders work;
- Look into the availability of nutritional, economic, and mental health support or other assistance programs for patients undergoing treatment for drug-resistant TB; and
- Survey healthcare workers and former and current TB patients to understand their experiences and concerns, document policy-practice gaps, and articulate barriers to accessing treatment.

2

Apply pressure to government and other national and local actors to increase the number of people with drug-resistant TB that are diagnosed and treated with the standardized, modified, or individualized regimens recommended by the WHO.

- Generate demand by empowering TB-affected communities to conduct TB diagnosis and treatment literacy trainings and to monitor the availability of TB tests and treatment regimens locally;
- Create links between members of TB-affected communities and community-based and civil society organizations;
- Build rapport with the National TB Program and providers in the private sector to understand their positions and needs, and to identify entry points and opportunities for advocacy;
- Write to members of parliament and officials at government agencies, including those at the district or other sub-national levels, involved in appropriating domestic and donor funding to health programs;
- Engage members of your Country Coordinating Mechanism (CCM) and any other bodies that inform funding requests made to international donors.

3

Hold drug sponsors and generics suppliers of bedaquiline, delamanid, and pretomanid accountable for making these medicines available, accessible, and affordable.

- Demand transparency on volumes, costs of goods, pricing, and the terms and conditions of licensing agreements;
- Push for a single global access price based on costs-of-goods-sold (COGS; the amount it costs a manufacturer to produce a medicine) and annual volumes;
- Work with lawyers, academics, and public interest organizations to explore national pro-access policies, legal safeguards, and other mechanisms available to support market entry of additional generics manufacturers;
- Advocate for new medicines and their generic equivalents to be registered with your national regulatory authority, and for your national regulatory authority to expedite its review of applications for the registration of drug-resistant TB medicines.

4

Advocate for governments, drug sponsors, and other funders of TB research and development (R&D) to continue to invest in initiatives designed to fill critical data gaps and further optimize treatment for drug-resistant TB.

- Read up on and sensitize policymakers to the TB treatment pipeline,⁴¹ including how, if proven, the medicines and regimens contained therein may make treatment for drug-resistant TB shorter, simpler, safer, and more effective;
- Encourage your government to increase its investments in TB R&D,⁴² and to contribute to the development of appropriate incentives for, and innovative models of, research that promote transparency, collaboration, and access;
- Set up or apply to participate in community advisory boards (CABs) or other mechanisms through which TB-affected communities can engage with TB drug and study sponsors to ensure that research investments reflect community needs and priorities.

THANK YOU & JOIN US TOMORROW



Thursday, Sept. 3rd @8:00 AM ET

TB Diagnostic Tools

- **Introduction**, David Branigan, Treatment Action Group (TAG)
- **The Highest Standard of Care for TB Diagnosis: The Tools We Have and How They Should Be Used Together**, Dr. Madhukar Pai, McGill University
- **Accessing Diagnostic Testing for TB and DR-TB at the Community Level: Challenges and Proposed Solutions**, Adebola Tope Adams, Nigeria TB People
- **Translating Policy into Practice: Scaling Up Rapid Molecular Tests as the Initial TB Test for All & LAM Testing among PLWHA**, Stijn Deborgraeve, MSF Access Campaign
- **Opportunities and Challenges for TB Diagnostics Advocacy in the Context of COVID-19: Holding Actors Accountable & Mobilizing Political Will for Action**, Blessina Kumar, Global Coalition of TB Activists (GCTA)
- **Question and Answer Segment**, Facilitated by Lynette Mabote, Treatment Action Group (TAG)



Not too late to register!!

[https://attendee.gotowebinar.com/register/5279283499429692944.](https://attendee.gotowebinar.com/register/5279283499429692944)