



STIJN DEBORGGRAEVE

MSF ACCESS CAMPAIGN

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TB ADVOCACY

Swiss TPH Hybrid Symposium
The Tuberculosis Pandemic – a Call to Action
Science, Application, Politics
21-22 March 2023, Basel, Switzerland

MEDICINES **SHOULDN'T** BE A LUXURY





15,400

PEOPLE STARTED ON TB TREATMENT IN
MSF PROGRAMMES IN 2021

1,840

PEOPLE STARTED ON DRUG-RESISTANT
TB TREATMENT IN MSF PROGRAMMES IN
2021

TUBERCULOSIS IS ONE OF THE TOP INFECTIOUS KILLERS IN THE WORLD

World Health Organization

IN 2021

1.6 million people died from TB

including **187 000 people** with HIV

Around **3 in 10 people** living with TB

are not diagnosed or treated





Photo: MSF/Igor Barbero



ISSUE BRIEF

MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN

DR-TB DRUGS UNDER THE MICROSCOPE 2022

8TH EDITION

Pricing and patent landscape of medicines for adults and children

DCA_10.5/140Index 014

EXECUTIVE SUMMARY

In 2021 and 2022, tuberculosis (TB) research delivered promising results about medicines and treatment regimens with the capacity to treat people affected by drug resistant (DR)-TB more quickly and effectively, and with much improved tolerability for patients.

As a result, BPdM and BPdL, two new all-oral regimens, both of six months' duration, are recommended for multidrug resistant/ rifampicin resistant (MDR/RR) TB and extensively drug resistant (pre-XDR) TB. These are alternatives to longer or more toxic regimens. More evidence is being generated by ongoing clinical trials assessing short all-oral regimens for fluoroquinolone (FQ) susceptible MDR-TB and FQ resistant MDR-TB.

Children affected by DR-TB can now be treated with regimens fully made of medicines available in child-friendly formulations. Previously, children had to be treated with adult formulations that had to be crushed or split, which carried the risk of not achieving correct therapeutic levels.

While the availability of patient-friendly medicines and regimens is a positive development, they continue to remain inaccessible to many people, in part due to their high prices and licensing arrangements by pharmaceutical corporations and other drug developers.

Bedaquiline, a component of all short and most long regimens to treat DR-TB in adults, currently accounts for 35-40% and 35-70% respectively of the overall cost of regimens. The compound patent on bedaquiline is set to expire in July 2023, but the restrictive terms of a voluntary license between pharmaceutical corporation Johnson & Johnson (J&J) and not-for-profit organisation TB Alliance (TBA) may act as a barrier to the entry on the market of generic versions of the drug. This will in turn delay the scale-up of more affordable bedaquiline-containing regimens.

Protomanid is a component of the two new all-oral regimens recommended by World Health Organization (WHO). The medicine is currently priced at US\$56/month at the Global Drug Facility (GDF). However, given the significant public and philanthropic resources that funded the development of the medicine this price is unjustified. Researchers estimate that protomanid can be produced and sold at a profit for less than \$35/month.

Delamanid is one of the most expensive medicines used to treat DR-TB. Its high prices – it is 15-18 times more expensive than what is estimated it could be profitably sold for – represent a major challenge to procurement of sufficient quantities of the medicine by national TB programmes and other TB care providers. Generic competition is needed to contribute to making a more affordable version of delamanid available.

Due to the impact of the COVID pandemic on health systems, the number of people diagnosed with and on treatment for TB, including DR-TB, has declined dramatically in the last two years. Now more than ever there is a need to scale up access to these shorter and more effective treatments. But to do so, pharmaceutical corporations' onerous practices and their opaque and restrictive licensing arrangements need to be scrutinised and contested.

Given the limited number of children being diagnosed with and treated for DR-TB, manufacturers may not consider the paediatric TB market viable. It is imperative that pooling procurement across national TB programmes is considered to ensure sustainable supply, alongside stepping up efforts to diagnose and treat more children with DR-TB.

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©. Nagesh Kumar/MSF

Volunteer, 7 years old and living with DR-TB, held by her mother Velina, interacts with MSF nurse Pradha.

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TB ADVOCACY

Innovation

Policies

Use

Access

Political will

Innovation



<https://msf-access.medium.com/the-deadly-gap-in-diagnosing-children-with-tuberculosis-2f0673117940>

“In our clinic, every day we see children with symptoms that could be TB. We are an experienced team and have the laboratory TB tests available but for most children who come to us, we just cannot confirm the diagnosis of TB.”

- Dr Lazro Fidelle, Malakal, South Sudan

“Our biggest challenge is collecting a sputum sample from the child to test for TB. While sputum is the standard specimen that we use to detect TB, small children are often not able to produce sufficient sputum to test.”

- Dr Lazro Fidelle, Malakal, South Sudan

“Most of the time we go ahead and treat the child without any positive lab test results. However, this decision to treat must always balance the need for timely and lifesaving treatment with the need to avoid unnecessary treatment of children who may not have TB but another respiratory infection. So we welcome the updated WHO guidelines which now provide clear evidence-based clinical algorithms to diagnose TB, even when test results are not available.”

- Dr Lazro Fidelle, Malakal, South Sudan

Policies



Step Up for TB

2020 Tuberculosis Policies
in 37 Countries

A survey of prevention, testing, and treatment policies and practices



Key findings

RAPID MOLECULAR DIAGNOSTICS

28/34 (82%) COUNTRIES' policies indicate that a rapid molecular diagnostic is the initial test for all people with signs and symptoms of TB.*

17/24 (71%) COUNTRIES' policies do not limit the use of rapid molecular diagnostics to certain facilities, among countries with rapid molecular diagnostics as the initial test for all people with signs and symptoms of TB.

TB LAM

13/37 (35%) COUNTRIES' policies do not require a CD4 count to routinely test people living with HIV who are severely sick or have advanced HIV disease using TB LAM, in line with WHO recommendations; **1/37 (3%)** country policy does require a CD4 count; and **23/37 (62%)** countries do not indicate TB LAM in their policies for routine use.

10/14 (71%) COUNTRIES with policies to routinely test people living with HIV who are severely sick or have advanced HIV disease using TB LAM have implemented this policy and use it in practice.

5/8 (63%) COUNTRIES that have implemented TB LAM for routine use have done so in both inpatient and outpatient settings, while **3/8 (38%)** countries limit routine use of TB LAM to inpatient settings, although the test is also recommended by WHO for outpatients.^{vi}

9/13 (69%) COUNTRIES' policies indicate that TB treatment can be initiated based on TB LAM results without a confirmatory test. In the remaining 4 countries, either bacteriological confirmation using another test is required or the policies were not clear.^{vi}

DRUG SUSCEPTIBILITY TESTING

31/36 (86%) COUNTRIES' policies indicate rifampicin resistance testing for all people with bacteriologically confirmed TB.

11/36 (31%) COUNTRIES' policies indicate isoniazid resistance testing for all people starting on drug-susceptible TB treatment.

37/37 (100%) COUNTRIES' policies indicate that people with rifampicin-resistant TB are further tested for resistance to at least fluoroquinolones.

10/35 (29%) COUNTRIES have drug susceptibility testing routinely available for the drug-resistant medicines bedaquiline, delamanid, linezolid and/or clofazimine, when these medicines are used in country, according to national TB programmes.

6/33 (18%) COUNTRIES' policies indicate rifampicin and isoniazid resistance for all people starting on treatment; at least fluoroquinolone resistance testing for all people with rifampicin-resistant TB; and drug susceptibility testing methods available in country for rifampicin, isoniazid, fluoroquinolones, bedaquiline, delamanid, linezolid and/or clofazimine, when these drugs are used for routine treatment.

Use

EXECUTIVE SUMMARY DASHBOARD

Indicator number	Diagnosing TB		
	1	2	3
Legend ... National policies indicate N/A, not applicable Grey - no data *This table consists of two or more individual indicators. 'No data' is used when there is no data for one or more of the individual indicators considered.	... a rapid molecular diagnostic (RMT) as the initial test for TB	... urinary TB LAM for routine diagnosis of TB in people living with HIV (PLHIV) and the test is routinely used in both inpatient (IPC) and outpatient (OPC) settings*	... Rif and IsonH resistance testing for all people starting on treatment, at least FQI resistance testing for all people with RR-TB, and DDT methods available in country for RR, RRH, FQI, Ison, Dlx, Lzd, and Clz, when these medicines are used for routine treatment*
Azerbaijan			
Bangladesh			
Belarus			
Brazil			
Cameroon			
CAH			
DRC			
DRC			
Ecuador			
Ethiopia			
India			
Indonesia			
Kazakhstan			
Kenya			
Kyrgyzstan			
Lesotho			
Liberia			
Malawi			
Mozambique			
Namibia			
Nigeria			
Pakistan			
PHU			
Philippines			
R. Moldova			
Russian Fed.			
Sierra Leone			
South Africa			
Tajikistan			
Thailand			
Uganda			
Ukraine			
UK, Tanzania			
Uzbekistan			
Viet Nam			
Zambia			
Zimbabwe			



Step Up for TB

2020 Tuberculosis Policies in 37 Countries

A survey of prevention, testing, and treatment policies and practices



Step Up for TB 2020 Activist Toolkit

Stop TB Partnership and Médecins Sans Frontières

TUBERCULOSIS IS
THE LEADING KILLER OF
PEOPLE LIVING WITH HIV

World Health
Organization
Western Pacific Region



IN 2021, THERE WERE 6900 DEATHS FROM TB AMONG
PEOPLE LIVING WITH HIV IN THE WESTERN PACIFIC



38 000 people
living with HIV in the
Region developed TB

Only 24%
accessed life-saving
antiretroviral therapy

TECHNICAL BRIEF | 03 MARCH 2022

20-tool checklist for diagnosing, treating and preventing AIDS

Diagnostic and treatment checklist for the management of HIV and advanced HIV disease in
outpatient settings

HIV/AIDS

Download



<https://msfaccess.org/20-tool-checklist-diagnosing-treating-and-preventing-aids>

PRESS RELEASE | 25 OCTOBER 2018

**Activists call on countries and
donors to immediately scale up
use of life-saving TB LAM test**

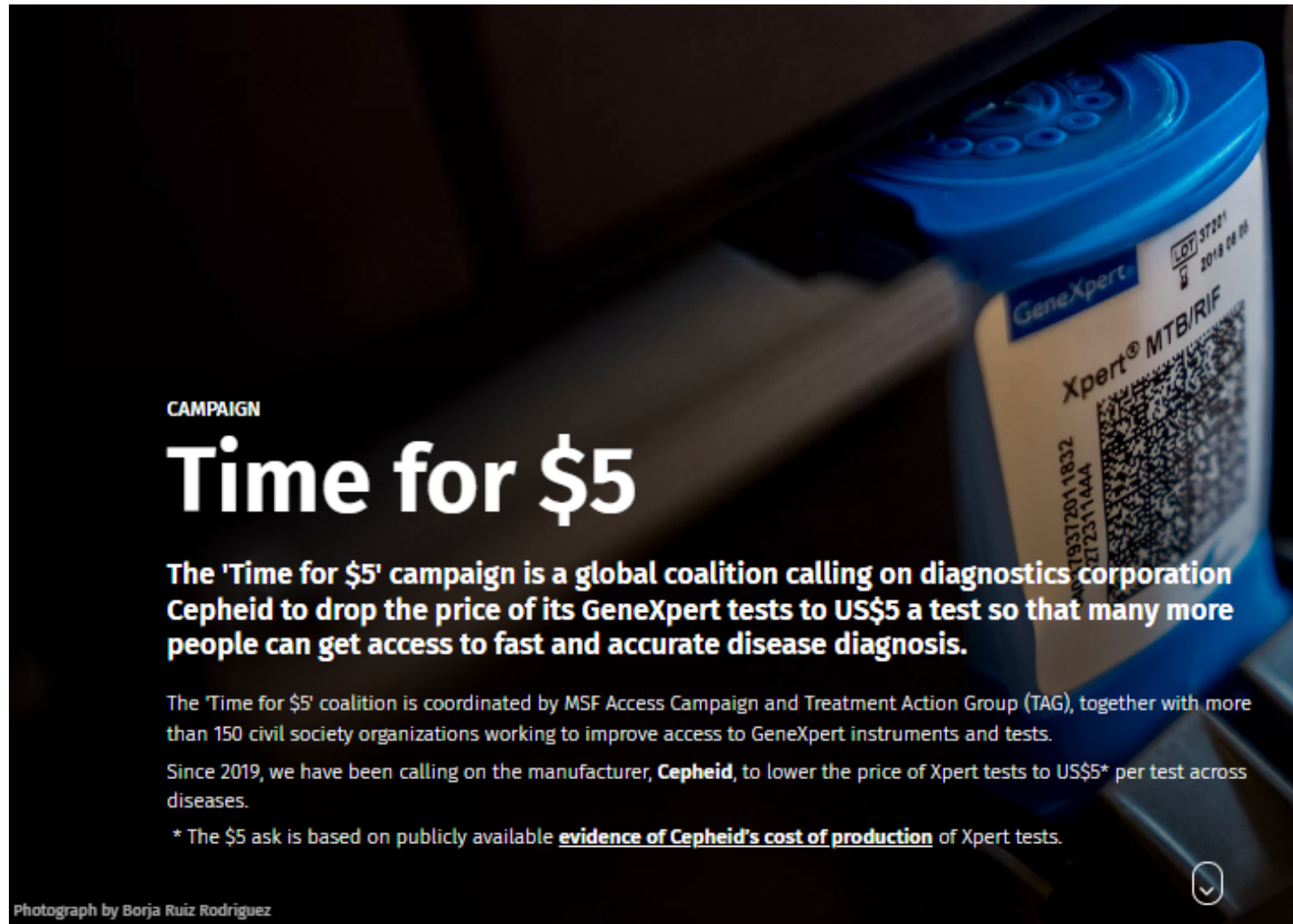
11 min

TUBERCULOSIS

Netherlands



Access



CAMPAIGN

Time for \$5

The 'Time for \$5' campaign is a global coalition calling on diagnostics corporation Cepheid to drop the price of its GeneXpert tests to US\$5 a test so that many more people can get access to fast and accurate disease diagnosis.

The 'Time for \$5' coalition is coordinated by MSF Access Campaign and Treatment Action Group (TAG), together with more than 150 civil society organizations working to improve access to GeneXpert instruments and tests.

Since 2019, we have been calling on the manufacturer, **Cepheid**, to lower the price of Xpert tests to US\$5* per test across diseases.

* The \$5 ask is based on publicly available [evidence of Cepheid's cost of production](#) of Xpert tests.

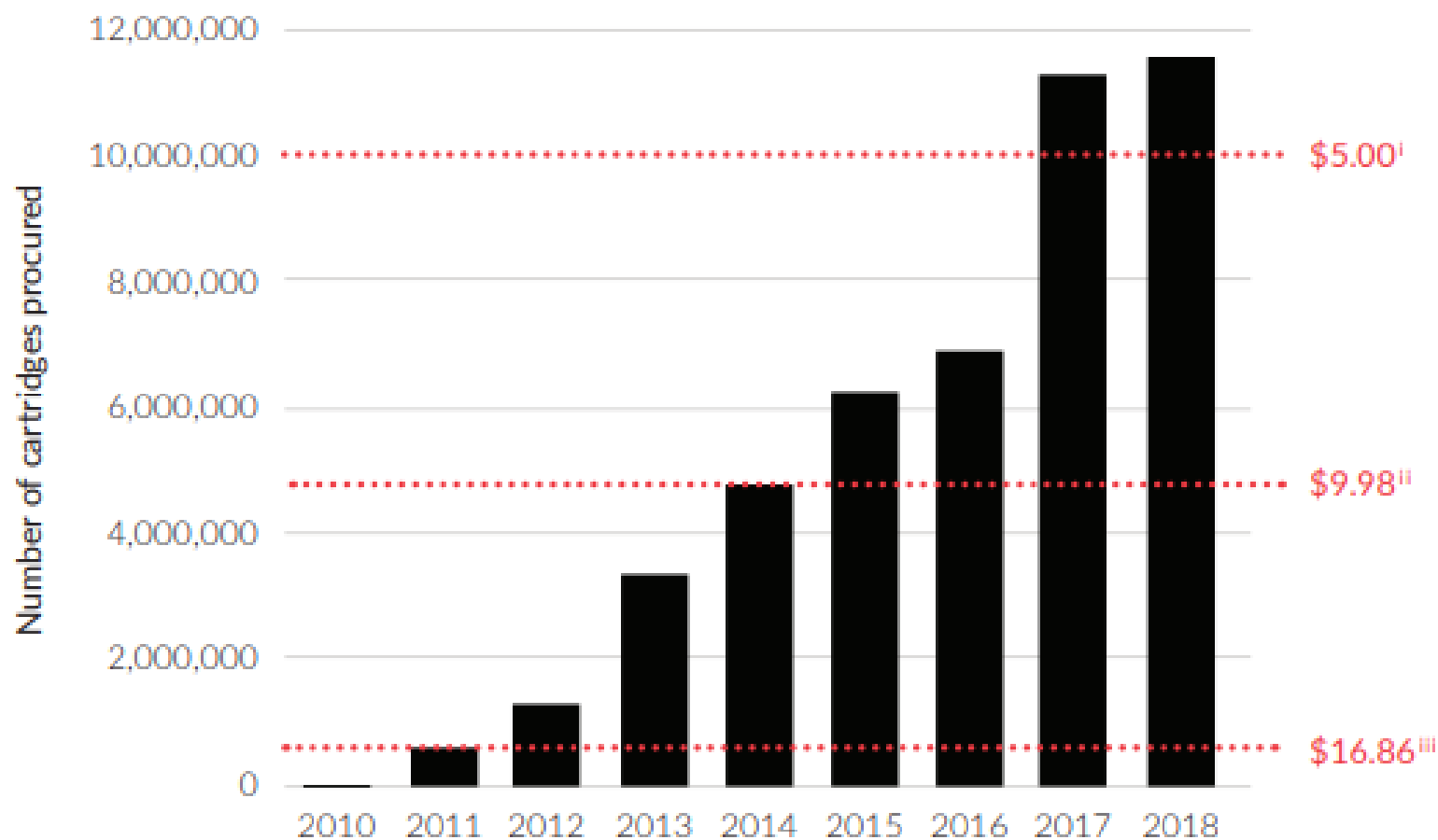
Photograph by Borja Ruiz Rodriguez



But Cepheid refuses to reduce the price and still prioritizes making profit over saving lives.

<https://msfaccess.org/time-for-5>

Figure 1: Annual volumes and estimated volume-based prices of Xpert TB test cartridges procured by high-burden countries, 2010–2018^{28, 29, 30}



TAG
Treatment Action Group



RESEARCH ARTICLE | 31 August 2021

PLOS ONE: Public investments in the development of GeneXpert molecular diagnostic technology

🕒 2 min

[Read the full story](#)



Political will



Towards the
UNITED NATIONS
HIGH-LEVEL MEETING ON THE
FIGHT TO END TUBERCULOSIS
22 SEPTEMBER 2023, UNHQ, NEW YORK



MSF Statement on EB152/5 - Strengthening diagnostics capacity

🕒 1 min

DIAGNOSTICS



UN Photo/Christopher Black

MSF @ the 152nd WHO Executive Board



The resolution recognises that affordable prices of diagnostics are a key enabler for strengthening diagnostics capacity. However, it fails to take into account the need to improve transparency in public investments, cost of production and pricing structure of diagnostics.

<https://msfaccess.org/msf-statement-eb1525-strengthening-diagnostics-capacity>