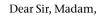


IF @JNJCARES, **#NO MORE TEA**



ÉDITO

The COVID-19 pandemic almost feels like a distant, unkind, memory from times past, even though the virus is still causing illness amongst us and is continuing to burden our health systems worldwide. As humankind we've managed to curb the course of this pandemic when vaccines quickly appeared on the market and we have sustained access to new vaccines that protect the most vulnerable against new variants of the virus.

J&J release earnings at NY Stock Exchange 22/01/2020

The relative swift appearance of the vaccines against COVID-19 were actually built on decades of knowledge forged in our universities and research institutes and largely paid for in its development by taxpayers globally. However, it also became rapidly evident that vaccines and other lifesaving tools such as medicines and laboratory tests were not available to large parts of the world, leaving many health care workers and populations largely unprotected against this virus. Parts of the world in which MSF provides medical care on a daily basis where we witnesses suffering caused by the lack of access.

Shortages in life saving medicines and tools aren't new and MSF has always been an active advocate to ensure that life saving medicines are affordable and available worlwide. As early as the 1990s we started with this campaign whilst the HIV/AIDS epidemic raging on the populations in Africa. Still today 1.5 million people die from vaccine preventable diseases every year. Aside from individuals actively making the choice not to be vaccinated we also see other factors attributed to this. The truth is people sometimes simply don't have access to safe affordable. Many governments also can't afford the prices of vaccines or simply don't have sufficient access to them. The work that our MSF Access Campaign team does, testifies to these facts.

Intellectual property (IP) also plays a complex role here but aligned with the decades of research done by MSF it is evident that the current IP system, the right to property are protected at the expense of billions of people who are thereby denied access to essential medicines. It is almost certain that there will be new epidemics in the future. We must prepare for this. The right to healthcare for the majority must become central. That requires collective solutions.' Countries must decide to change the TRIPS (Trade Related Intellectual Property Rights) treaty within the World Trade Organization so that patents on essential lifesaving medicines are no longer allowed. By lifting intellectual property on vaccines, increasing research capacity in the South and encouraging more equitable cooperation between scientists in North and South.

'Access to vaccines and medicines should not depend on charity but should become a legal obligation.

Even today, with a recent pandemic where one might have hoped that equity to access vaccines would have become a problem of the past. Unfortunately, this is not the case. However recent success stories where continued advocacy from MSF and other organization we also see little successes in companies lowering prices on medicines and diagnostic tools. This should strengthen our mission to keep on investing in medical advocacy next to the delivery of medical to those that need it most, wherever they are in the world.



Yours faithfully,

Amrish Baidjoe, Director of LuxOR Operational Research and Epidemiology Support unit



Dr James Orbinski, MSF International President, in his speech at the award of the Nobel Peace Prize to Médecing Sans Frontières on December 10th 1999 in Norway. © Patrick Robert

For Médecins Sans Frontières, medical action and bearing witness are inextricably linked to activities in the field.

MSF speaks out publicly to try to bring a crisis out of oblivion, to alert public opinion to abuses committed far from the cameras, to criticize the inadequacies of the aid system, or when assistance is diverted from its primary objective to serve political interests. The organisation rejects the idea of medicine on the cheap for poor countries, and strives to provide quality care for patients and to change practices. Every day, the Access to Essential Medicines Campaign strives to reduce the price of vaccines and improve access to treatment for the people who need it most. To promote the research and development of new treatments, the Drugs for Neglected Diseases initiative (DNDi) lobbies the pharmaceutical sector.

When the Nobel Prize was awarded in Oslo, James Orbinski, then President of the International Council of Médecins Sans Frontières, publicly denounced the Russian army's abuses in Chechnya and called on Boris Yeltsin to stop the murderous bombings. Since the start of operations in Chechnya, Moscow has banned MSF from visiting Grozny, the Chechen capital.

Today, a growing injustice confronts us. More than 90% of all death and suffering from infectious diseases occurs in the developing world. Some of the reasons that people die from diseases like AIDS, TB, sleeping sickness and other tropical diseases is that lifesaving essential medicines are either too expensive, are not available because they are not seen as financially viable, or because there is virtually no new research and development for priority tropical diseases. This market failure is our next challenge. The challenge however, is not ours alone. It is also for governments, international government institutions, the pharmaceutical industry and other NGOs to confront this injustice. What we as a civil society movement demand is change, not charity.

MSF's Nobel Peace Prize Lecture by Dr. James Orbinski, MSF International President, December 10th, 1999

The Nobel Peace Prize: launches1 the Access to Essential MedicinesCampaign



The donation received from the Nobel Prize, almost six million francs (900,000 euros), was used to officially launch the **Campaign for Access to Essential Medicines (CAME)** that same year, out of medical necessity and frustration at the deaths of people suffering from curable diseases.

This authority is the movement's response to the shortage of effective therapeutic means to treat patients affected by tropical and infectious diseases, which are among the leading causes of death worldwide. **CAME's aim is to contribute to the production of medicines that are no longer manufactured, to make them accessible, and to stimulate research and development into treatments for neglected diseases.**

From the mid-1990s onwards, the treatment of HIV in developed countries with effective new drugs called antiretrovirals produced spectacular results. The AIDS mortality rate fell sharply and steadily. In developing countries, on the other hand, the high prices charged by pharmaceutical companies for antiretrovirals have put these drugs beyond the reach of most people living with the virus. The number of AIDS deaths continued to rise until patients and healthcare advocates mobilised to generate political pressure. This led to dramatic price cuts for HIV drugs, enabling millions of people to receive this life-saving treatment.

The lesson was clear: if the best medicines and tests were available to people everywhere, not just in wealthy countries, many more lives could be saved. In the years since, in response to the needs of our teams, we have expanded our work to include tuberculosis, sleeping sickness, malaria, vaccines, drug-resistant infections and more.

OBJECTIVES OF THE ACCESS CAMPAIGN

- > putting these inequalities on the political agenda
- > offer benefits to the people we care for
- Iower drug prices
- > expand treatment options
- > ensure that medicines are adapted to the conditions in which we work.

ACCESS CAMPAIGN'S CONTRIBUTIONS OVER THE LAST 24 YEARS

- > lowering the price of HIV drugs from\$10,000 to \$100 per year
- > reducing the price of hepatitis C treatment from \$1,000 to \$1 per pill
- > negotiate affordable access to the pneumonia
- vaccine for humanitarian workers
- > impose more effective treatment for malaria, which was not used in most African countries («ACT NOW» campaign in 2003).

"MSF's fight with the Access Campaign for access to ARVs is the most successful and has been a real game changer. When it comes to the treatment of resistant tuberculosis, MSF plays a very important role on the international scene, in terms of its impact on health policies. There is a need for a short, oral, injection-free treatment with few side effects. Treatment should also be extended to other equally vulnerable groups, such as prisoners, migrants, etc. The problem of access remains that we need more research, more oral solutions that can be tolerated, short solutions for short courses of treatment. One size doesn't fit all. Having several options can help."



DR GABRIELLA FERLAZZO Board Member at MSF Luxembourg, TB Medical Adviser at MSF Access Campaign Infectious Diseases specialist, TB/HIV Public Health Consultant, Substance Abuse MD & training in Mental Health

A worldwide 2 revolt for access: the greatest hits

By the mid-1990s, the HIV/AIDS epidemic was raging around the world. New life-saving antiretroviral drugs had produced spectacular results and transformed HIV into a manageable chronic disease in rich countries. But their price made them unaffordable in other countries. What's more, for neglected diseases such as tuberculosis, malaria and sleeping sickness, treatments were either non-existent, ineffective, toxic or ill-suited to the contexts in which we work.

2001 - The most incredible success story: Big Pharma vs Mandela - getting lifesaving medicines to people with HIV/AIDS

One of the Campaign's first priorities was to expand access to life-saving antiretrovirals, which were then being sold at over USD 10,000 per person per year because of patent monopolies.

An emerging movement in favour of access to medicines has put pressure on pharmaceutical companies, governments and other «powers that be» to end this deadly impasse and obtain lower prices for drugs in order to improve access to HIV treatment.

In South Africa, one of the epicentres of the AIDS epidemic, a lawsuit brought in 1997 by 39 pharmaceutical companies threatened to block imports of low-cost generic treatments. MSF supported civil society demonstrations, campaigns of defiance and legal action. More than 300,000 people in 130 countries signed the international «Drop the case» petition launched by MSF. In April 2001, faced with a disastrous image around the world, these laboratories announced that they were dropping the case unconditionally.

By overcoming corporate monopolies and encouraging generic production and competition, the price of antiretroviral drugs fell by 99% over the following decade, paving the way for treatment of people living with HIV/AIDS to be extended to more than 22 million people by the end of 2018.

Protesters demonstrate outside Supreme Court in Pretoria, South Africa Monday March 5, 2001. © Christian Schwetz



3 questions with Dr Eric Goemaere

Dr Eric Goemaere opened MSF's first HIV treatment programme in South Africa in 2000, in Khayelitsha.

At the time, the medical situation was dire, with many sick people coming to the clinic seeking treatment. Access to antiretroviral (ARV) and other essential drugs was very difficult due to high prices and patent barriers. Dr Goemaere, patient advocates, and health rights groups stood up to the pharmaceutical industry, and government denialism and inaction, to get these medicines to people who needed them to survive.

What was the crisis you were facing as an MSF doctor treating HIV/AIDS in South Africa in the 2000s?

The majority of people [coming to our clinic] could not walk anymore. They were brought literally in wheelbarrows, or carried on the backs of their relatives. People were dying in the waiting room. While we were consulting behind the door, regularly we could hear people screaming, and this was a sign there was another death. And honestly, there was no single day without a death in the waiting room.

What were the access barriers to ARV drugs at the time?

People could not afford it. It was as simple as that. [And] there was a blockage at the government level. All sorts of things came out – that they were toxic, that the drugs were killing people, problems with the tests. There was a lot of denial on ARVs.

How were you able to get drugs to patients then?

We shipped them clandestinely, because we could not officially pass them through. The idea was the defiance campaign [of illegally importing affordable HIV drugs] will only work if we put a few people on treatment, and everybody will see it works. It's exactly what we did.



▷ Babalwa Tembani, a young client on ART in the Khayelitsha clinics explains her experience to former South African president Nelson Mandela, at the right of Dr Eric Goemaere, Head of Mission for the MSF Khayelitsha

project, 12/12/2002 © Eric Mille

Testimony of Dr Rony Zachariah, former coordinator of the Luxembourg Operational Research unit:

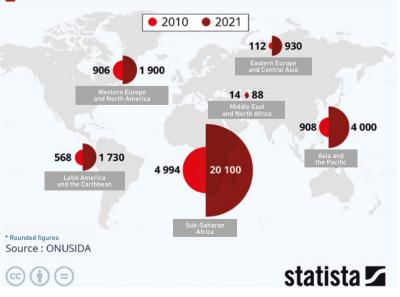
"We are in the year 2000, advocating life-saving antiretroviral treatment (ART) in Africa. But alas! Many ignored us on the pretext that ART was too complex and expensive. Some politicians even claimed that «Africans

don't have watches and can't take AIDS treatment properly». This despite the fact that more than 17 million people had already died of HIV/AIDS in Africa. The moral imperative to demonstrate feasibility was incumbent on us.

Five years later, in rural Malawi, we celebrated «universal access» - everyone who needed antiretroviral treatment received it. More than 10,000 lives were saved, we proved the sceptics wrong and brought hope to many people's lives."

Ever more HIV-positive patients on treatment

Number of HIV-infected people on antiretroviral treatment (ART), by region of the world, in thousands*



Today, the Access campaign is still calling for an end to the pharmaceutical industry's high prices through price transparency, and is highlighting the abuses linked to the issue of patents. Normally, a patent is granted for 20 years. But when this period has expired, manufacturers make minimal changes to the drug's formula to renew patents for a further 20 years. This practice, known as «Evergreening», allows pharmaceutical companies to protect and extend their monopoly over a longer period, making it impossible to make the drug available to everyone, even after 20 years. This is why it is essential to encourage medical innovation as a public health interest.

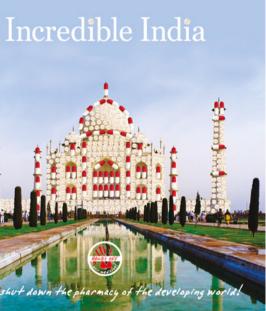
It is also essential to protect the governments of countries that wish to exercise their legal right to access medicines. In 2005, the Indian government introduced protection for public health by tightening the criteria for patentability. Indian law makes it impossible to patent «simple» derivatives of an existing substance or process without improving its therapeutic efficacy. India authorises the production of low-cost generic medicines to protect the right to health and access to medicines, which benefits thousands of people in low- and middle-income countries.



↗ Incredible India ↑ New Delhi. Hundreds of Indian activists protested in New Delhi on Monday against a challenge to the country's patent law by Swiss pharmaceutical giant Novartis. 29/01/2007 © Sheila Shettle

2006 - Novartis 'Drop the Case' Campaign: India, the pharmacy of the developing world.

In 2006, the Swiss pharmaceutical company Novartis took legal action against the Indian government for refusing to patent the cancer drug Glivec. Marketed as a generic in India, the drug costs less than \$200, compared with \$2,600 in countries where Novartis has obtained a patent. In 2006, Médecins Sans Frontières launched a «Novartis - Drop the case» campaign to get the company to drop its legal action. Nearly 500,000 people signed the «Drop the Case» petition, which received wide international media coverage and raised India's profile as a producer of generic medicines. Novartis lost its case in 2007 and then appealed against this decision in 2009. In 2013, the Indian Supreme Court upheld the interpretation of the Patent Act. This is a major victory for patient access to affordable medicines in developing countries that depend on affordable generic medicines to save lives and protect health.



In recent years, two new drugs (Bedaquiline and Delamanid) and a powerful diagnostic analysis device (GeneXpert) have been brought to market, ending a decades-long innovation gap. However, access to and use of these new tools lags behind, as does further research and development into new medicines.

³ Ongoing campaigns

2019 - #NoMoreTears: affordable access to anti-tuberculosis drugs.

MSF has joined activists and civil society around the world in demanding that crucial drugs to treat drug-resistant tuberculosis (DR-TB) be made affordable. DR-TB remains extremely difficult to treat. Treatments are expensive, have serious side effects and low cure rates. In 2019, MSF launched a global #No-MoreTears campaign, calling on the pharmaceutical company Johnson & Johnson (J&J) to lower the price of Bedaquiline, the anti-tuberculosis drug it produces, to a maximum of US\$1 per day, for all patients worldwide, in order to treat more patients and reduce mortality. At the time, Johnson & Johnson was the only manufacturer of Bedaquiline and had patented the drug in most countries, thereby controlling the price at which it was sold. 120,700 people signed the petition. In July 2020, J&J lowered the price to \$1.50 per day.

Despite recent improvements in tuberculosis drugs and diagnostics, progress has been slow in extending treatment to people with tuberculosis.

In 2020, 1.5 million people died from the disease, which, according to the World Health Organisation (WHO), makes it the second most deadly in the world after Covid-19.

The most difficult cases to treat are multidrug-resistant tuberculosis, a form that does not respond to standard drugs. For years, patients have had to undergo long, ineffective and painful treatments. Recently, a new treatment has been developed, but it is still not available to those who need it most. Tuberculosis is one of the world's most serious health crises.

MSF protested in front of the New York Stock Exchange in New York on January 22, 2020, demanding the pharmaceutical corporation Johnson & Johnson (J&J) make the tuberculosis (TB) drug bedaquiline available for all people with drug-resistant TB (DR-TB) for no more than a dollar a day.



Vaishnavi, pulmonary DRTB patient from Thane @Prem Hessenkamp

Christophe Perrin, as TB Advocacy Pharmacist at MSF Access Campaign

- reacts after the announcement of Stop TB Partnership/ Global Drug Facility and Johnson & Johnson on 18 July 2023:

"MSF reiterates call for J&J to withdraw or abandon extended patents on key TB medicines as main patent expires today, opening the door to more affordable generics, Recent deal offering controlled generics access in limited countries does not go far enough."

- responds to groundbreaking news that Johnson & Johnson will not enforce patents on key TB drug bedaquiline in lowand middle-income countries on 30 September 2023:

"We welcome Johnson & Johnson's (J&J) announcement finally paving the way for unfettered access to affordable generic versions of bedaquiline for all people living with drug-resistant tuberculosis (DR-TB) who need the drug in low- and middle-income countries. We need all newer TB innovations to be as affordable as absolutely possible, so governments can scale up prevention, testing and treatment to beat back this curable disease."

"This huge success is a testament to the persistent efforts of TB activists, civil society and also countries prioritising public health over corporations' interests."

"After J&J lost its attempt to extend its monopoly in India, national TB treatment programmes from Ukraine and Belarus requested J&J to drop its secondary patents in their countries and others heavily affected by TB. The recent investigation by the South African Competition Commission undoubtedly added significant pressure on [&], ahead of their announcement."

"We now want to see Japanese pharmaceutical corporation Otsuka follow suit and publicly announce that they will not enforce any secondary patents in low- and middle-income countries for the other critical newer TB drug delamanid, especially as the corporation's primary patent is set to expire in 10 days in India and other countries. Delamanid is another key DR-TB drug used in combination with bedaquiline, and is particularly important for children."

2019 - Out of reach: a revolutionary diagnostic test to save lives 'Time for \$5'

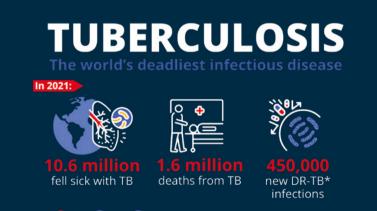
Since its arrival on the market in 2010, the GeneXpert diagnostic test from US company Cepheid has revolutionized the rapid and accurate diagnosis of tuberculosis (TB). The World Health Organization (WHO) recommends the Xpert MTB/RIF test as the initial test for all people with signs and symptoms of TB. However, due to the high cost of the GeneXpert instrument and its tests, most countries with a high TB burden are unable to extend the test to all those who need it. Instead, carers continue to rely on microscopic examination of sputum smears, which is less expensive and less accurate. In addition to tuberculosis, several other Xpert tests have been developed to combat other difficult diseases, which have been added to Cepheid's preferential pricing programme for high-burden developing countries (HBDCs). These diseases include HIV, hepatitis B and C, COVID, human papillomavirus (HPV), Ebola and various sexually transmitted diseases.

MSF'S ANALYSIS

SHOWED THAT IT COSTS CEPHEID LESS THAN 5 DOLLARS TO MANUFACTURE A GENEXPERT TEST,

- whereas Cepheid has been charging MSF and the most affected developing countries:
- > double this price per tuberculosis test for over 10 years,
- > at least three times for tests for HIV, hepatitis, COVID and sexually transmitted diseases, > and four times for tests for Ebola and extensively drug-resistant tuberculosis.





More than **1 in 3** people



The 'Time for \$5' Campaign

calls on US diagnostics corporation Cepheid, and its parent company Danaher, to drop the price of its lifesaving GeneXpert tests to US\$5 a test, so that many more people can get fast, accurate disease diagnosis, and receive treatment right away.

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 reiterating our request to the manufacturer, Cepheid, to lower the price of GeneXpert tests to \$5* per test for all diseases.

19 SEPTEMBER 2023

"Thanks to the support of this campaign, Danaher and Cepheid have announced that they will reduce the price of the leading test for drug-resistant tuberculosis (Xpert MTB/ RIF) by 20% in high-burden countries, from \$9.98 to \$7.97 per test. Although it does not represent the 50% reduction to \$5 that we are calling for, this price cut is an important step in the right direction, given that companies have refused to reduce the price of this essential test for more than ten years."







ING DRU

GET IT's

Christos Christou, President of MSF International, reacts after the two recent victories in September 2023:

DID

TRACK

Over the last 10 weeks, the MSF Access Campaign has seen two significant milestones in their tireless work to improve access to tuberculosis testing and treatment:

1. US diagnostics corporation Cepheid, and its parent company Danaher, dropped the price of the GeneXpert TB diagnostic test by 20% - the first time they have dropped the price in over 10 years.

2. US pharmaceutical corporation Johnson & Johnson slashed

the price for the lifesaving TB medicine bedaquiline by more than 50%. These exceptional and momentous victories have been a direct result of sustained public pressure by the Access Campaign, together with civil society and TB activists

from around the world.

Along with the commitments made at the UN High-Level Meeting on TB, these price drops will play an important role in paving the way for countries with a high burden of people living with TB to scale up treatment and care.

It is a moment of hope!

Battery Park Picture 20/09/2023: We gathered today with John Green and other TB activists in New York City's Battery Park - welcoming yesterday's 20% price reduction of GeneXpert TB tests by Cepheid and Danaher. But also calling for price drops for other expensive tests, like the \$15 XDR-TB test. @ Marilia Gurgel



The Drugs for **Neglected Diseases** initiative (DNDi)

Millions of people around the world die every year for lack of treatment. Yet only a tiny proportion of the world's pharmaceutical research and development is focused on diseases affecting poor and vulnerable communities.

When MSF was awarded the Nobel Peace Prize in 1999, it dedicated part of its prize money to resolving this fatal imbalance and exploring a new alternative not-for-profit model for developing medicines for neglected patients. This was an important step in its efforts to align drug development more closely with patient need.

In 2003, MSF, the WHO (World Health Organization) and five international research institutes, including the Institut Pasteur, founded the Drugs for Neglected Diseases initiative (DNDi). This non-profit organization is a collaborative, patient-centered initiative that has already made significant progress since its creation.

Its work is helping to advance research and the creation of solutions to treat diseases, particularly the most serious ones prevalent in tropical countries such as malaria, leishmaniasis and sleeping sickness, which are still neglected by pharmaceutical laboratories due to the insolvency of the populations concerned. In 2003, these neglected diseases affected around one billion people worldwide, including 500 million children. They are responsible for the deaths of several hundred thousand people every year.

DNDi has developed 12 new treatments for six deadly diseases (such as malaria, sleeping sickness, Chagas disease and pediatric HIV/TB co-infection, among others) and has proved that an alternative to disease is possible. One of its antimalarial drug combinations, ASAQ, has been used to treat more than 500 million people.

DNDi has proved to be an effective catalyst for new approaches to patient-cent red drug development and access. It is a good example of the ways in which we encourage change and creativity in medical R&D.

Kala Azar MSF Project - Abdurafi, Ethiopia. Dr. Ernest Nshimiyimana, MSF medical team leader, checks kala azar patients in the ward for patients with kala azar coinfections, at the Abdurafi MSF health centre.

DNDi has developed 12 new treatments for six deadly diseases (such as malaria, sleeping sickness, Chagas disease and paediatric HIV/ TB co-infection, among others) and has proved that an alternative to disease is possible.



Find all the latest news from access campaign on www.msfaccess.org



Do you want to know more about our missions? Support a particular project? Let's talk about it!



Eléonore Macé de Gastines Philanthropy Project Officer eleonore.mace.de.gastines@luxembourg.msf.org +352 33 25 15 – 304



Eléonore Vernier

One-to-One Officer – interim of Pascale Soares – Major Gifts and Partnerships Manager Médecins Sans Frontières Luxembourg eleonore.vernier@luxembourg.msf.org +352 33 25 15

MÉDECINS SANS FRONTIÈRES LUXEMBOURG

68, rue de Gasperich L-1617 Luxembourg Tél: +352 33 25 15

WWW.MSF.LU



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