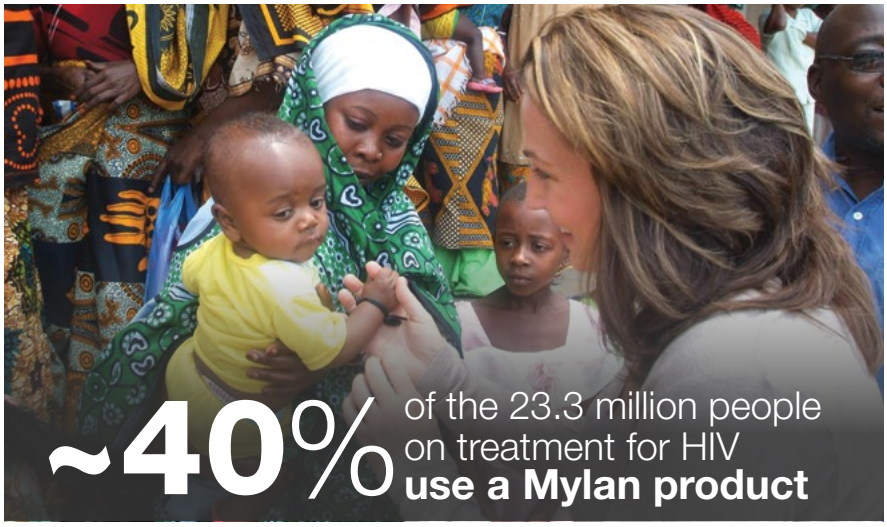
A History of Working to **Stem the Tide of HIV/AIDS**

Recognizing an Urgent Need

Mylan's impact on the HIV/AIDS community around the world is significant. Our numbers tell an amazing story: We manufacture ~5 billion ARV tablets and capsules every year and about 50% of our company's total active pharmaceutical ingredient (API) capacity is devoted to ARVs. Why such a huge emphasis? Because more than a decade ago, Mylan recognized an incredible need around the world and sought to make a difference in the lives of patients living with HIV. Today, we provide access to high quality and affordable ARVs in more than 100 countries and ~40% of the 23.3 million people on treatment for HIV use a Mylan product.[1] Approximately 60% of the world's HIV+ children on treatment rely on one of our medications.

Our HIV/AIDS efforts began in 2007, when we acquired a controlling interest in Matrix, the world's second largest API player at the time and a company with strong scientific capabilities. Mylan and its executive team were attracted to the humanitarian support that Matrix, led by its Chairman N. Prasad, had been providing in response to the global AIDS crisis. That work began in 2003, when Prasad met a man on an airplane who explained that his job was to secure land for new cemeteries to accommodate the rising number of people dying from AIDS in Africa. Many were unable to access expensive but life-saving treatment. As a result, Prasad challenged his team to create cost-effective ARVs to help the population of Africa have access to the medicines they desperately needed.



Ten years ago, Mylan's leaders went to several countries in Africa to learn about the regional needs, infrastructure and stakeholders that are part of providing access to ARV treatment. What they learned informed our work and partnerships, reinforcing our focus on breaking down barriers and increasing the number of people with access to affordable treatment for HIV.

Expanding Our Presence

In 2007, Mylan received its first U.S. FDA approval for an HIV treatment, via the FDA's President's Emergency Plan for AIDS Relief (PEPFAR) pathway. That FDA approval would be the first of many – now over 40 – as we worked tirelessly to create access for these life-saving medicines in countries hardest hit by HIV.

Many of these countries were low- and lower-middle-income countries, often seen as unprofitable or too full of regulatory hurdles for some pharmaceutical companies. In 2009, we introduced the first generic one-tablet-once-a-day combination for developing countries, only three years after the originator product launched in the U.S. That was unprecedented at a time when medicines took a decade or longer to reach patients in low- and lower-middle-income countries. The medicine was offered for less than half the originator's list price. Though we continued to be the product's sole generic supplier for nearly three years, we cut its list price even further – by more than half – over that period as we were able to identify opportunities for efficiency. Today, our list price is less than one quarter of what it was at launch.

Innovating to Help All Patients

As our footprint expanded around the world, we continued to respond to the diverse needs of patients. In sub-Saharan Africa, for example, a lack of refrigeration presented major barriers to getting medicines to those who needed them. To change that, we introduced in 2009 the first generic, heat-stable form of the WHO's preferred second-line drug. A few years later, we set out to help pediatric patients. Because children typically have difficulty swallowing tablets, many pediatric medicines in high-income countries come in the form of syrups. But in some countries, syrups are difficult to transport, often requiring cold storage, and can taste strongly bitter. Our scientists developed a dispersible tablet version of an important combination that dissolves into a child's drink. Later, we developed a heat-stable, taste-masked version of the medicine most recommended by the WHO for HIV-positive infants.

[1] As of end of 2018, unaids.org

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We recognized, of course, that vital medicines are no good if they don't get to the people who need them most. To maximize our impact around the world, we needed partners. In August 2017, we were the first company in the world to launch the first fixed-dose combination of its kind, Tenofovir Disoproxil Fumarate, Lamivudine and Dolutegravir (TLD), what has become the WHO's preferred first-line HIV treatment. With that approval, we also announced a deal with the Bill & Melinda Gates Foundation, the Clinton Health Access Initiative (CHAI), the Department for International Development (DFID) and others to price the new drug the same as existing ones so cost wasn't a barrier to treatment. We continue to work with these and many other organizations around the world to ensure patients have access to treatment.

Investing to Make HIV/AIDS Care Affordable and Sustainable

We have also invested in ensuring patients can afford the important HIV/AIDS treatments they need. Our price for the current WHO preferred HIV therapy[1] is about $0.20 a day; innovator list prices for similar regimens are ten times this for developing countries and ~$100 a day for patients in the U.S.[2] We have helped reduce the cost of treating patients in low- and lower-middle-income countries by more than 80% over the past decade.

We've done this in part by investing more than $250 million during that time in expanding our capacity to reach HIV patients in low- and lower-middle-income countries. In fact, we reach five times as many HIV patients per day around the world as the branded originators combined.

Hoping to replicate our success in low- and lower-middle-income countries, we also have been working to reduce the cost of HIV treatment in the U.S., where the list price of treatment is often over $30,000 per year. In 2018, we launched a set of three new branded combination therapies with list prices 40% below the cost of their nearest competitors.

Partnering with Patients Through Their Entire Journey

Although HIV infection is preventable, significant HIV transmission continues across high income countries and dedicated work is still needed. Our efforts to stem the tide of HIV/AIDS around the world doesn't just include treatment options but also being a part of the entire patient journey. That's why we support patients through the sponsorship of free community HIV/AIDS testing. We are proud supporters of many patient organizations, including the European AIDS Treatment Group, HIV Ireland and the Gender Orientation Sexual Health HIV Organisation (GOSHH).

We market HIV self-test kits in an ever-expanding list of countries around the world. The kits offer patients a discreet, at-home test that detects the presence or absence of HIV antibodies through a fingerstick. It uses one-fifth the volume of blood necessary for other tests and provides the result in just 15 minutes. In Ireland, the patient group GOSHH in 2019 provided patient support services for our HIV self-test kit supplied there. In 2019, we announced with our partner and medical device manufacturer Atomo Diagnostics that the Mylan HIV Self Test received WHO prequalification approval, a milestone that will expand its adoption. The test, which has launched in many countries with additional partners, was made available in Botswana and Namibia in 2019.

We also are deeply committed to encouraging authorities globally to embrace PrEP (pre-exposure prophylaxis) as a proven way to prevent infections. In the U.K., Mylan is proud to be supporting England's National Health Service in the world's largest PrEP implementation trial targeting people at high risk of HIV infection. In many countries, we advocate for this vital medicine to be reimbursed and made available under medical supervision. In Ireland, for example, we joined patient groups and others to successfully advocate for the implementation of a PrEP program. A free program was announced by the government about a year after we made our HIV self test available at retail pharmacies in Ireland, further demonstrating our commitment to prevention of infections in the community.

With these exciting developments and PrEP already well established in large European countries like France and England, we believe the time is now for all stakeholders to work together to prevent HIV. And soon, we believe PrEP will be the major global driving force preventing the disease.

At Mylan, we are immensely proud of our work to make a difference in the lives of people living with HIV/AIDS. We have become the world's largest producer by volume of ARV drugs in low- and lower-middle-income countries, and ~40% of the FDA's tentative approvals of new products under PEPFAR in the last decade are Mylan medicines. Our continued investment in local manufacturing of ARVs, productive and efficient partnerships, and focus on being first-to-file for important drug applications has established us as a leader in the prevention, testing, and treatment of HIV/AIDS. Our journey is truly a testament to our unwavering belief that people everywhere deserve access to life-saving medicines.

[1]For adults and adolescents: TDF + 3TC (or FTC) +DGT. See WHO guide for other populations and special circumstances
[2]MSF Access Campaign: Stopping Senseless Deaths

PATIENT HEALTH:
2019 HIGHLIGHTS

Fighting Infectious Diseases

People living with HIV/AIDS, hepatitis and tuberculosis who receive the proper care can lead long and healthy lives. However, preventing and diagnosing the diseases and ensuring patients have access to life-saving medications, especially in low- and lower-middle-income countries where the burden is most prevalent, are still global challenges.

HIV/AIDS

- Committed to expanding our capacity ten-fold from 20,000 to 200,000 monthly pediatric doses of our Lopinavir/Ritonavir granules, a first-line product critical to children with HIV.
- Launched HIV self tests in Botswana, Laos, Namibia and Portugal. We also introduced a new chat bot to assist website visitors with questions about the testing kits.
- Expanded our agreement as the sole provider with the National Health Service England PrEP trial from 10,000 users to over 15,000.
- Became the first generic manufacturer to receive FDA tentative approval through the PEPFAR expedited review process for tenofovir alafenamide, lamivudine and dolutegravir.[1]
- Partnered with HarborPath, a U.S. organization dedicated to assisting patients in gaining access to their entire regimen of HIV/AIDS medication to donate our HIV combination therapies, Symfi®, Symfi Lo® and Cimduo®, to uninsured individuals.
- Worked with the Bill & Melinda Gates Foundation and the Children's Investment Fund Foundation for grants that will allow Mylan to develop what we expect will be the first-ever combination tablet to prevent both HIV and pregnancy in women of childbearing age.

Mylan has continued to increase its commitment to WHO prequalification

Prequalification allows for U.N. procurement and accelerated registration processes in low- and middle-income countries, an important part of increasing access. With 69 products[2], Mylan is among the leaders in products listed on the WHO list of prequalified products.

In 2019, Mylan received prequalification approval by the WHO for the Mylan HIV Self Test, which enables individuals to test in the comfort and privacy of their own home, making the test an effective way of reaching hard-to-reach populations. Our partnership with Atomo Diagnostics, the manufacturer of the test, covers more than 100 countries across Africa, Asia, the Middle East, the Commonwealth of Independent States (CIS) and Latin America.

- **Mylan also became the first licensed generic manufacturer to receive WHO prequalification for daclatasvir[3], a DAA used to treat hepatitis C, and made it available for one of the lowest prices in the world.[4]**

[1] President's Emergency Plan for AIDS Relief (PEPFAR) database
[2] WHO Pre-Qualification list as per 2/26/20
[3] Essential Medicines and Health Products: Prequalification of medicines: Hepatitis
[4] Clinton Health Access Initiative: Partnerships will help Rwanda eliminate hepatitis C in five years

PATIENT HEALTH:
2019 HIGHLIGHTS

Hepatitis

- Became the preferred partner for India's National Viral Hepatitis Control Program, supplying medicine for more than 150,000 patients in more than 11 Indian states.
- Screened ~200,000 people for hepatitis through our Ashray program, which offers free and subsidized screening and diagnostics, emotional support and helplines.
- Partnered with the Center for Disease Analysis Foundation to support the launch of the Uzbekistan Hepatitis Elimination Pilot (UHEP). This program is leveraging innovative financing tools to help fill the funding gap for tackling hepatitis and, if successful, has the potential to scale nationally.
- Developed a next generation HepBuzz mobile application, which aims to provide a one-stop solution for simplifying hepatitis B and C management. The innovation received an award for "leveraging technology for use of mobile application" at the 4th Annual Digital India Health Summit and Awards.

Working to Eliminate Hepatitis C in Egypt

A little over a decade ago, Egypt had the highest hepatitis C prevalence rate in the world at ~15%. That startling statistic led government efforts and public-private partnerships to spread awareness of the disease and newer treatments with a goal of eliminating hepatitis C and, later, for the country's president to launch an effort to get every citizen in the country tested.

Over the last few years, Mylan supported the nonprofit group Tahya Misr to sponsor ~1 million hepatitis C screening kits at low cost. We also donated a medically equipped bus for the nationwide testing program and have provided quality direct-acting antiretrovirals at very low costs under the program. In all, Mylan's efforts have resulted in ~150,000 patients being treated in Egypt over the last few years.

Egypt has made tremendous strides in lowering the prevalence of hepatitis C in the country, thanks to government efforts and partnerships like Mylan's with Tahya Misr. We believe the program in Egypt stands as a strong example of how public health gains can be made in low-resource contexts provided there is strong government will, budgetary commitment and smart drug procurement to make life-saving treatments affordable.

Tackling Tuberculosis with **Passion and Partnership**

Expanding Our Focus

Tuberculosis (TB) is one of the top 10 causes of death worldwide, killing an estimated 1.6 million people a year.[1] Nearly all of these deaths occur in low- and lower-middle-income countries, where drug resistance poses a serious challenge to treating the disease. TB is also the leading cause of death among people with HIV/AIDS.[2]

Mylan received the Platinum Pledge recognition from United States Agency for International Development (USAID) for its work to help tuberculosis patients in India.

Because of our longstanding commitment to battling infectious diseases like HIV, we recognized the need to bring that same commitment to addressing the TB epidemic. In 2019, we announced a global partnership with the nonprofit drug developer TB Alliance for the molecule pretomanid as part of two drug regimens. The news came two years after we secured licensing of another TB treatment, delamanid, from Otsuka.

In August 2019, pretomanid was approved by the U.S. FDA in a combination regimen with bedaquiline and linezolid for treating people with extensively drug-resistant, treatment intolerant or non-responsive TB. Pretomanid's approval came via the Limited Population Pathway for Antibacterial and Antifungal Drugs, which encourages the development of antibacterial and antifungal drugs to treat serious, life-threatening infections, such as TB, that affect a limited patient population. It marks the first-ever FDA approval of a treatment for XDR-TB.

Mylan and Otsuka have provided 400 patient treatment courses of delamanid to the Indian government. In parallel, we are partnering on a technology transfer project to produce the medicine locally in India, which will make the current treatment more affordable and more accessible for patients.

Our global collaboration with TB Alliance enabled us to make the product available for public procurers in low-income countries just a few months after FDA approval. This represented an unprecedented accomplishment: Previously, it had taken several years for the launch of novel TB drugs from the time they were approved by stringent regulatory authorities such as the FDA or European Medicines Agency to when they were available to patients in developing countries, which have by far the highest burden of the disease.

Committed to Affordability

In addition to making pretomanid available for patients in low- and middle-income countries, we're also committed to making it affordable. Mylan has agreed with the Global Drug Facility (GDF), as part of the StopTB Partnership, to make pretomanid available for purchase by low- and middle-income countries at $2 a day. This puts the cost of the regimen at $1,040 per treatment course when bought from the GDF.[3] Further, our license agreement with TB Alliance for these countries is non-exclusive, reflecting our shared commitment to ensure affordable and sustainable access to new treatments from multiple sources.

TB Alliance also is currently conducting clinical trials to determine whether pretomanid may also be useful as part of a different treatment regimen, called BPaMZ, for treatment of drug-sensitive and multi-drug resistant TB. If this new use is approved by health authorities, Mylan will be TB Alliance's global production, commercialization and distribution partner for this treatment as well. As part of our agreement, we also received a sublicense for bedaquiline for the treatment of drug-sensitive TB for use in the BPaMZ regimen, making us the first generic company to receive such a sublicense. With this, Mylan will be the only company in the world able to market and supply each of the three new drugs – delamanid, pretomanid, and bedaquiline – developed over the past decade for treatment of active TB. The development will bring significant opportunity to achieve greater access for patients in high burden countries.

[1] WHO Tuberculosis Fact Sheet
[2] UNAIDS Topic: Tuberculosis
[3] StopTBPartnership News