

2019 GLOBAL SOCIAL RESPONSIBILITY REPORT





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The I-Icon throughout this report indicates there is additional information for a topic in section III of this report. Section III provides a comprehensive description of Mylan's management, governance and organization of important social responsibility and ESG matters, as well as performance data.

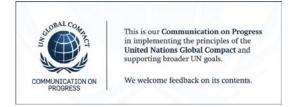


#### ABOUT THIS REPORT

#### Mylan's 2019 Global Social Responsibility Progress Report

This report provides an overview of Mylan's global efforts related to environmental, social and governance (ESG) matters.

Additionally, within each chapter this edition includes a historical retrospective across Mylan's impact areas as we are approaching a potential milestone for Mylan, with the planned combination of Mylan with Pfizer's Upjohn Division in 2020 to form a new company – VIATRIS $^{\text{TM}}$ .



We trust that the information provided offers a useful view of how we've delivered on our mission of providing access from the day we were founded in 1961 until today.

We remain committed to annual reporting on important ESG matters and continually work to enhance our disclosure. The content of this report is based, in part, on an issues assessment conducted in 2018 with internal and external stakeholders and is prepared in accordance with Global Reporting Initiative (GRI) Standards: Core level. This report also includes references to selected SASB indicators.

Mylan is a signatory to the United Nations Global Compact (UNGC) and is committed to the Compact's 10 principles related to human rights, labor, environment and anti-corruption. As a Compact signatory, this report constitutes Mylan's Communication on Progress Report.

Mylan N.V. and certain subsidiaries<sup>2</sup> are also subject to statutory sustainability reporting in the EU, following the EU Non-Financial Reporting Directive (EU NFR). This report, together with Mylan's statutory filings, is intended to fulfill our applicable reporting requirements.

Information contained in this report reflects work and progress from Jan. 1, 2019 – Dec. 31, 2019, unless otherwise noted. Reporting on other matters specific to financial performance of Mylan N.V. and our subsidiaries can be found in Mylan's 2019 Annual Report on Form 10-K.

More information on Mylan's work, policies and management processes is also available at Mylan.com.



### ADDRESSING THE COVID-19 PANDEMIC

While the information presented in this report pertains to the 2019 calendar year, the world in which we are publishing this report has changed dramatically due to the COVID-19 pandemic. As the situation surrounding the pandemic continues to evolve, Mylan's priorities will remain protecting employees, continuing to supply critical medicines to patients, utilizing the company's scientific and operational expertise to assist where possible in the needed potential prevention and treatment efforts, and extending support to communities where the company operates.

These truly unprecedented times require everyone in the healthcare industry and beyond to work together to meet the challenges both at hand and ahead.

Mylan pledges to continue to do its part to support employees, patients, partners and communities throughout this multi-stage journey.

We thank our employees for the important work they continue to perform every day to help us deliver on our mission of providing medicines to our patients, and we send our deepest appreciation to all of the healthcare workers and first responders working tirelessly around the globe to care for those affected by COVID-19.

For more information on Mylan's COVID-19 efforts, visit Mylan's COVID-19 newsroom.

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#### LEGACY OF IMPACT: HIGHLIGHTS 1961 - TODAY

#### **PATIENTS**

Mylan received its first U.S. FDA approval for a generic drug in 1966 with penicillin G tablets and, with the 1984 approval of Maxzide®, became the first generics manufacturer to win approval for a patented drug.

Today, Mylan supplies products capable of addressing 9 of the top 10 causes of death globally.1

Mylan has long been committed to delivering access, such as bringing antiretroviral (ARV) medicines to difficult-to-reach parts of the world for patients with HIV/AIDS. Today, **about 40% of all people treated for the disease depend on our ARVs every day.** 

#### **EMPLOYEES**

Mylan was founded in the U.S. by two Army buddies in 1961 and since then has grown to ~35,000 colleagues around the world.

Heather Bresch became the first woman to run a Fortune 500 pharmaceutical company with her appointment to CEO in 2012.

In the 2018 inaugural global employee survey, **81% of Mylan employees said they saw a clear link between their work and Mylan's mission** to provide the world's 7 billion people with access to high quality medicine.

#### **ENVIRONMENT**

Mylan is committed to the AMR Industry Alliance's Common Antibiotic Manufacturing Framework.

Mylan has utilized thermal oxidizer technology for nearly three decades and, as a result, has eliminated well over 3.5 million pounds of VOC/HAP (volatile organic compounds and hazardous air pollutants) emissions from the atmosphere.

In 2009, we began installing **zero-liquid discharge (ZLD) technology across facilities in India.** Today, 10 Mylan facilities apply the technology.

#### POLICY

In 1982, Mylan helped establish the Generic Pharmaceutical Industry Association (GPIA). During the next few years, GPIA, Mylan and others advocated for the Hatch-Waxman Act, which became the framework that gave birth to the U.S. generics industry.

Mylan has advocated for the generics industry to have a seat at the table in global issues affecting patients as active members of various forums including Medicines for Europe and the International Generic and Biosimilar Medicines Association (IGBA).

Mylan spearheaded 2012 legislation to strengthen the global drug supply chain and make it safer for patients with the passage of Generic Drug User Fee Amendments and the FDA Innovation and Safety Act.

#### COMMUNITY

Since 2002, Mylan has funded the **Mylan Charitable Foundation**, which has awarded grants supporting efforts to enhance the quality of life and meet needs in and around the communities where **Mylan operates**, primarily working with child-related issues in the areas of education, social services and health, by encouraging self-sustaining and ongoing positive change.

Over the past five years, **Mylan has donated over \$230 million dollars worth of medicine**<sup>2</sup> **to charitable organizations** that assist people in need around the globe.

Mylan's social responsibility programs in health, community welfare and education have impacted the lives of more than 11 million people in India over the past five years.

<sup>&</sup>lt;sup>1</sup>The remaining cause of death is road injury. Source: Global Health Estimates 2016: Deaths by Cause, Age, Sex, by Country and by Region. 2000-2016 Geneva, World Health Organization; 2018

<sup>2</sup>Amount based on manufacturing cost. Active products in our portfolio are valued at February 2020 cost and discontinued products no longer in the portfolio are valued at the last available cost prior to discontinuation.

## OUR IMPACT: 2019 HIGHLIGHTS

~62 billion doses sold across more than 165 countries and territories, including 88.5% of lowand lower-middle-income countries<sup>1</sup>

Received prequalification approval by WHO for the **Mylan HIV Self Test, an innovative home-testing kit**  Supplied medicine in 94 out of 106 access countries<sup>2</sup>

First generic manufacturer to receive WHO prequalification for daclatasvir to treat hepatitis C

Mylan reaches ~5 times as many HIV patients per day around the world as the branded originators do combined<sup>3</sup>

~60% of the world's HIV+ children receiving treatment rely on a Mylan medication

~10 million people on HIV treatment depend on a Mylan product

86% participation in employee engagement survey

90% of employees set performance objectives

Collaborated with >60 industry trade associations worldwide on issues of global public health

Selected to participate in WHO prequalification pilots and implementation workshops

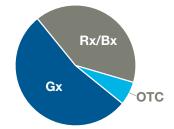
Regulatory
approvals for
biosimilars in
>85 countries

Announced a **global partnership with TB Alliance** for the antibiotic pretomanid as part of two drug regimens to increase access to tuberculosis treatment in many low- and middle-income countries

#### Net Sales by Segment



#### Net Sales by Product Type



Rx: Physician prescribed and marketed mostly with a brand name

Bx: Branded generics

Gx: Unbranded generics

**OTC**: Over-the-counter and consumer



<sup>1</sup>Income groups from the World Bank list of economies (Published July 2019) <sup>2</sup>As defined by the Access to Medicine Foundation

Based on internal estimates and North American and European IQVIA [HIV drug treatment] sales volume for branded originators, which we define as Gilead Sciences, GlaxoSmithKline, Johnson&Johnson, Merck & Co., Bristol-Myers Squibb and Abbvie

## NEARLY 60 YEARS OF UNCONVENTIONAL SUCCESS





#### A MESSAGE FROM THE CEO:

## Reflecting on our **JOURNEY**

If you have ever interacted with someone from Mylan, you know our mission is a cause that is deeply personal. Providing access to high quality medicine has been our purpose since the very beginning in 1961 in my home state of West Virginia, U.S. It has since expanded to include the lofty goal we set for ourselves at the beginning of my CEO tenure eight years ago - to provide the world's 7 billion people access to high quality medicine.

Starting with its very founding by two Army buddies determined to succeed at providing patients in need with access to medicine, and throughout our journey to become a global healthcare company, Mylan's story has been a uniquely special one. From founder Mike Puskar's effort to establish the company's fingerprint, to Executive Chairman Robert J. Coury's work to expand our global footprint, and my focus on establishing a sustainable blueprint for the company, our DNA has been defined by a passion for expanding patient access to medicine. And I believe Viatris, the new company to be created by Mylan's planned combination with Upjohn, a division of Pfizer, will continue to carry on this mission.

Throughout our journey, we have taken our leadership responsibilities seriously and at every step have remained committed to our core founding principles - doing what's right, not what's easy. Our continued commitment to the U.N. Global Compact and the Compact's 10 principles is but one example of that dedication.

Health and well-being are interlinked throughout the U.N.'s 2030 Agenda for Sustainable Development, as health has multiple social, environmental and economic determinants. Moreover, good health enables participation in education, work life and decision-making. This critical linkage has never been more apparent than now, as the world grapples with the life-altering impacts of the COVID-19 pandemic.

We remain committed to helping lead positive, sustained change during these challenging times. The global social responsibility efforts within Mylan, in collaboration with our many external partners, reinforce that commitment.

We often take the path less traveled, and our efforts have had lasting impact. I am incredibly proud that Mylan has never shied away from challenging the status quo. That has included being active in addressing the concerns around the globe about prescription-drug prices; opioid addiction; fighting for the same quality standards no matter where a product is made; and helping to illuminate the complex supply chains that often make it difficult for patients and payers to get the full benefits of less costly medication. We have always considered our role and how we can help address these issues in ways that best reflect our mission. One of our strongest legacies lies in the tireless work to provide access to treatment for HIV+ patients across the globe. Today, we help treat ~40% of the world's HIV+ patients on treatment.

These and many more demonstrations of our efforts to break down barriers to access have continued to fuel my passion for the important work of this industry through the years.

In 2019 alone, Mylan:

- Expanded our partnership with the non-profit drug developer TB Alliance for the antibiotic pretomanid as part of two drug regimens, which will promote access to tuberculosis treatments to patients in low- and middle-income countries.
- Participated in the World Health Organization (WHO) prequalification pilot for cancer biologics on the Essential Medicines List.
- Became the first licensed generic manufacturer to receive WHO prequalification for daclatasvir, a direct-acting antiretroviral (DAA) used to treat hepatitis C, and made it available for one of the lowest prices in the world.

In 2019, we began work across the company to identify future goals and targets in the areas of Access, Diversity and Inclusion, and Environmental Health and Safety. I expect that the continuing commitment to achieving meaningful, lasting impact within the new planned company, Viatris, will drive those efforts forward.

As the first woman to be appointed CEO of a major pharmaceutical company, I am especially mindful of the importance of diversity and inclusion. When I took on this role in 2012, I was the 18th woman to join the ranks of Fortune 500 CEOs. Today, as I prepare to retire from Mylan at the conclusion of its planned transition to Viatris, there are still less than 40.

Capability knows no gender, but opportunity certainly does, and differing backgrounds and perspectives bring critical value to any team. Taken together, these concepts form the foundation of inclusive leadership, which is something I've been fortunate to experience firsthand during my years working with Mylan's management team. While my time as Mylan's CEO may be coming to an end, I will remain an active advocate for inclusive leadership and the actions required – from both men and women together – to move us toward a more equitable future.

As I said when I announced my retirement, my personal and professional journey with Mylan has been life-altering, and the many relationships I have forged will be life-long. I have been privileged to work with an incredibly talented and dedicated group of colleagues. I wish to take this opportunity to express my gratitude to all of Mylan's employees and partners for their hard work and collaboration over the years.

Working across boundaries with our partners and leveraging the passion of our employees have been essential components for Mylan's accomplishments throughout the decades, and I am convinced that they will be more important than ever as our collective mission continues. As I have always believed, it is not the abilities of each individual player that leads to lasting success, but the strength of the entire team – the "Power of Us" truly can change the world.

Heather Bresch, CEO



Mylan supports the 2030 Agenda for Sustainable Development, as articulated by the U.N., in the adoption of the Sustainable Development Goals (SDGs), by all U.N. member states in 2015. And we know that companies must play an active role for these goals to be achieved.

Good Health and Well-Being (3) is the goal where we can have our most significant positive impact. Our portfolio, footprint and our partnerships enable us to truly contribute to this goal.

As a global healthcare company, how we conduct ourselves and interact with our partners impacts that and other goals. Therefore, we work to ensure a safe, fair and inclusive workplace. We nurture a culture of integrity and uphold ethical business practices. We support local communities and work diligently to reduce our environmental impact. These efforts are all integral to delivering on our mission of creating better health for a better world.

#### SDGs most relevant to Mylan



















See p. 52, 88-96 for more information on the SDGs and Mylan's approach.

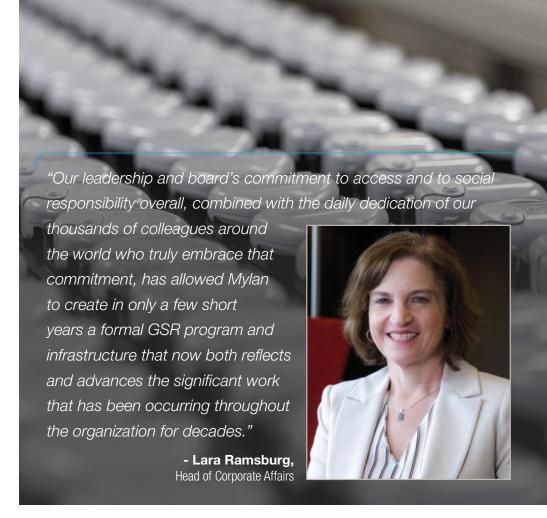
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## Building on our Success While Addressing Challenges and **Preparing for the Future**

As Mylan has grown from a small regional company to one that serves patients in nearly every corner of the world, we have also expanded our commitment to social responsibility. It is an intrinsic component of our operations and part of our overall focus of ensuring long-term, sustainable results and positive impact. We know well that our actions affect not only the communities we serve but also our ability to fulfill our mission to provide 7 billion people access to high quality medicine.

In recent years, we have witnessed growing interest among stakeholders in companies that look to realize opportunities and create value by meeting societal needs and aspirations while effectively managing inherent risks. Our business model - built on access, diversification and durability, coupled with our commitment to social responsibility - has positioned Mylan well to be a long-term partner in this evolution.

In 2017, we formalized our approach to global social responsibility (GSR) oversight and reporting and since then have been purposefully building out our program with respect to GSR management, initiatives and communication. Our work has been informed by knowledge and insights from colleagues, business partners, investors, advocates and policymakers - to name just a few. We have established a solid foundation of central governance and board oversight, and relevant GSR topics are considered as a component of the company's enterprise risk management process.



To further our progress, as we entered 2019, we set out to establish companywide GSR goals and initiated workstreams to deliver on that commitment. We identified Access, Environmental Health and Safety, and Diversity and Inclusion as our initial areas of focus. However, we now are looking towards the intended combination of Mylan with Upjohn, a division of Pfizer, that is currently expected to occur in the second half of 2020. If the combination is completed, it will be more appropriate, and relevant, to establish goals once the combined company, Viatris, is formed and we are able to assess the goals that will be the most relevant to the new company. Across Mylan, functions that are key to our environmental, social and governance performance have made noteworthy progress that will continue to form the foundation for the future.

We also continued our engagement with key stakeholders in 2019. The discussions provided valuable insights about their expectations of Mylan and their perspectives about the pharmaceutical industry while also offering an important opportunity to share what we believe makes Mylan different. Topics that continue to be of great interest to stakeholders include: our ongoing business transformation efforts, our approach to pricing – including what we learned from EpiPen, quality and risk management, our corporate culture, our commitment to help address the misuse of opioids, and our work to reduce our environmental impact.

Throughout the year, we continued our efforts in, as well as enhanced our communication around, GSR-related areas of interest to our stakeholders. We have strengthened our communication around what access means to Mylan. We have worked to better convey how the durability of our business model combined with the breadth of our product portfolio and the

Our definition of access is making sure the medicine we make is actually getting into the hands of patients in the more than 165 countries and territories we serve.

scale of our footprint has allowed us to make a lasting impact on access to medicine and how we differentiate ourselves from others in our industry. We have experienced the value of taking an active role across the world, in various forums, to advocate for access and quality, address the challenges patients face in accessing affordable alternatives, mitigate the risk for and impact from drug shortages, and promote responsible environmental conduct. We've also seen the critical importance of showing our dedication to high standards in our operations across our entire network. We refined our internal reporting processes on GSR topics and implemented a new digital platform to facilitate oversight. As always, while we have made progress, much work remains. All the above items must be constantly monitored, nurtured and refined for continued progress.

#### **Transforming Our Business**

2019 was a year of transformation and transition for Mylan, in the context of a healthcare landscape that is itself everchanging. Demographic forces, budget constraints, regulatory development, global trade relations, and an increasingly complex and competitive industry continue to challenge both companies and public healthcare systems. Keeping these forces and access in mind, we commenced an analysis of our operations with the goal to ensure a sustainable business that can continue to deliver high quality medicine.

We have assembled a world-class portfolio and pipeline, which have been and will continue to be our foundation as we work to maximize everything that we have built to date. As the global economy continues to evolve and become increasingly competitive, Mylan is committed to ensuring the long-term viability of its business in service to the many patients who rely on our medicines around the world. This includes work we have undertaken to transform our business to unlock latent value and deliver improved economic profitability, while maintaining

our commitment to providing access. We have applied a highly disciplined approach to how we invest every dollar across the business and have focused on rationalization of products not earning their cost of capital while refocusing commercial resources to promote further growth of other products. Throughout the process, Mylan has paid special attention to the availability of single source medications critical to patient health. We also are further centralizing and rightsizing our commercial and operating infrastructure, which includes a continuous evaluation of sites across our network to further optimize required production capacity and efficiencies. We believe this effort and mindset will position Mylan to create an even more powerful platform for patients and other stakeholders in the future.

#### A Champion for Global Health

While more people than ever before are accessing essential health services, far too many are still missing out. The unequal distribution of education, health and living standards is a barrier to human development. With about 2 billion people worldwide living on very low incomes without access to medicine or robust health systems, the need for leadership through innovation and partnership is as critical as ever.

Mylan is dedicated to breaking down barriers to access to medicine, reaching patients and providing solutions that will help people live healthier lives. Viatris, the new company created by Mylan's planned combination with Upjohn, a division of Pfizer, will remain dedicated to this mission.

"As a global healthcare company, we have a unique opportunity and responsibility to actively play a part in advancing positive change that benefits a large span of stakeholders. Not only as it relates to access to medicine, but beyond. As someone who was unfamiliar with Mylan until I joined via the Meda integration in 2016, I have found myself

proud every day of my colleagues' work and the impact we have made and continue to make across the globe. As we continue to step up our social impact efforts, our potential to demonstrate additional leadership is significant."

- Lina Andersson, Head of Global Social Responsibility



## OUR AREAS OF IMPACT

We know that meeting diverse needs in a complex global healthcare environment requires sustained commitment, innovation and action. We also understand that not only what we do, but also how we do it, impacts billions around the world. That's why we're continuously working to conduct ourselves in a responsible manner and striving to make a positive impact, whether through serving patients, empowering employees, caring for the environment, supporting community well-being, advocating for global public health or ensuring we operate with integrity.

Since 2019 represents what is planned to be the company's last year under the name Mylan, we believed it was important to include in this report a historical perspective about our work and our impact around the world. Mylan has a long and rich history of creating better health for a better world, and we're proud to chronicle those contributions.

The following pages provide a summary of both our legacy of impact and a selection of 2019 highlights in these areas and more.











## A LEGACY OF IMPACT: **PATIENTS**

For nearly 60 years, increasing access to high quality medicine and improving patient health has been Mylan's mission. Setting what would become a lasting example of our willingness to go where no path exists and forging one, founders Don Panoz and Milan "Mike" Puskar together in 1961 created their own distribution network in White Sulphur Springs, West Virginia, to ensure access to affordable medicine in difficult-to-reach communities. Their pledge to help patients by setting new standards in healthcare put us on a course we've remained true to throughout our history as we've expanded into more than 165 countries and territories.

Despite many challenges along the way, Mylan helped shape an entire industry. Our attention to quality - and willingness to choose paths less traveled - enabled us to overcome these obstacles.

> From financial struggles in the 1960s to today's pricing pressures and complicated healthcare systems in addition

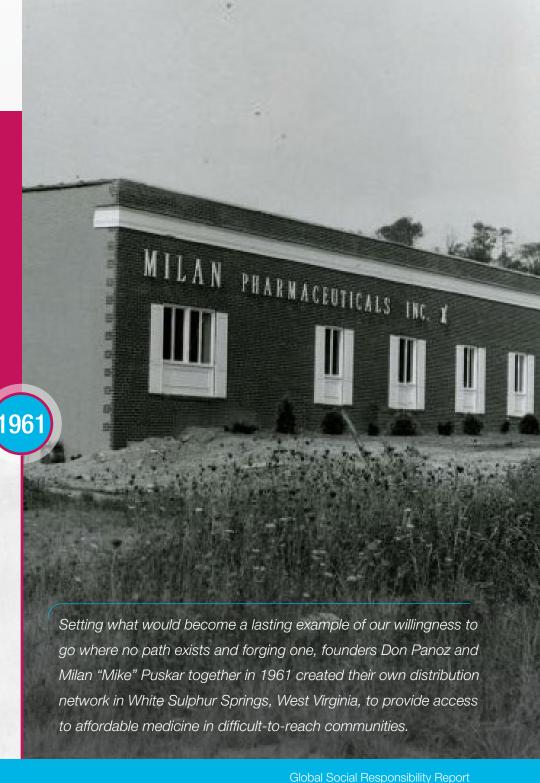
to the COVID-19 pandemic that we all now face, we learn to take lessons from both successes and failures. Regardless of the challenges, we are a company that, at health for a better world. As we look back on our nearly 60 years of history and service to patients, our relentless commitment to access will continue to guide our path forward.

In those early years, what was then known as "Milan" bought finished dose medicines and resold them from the trunk of a Pontiac Bonneville to rural pharmacies and physicians throughout the Appalachian region of the U.S. Later, we established

its core, is committed to delivering better

#### Penicillin G

Mylan received its first U.S. FDA approval for a generic drug in late 1966 with penicillin G tablets.



POTASSIUM PENICILLIN G

**TABLETS** 

100,000 UNITS U.S.P.

## **PATIENTS**

manufacturing operations in Morgantown, West Virginia. Our team there began by making vitamins and empty gelatin capsules but soon switched focus. In 1966, we received approval to manufacture penicillin G – Mylan's first U.S. Food and Drug Administration (FDA) approval.

The antibiotic marked our entrance into generic pharmaceuticals, creating an opportunity to serve patients in a new and more expansive way. From that moment, we've never stopped looking for innovative ways to develop, manufacture and supply the products patients need.

As Mylan's vision grew, so did the company. In 1972, Milan changed its name to Mylan Laboratories as a way to highlight its technical expertise. A year later, we went from being privately owned to a publicly traded company. The first shares of Mylan stock began trading in 1973 under the ticker symbol MYLN – an attempt to make it easier for investors to find the company at the end of fine-print stock listings in newspapers.

Relentless in our efforts to expand access, we have steadily grown our product line and the customers we reach. By 1984, Mylan broke new ground with the introduction of an antihypertensive called Maxzide® – making us the first generics manufacturer in the world to patent a new drug.¹ It was the precursor of our future research and development capabilities, which would help build one of the most robust pipelines in the industry.

As a U.S.-based company, Mylan had the majority of its customers east of the Mississippi River. Keeping this in mind, we opened our first distribution center in North Carolina in 1988, with a 25,000-square foot facility.



Today, our climatecontrolled distribution center in North Carolina has grown to 483,000 square feet and serves as a hub to ship both domestic and international product.

To further our mission and reach more people, we spent the 1990s strategically acquiring a number of companies to establish an even stronger presence in the pharmaceutical industry. And in 1995, Mylan had the most dispensed line of pharmaceuticals in America, brand or generic.

<sup>1</sup>Mylan: 50 Years of Unconventional Success by John Seaman and John T. Landry.



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## **PATIENTS**

Mylan's steady growth was aided by leaders who encouraged their employees to dream big. While Panoz left the company early on, Puskar remained close and after a short time away returned to Mylan to help re-energize the business. Puskar served as the company's president from 1976 to 2000, Chairman of the Board from 1993 to 2009 and CEO from 1993 to 2002, focusing on enhancing operations and developing new medicines.

The next decade would prove pivotal in Mylan's evolution. In February 2002, Robert J. Coury was elected to the Board of Directors, having previously served as a strategic advisor to the company. He became vice chairman shortly after his election and was made CEO in September of that same year. While during his many years of leadership, Puskar established the "fingerprint" for Mylan, Coury successfully expanded our reach beyond what many at that time thought was possible for a generics company.

Coury guided Mylan in establishing a durable business model within the industry, one that would responsibly harness the power of competition to drive innovations and create greater global access to medicine.

Under Coury's leadership, we expanded Mylan's "footprint" in 2007, scaling the company virtually overnight from operating in a single country to reaching countries around the world by acquiring a majority stake in Matrix Laboratories and completing our acquisition of Merck KGaA's generics business.



In 2011, Mylan celebrated its golden anniversary. A year later, the company would make history again, naming Heather Bresch as CEO – the first woman to run a Fortune 500 pharmaceutical company.

That same year, Bresch led Mylan and its industry partners as an outspoken advocate for the 2012 Generic Drug User Fee Act (GDUFA), which increased the FDA's ability to perform critical



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## **PATIENTS**

program functions and created quicker access to medicines for patients. Our support of this milestone law was an example of Mylan's commitment to patients around the world who rely on our high quality medicines.

During her tenure as CEO, Bresch built a "blueprint" for the organization to instill not only disciplined global processes, infrastructure and diversification but a future-focused "Healthcare 2020" strategy.



Much of this decade saw Mylan continuing its evolution while growing our commitment to patients in countries large and small, and across multiple product lines and capabilities.

#### **Strategic Acquisitions Over the Years**

Since Mylan went global in 2007, we continued strategic acquisitions to expand our ability to reach patients with the products they need, building on our foundation of manufacturing oral solid dose (OSD), transdermal and semisolid products and R&D.

YEAR	COMPANY	CAPABILITIES	
2007	Matrix	<ul><li>API</li><li>Manufacturing</li></ul>	• R&D
2007	Merck Generics	<ul><li>Commercial footprint</li><li>Portfolio</li></ul>	
2010	Bioniche Pharma	<ul><li>Injectables</li><li>R&amp;D</li></ul>	Manufacturing
2013	Agila Specialties	<ul> <li>Global injectable portfolio and pipeline</li> </ul>	<ul><li>R&amp;D</li><li>Manufacturing</li></ul>
2015	Famy Care	<ul> <li>Global women's health portfolio and pipeline</li> </ul>	<ul><li>R&amp;D</li><li>Manufacturing</li></ul>
2015	Abbott Established Brands	<ul><li>Established brands</li><li>Commercial infrastructure</li></ul>	<ul><li>Medical</li><li>Manufacturing</li></ul>
2016	Renaissance	<ul><li>Global topical platform</li><li>R&amp;D</li></ul>	Manufacturing
2016	Meda	<ul><li>OTC/Brands</li><li>Commercial infrastructure</li></ul>	<ul><li>OTC R&amp;D</li><li>Medical</li><li>Manufacturing</li></ul>
2017	Apicore	<ul><li>API</li><li>R&amp;D</li></ul>	
*List of acquisitions is representative of Mylan's growth and is not comprehensive.			

#### **Increasing Access Through Biosimilars**

Mylan has exhibited a passion to bring more affordable versions of complex biologic medicines to market in all parts of the world, including low- and middle-income countries where medicine is often most needed and least affordable. Today, biosimilars – lower-cost alternative versions of costlier biologics – represent a new standard of care that have increased patient access to critical treatments for conditions such as cancer, diabetes, arthritis and beyond.

Mylan has made a significant investment in biosimilar development over the past years. We introduced our first biosimilar – trastuzumab – in India in 2014, and today, we offer one of the industry's largest and most diverse biosimilars portfolios. We have 20 biosimilars or insulin analogs in development or on the market referencing many of the best-selling biologics globally focused on the areas of oncology, immunology, endocrinology, ophthalmology and dermatology. Mylan has received 150 marketing authorizations for its biosimilar products in more than 85 countries worldwide.

Mylan's commitment to biosimilars is the result of a partnership-driven model. We have been diligent in growing the portfolio depending on patient needs, technology, and the strengths of our partners. Mylan continues to position itself as a partner of choice within biosimilars.





## Providing Alternatives Through Wixela® Inhub®

Remaining steadfast in our efforts to expand access to medicines, one of those opportunities involved patients suffering from asthma and chronic obstructive pulmonary disease (COPD). ADVAIR DISKUS®, the mainstay of asthma

and COPD treatment, had no generic equivalent, and patients did not have access to an affordable alternative to treat their condition. Our team began to investigate the need to develop a more affordable treatment option. But since no generic existed for this complex product, the FDA had not developed regulatory guidance for a drug and device approval. The path forward was uncharted and took years.

Despite challenges, we never gave up on our goal to find a suitable product to help patients in need. Our passionate team members from dozens of disciplines around the company developed a product, prepared data and shared our findings with the U.S. FDA to help them establish regulatory requirements and set a path forward for a potential generic. In January 2019, Mylan announced the FDA approval and launched *Wixela Inhub*, the first generic of *ADVAIR DISKUS*, at a significantly discounted list price from the original brand product, further demonstrating the savings that generics can deliver for patients.

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## **PATIENTS**

#### **Notable Strategic Partnerships and Investments**

Since our founding, an important component of Mylan's work to break down barriers to patients' access to affordable high quality medicine has been to partner with other pharmaceutical companies. It has enabled us to share risks and costs, leverage strengths and scale up distribution. The result often is that medicines become available to a significantly larger group of patients. We have license agreements with several branded originators. Many of our noteworthy collaborations especially benefit patients in low- and middle-income countries. Mylan's partnerships have brought great diversification and access to markets across a broad range of capabilities, including biosimilars, complex products and more.













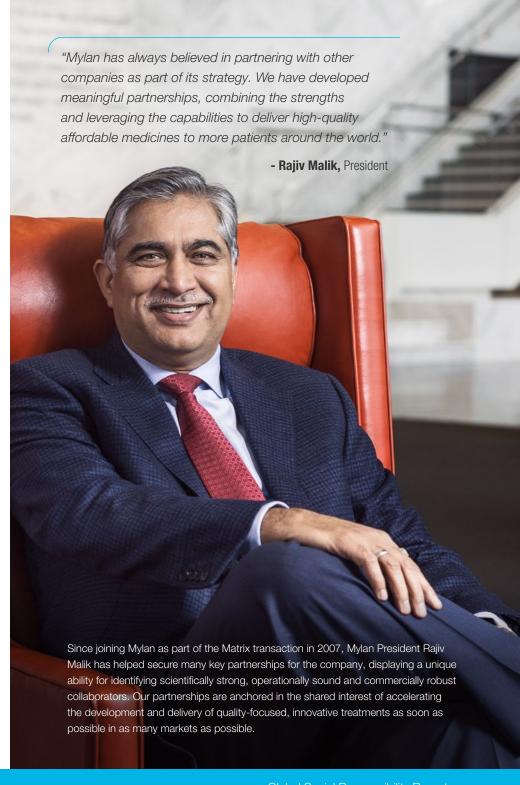












## A History of Working to **Stem the Tide of HIV/AIDS**

#### **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 23.31 million people on treatment for HIV use a Mylan product. 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



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.

<sup>1</sup>As of end of 2018, unaids.org

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.

#### **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.

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

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

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 therapy¹ 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

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



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.



#### **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.<sup>1</sup>
- ✓ 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 on a grant 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.

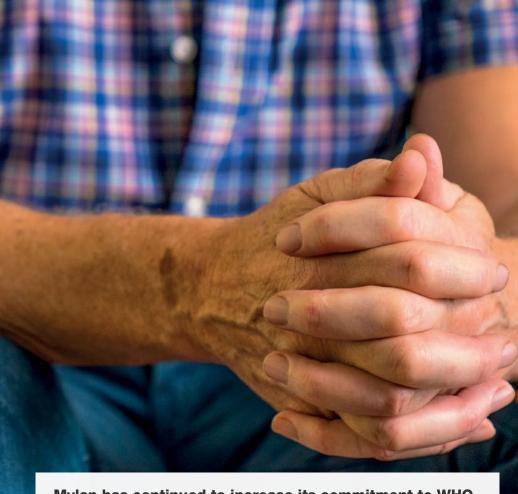
President's Emergency Plan for AIDS Relief (PEPFAR) database

WHO Pre-Qualification list as per 2/26/20

Essential Medicines and Health Products: Prequalification of medicines: Hepatitis

Clinton Health Access Initiative: Partnerships will help Rwanda eliminate hepatitis C in five years





## Mylan has continued to increase its commitment to WHO prequalification

Prequalification allows for U.N. procurement and accelerated registration processes in lowand middle-income countries, an important part of increasing access. With 69 products<sup>2</sup>, 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 daclatasvir³, a DAA used to treat hepatitis C, and made it available for one of the lowest prices in the world.⁴

See pages 57 and 83 for information on the products.



#### 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 publicprivate 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.<sup>2</sup>

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



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

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, lifethreatening 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 lowand 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.



#### **2019 HIGHLIGHTS**

#### **Easing the Burden of Non-Communicable Diseases**

Non-communicable diseases (NCD) affect people from all ages and genders in every region worldwide, accounting for ~71% of all deaths. More than three-quarters of these deaths occur in low- and middle-income countries,¹ where access to education, prevention, diagnostics and treatment is often limited. Mylan remains committed to reducing the impact of these diseases through ensuring access to high quality medicines, proactive outreach and more.



#### Oncology

- ✓ Continued our support of the Tata Memorial Centre's Affordable Cancer Care project
  in India. In 2019, the Centre trained nearly 600 frontline health workers and more
  than 200 medical officers on early detection and prevention of common cancers.
  Additionally, a group of doctors and nurses were also trained in chemotherapy in six
  districts there.
- ✓ Launched the first biosimilar trastuzumab in Canada, Australia and South Africa, developed along with our partner Biocon Biologics, increasing access to this treatment option for breast and gastric cancer patients. We also launched in the U.S., where we were the first to receive U.S. FDA approval.
- Increased access for patients with metastatic breast cancer by entering into a marketing license agreement with Eisai India to commercialize the innovator's second Eribulin brand, TECERIS®.
- Offered assistance for 3,000 oncology patients enrolled in our Ashray program, which offers free and subsidized screening and diagnostics, emotional support and helplines.
- ✓ Implemented an integrated multimedia awareness campaign about prostate cancer the most common cancer in men in the Netherlands aimed at educating the public about the importance of testing and early treatment.²

#### Cardiology

- ✓ Launched Rozor®/Twicor®, a fixed-dose combination of rosuvastatin and ezetimibe to reduce cholesterol (LDL-c) levels in five additional countries - France, Belgium, Romania, Slovakia and Bulgaria - and have expanded to newer strengths in Spain, Czech Republic, Portugal and Slovenia to help more patients achieve their LDL-c goals, improving their cardiovascular risk.
- Developed several digital platforms to provide general practitioners and specialists with access to medical information about dyslipidemia, which is a condition that causes abnormally elevated cholesterol or fats (lipids) in the blood.
- ✓ Enhanced our partnership with the European Atherosclerosis Society to disseminate the 2019 European Society of Cardiology guideline changes to help provide important education to more physicians across Europe.
- ✓ Created an awareness campaign in Italy about cardiovascular risks associated with cholesterol levels and the importance of healthy lifestyle choices.



#### Respiratory

- ✓ Provided the first epinephrine auto injector in Lebanon in partnership with Droguerie De L'Union, increasing access to this life-saving medication.
- ✓ Announced the expansion of our current development and commercialization agreement with Theravance Biopharma Ireland Limited, a subsidiary of Theravance Biopharma, Inc., for nebulized revefenacin to include China and certain adjacent territories. Revefenacin treats COPD, which accounts for ~910,000 deaths in China annually.<sup>3</sup>
- ✓ Received approval for Dymista® for use in children, ages 6–11, in Canada and South Korea, increasing access to this first-line treatment for symptoms of allergic rhinitis to this population.
- ✓ Provided patients living with asthma and COPD in the U.S. with a more affordable treatment option through the launch of Wixela® Inhub®, the first U.S. FDA-approved generic of ADVAIR DISKUS®.

<sup>1</sup>WHO Fact Sheet Noncommunicable Diseases

<sup>2</sup>Dutch Cancer Society: Prostate Cancer

<sup>3</sup>A Subnational Analysis of Mortality and Prevalence of COPD in China From 1990 to 2013: Findings From the Global Burden of Disease Study 2013



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#### PATIENT HEALTH:

#### 2019 HIGHLIGHTS



#### Women's Health

- ✓ Implemented an educational campaign in Italy for women, gynecologists and pharmacists about the physiological changes that occur over a woman's lifetime and the importance of proper feminine hygiene throughout every stage of life. The campaign reached about 7,000 pharmacies.
- ✓ Created a website for patients and healthcare providers focusing on educational information about menopausal and menstrual disorders. The site initially launched in Switzerland and will be adapted for additional countries in the future.
- Supported the development of an expert speaker academy in the U.K. to coach healthcare providers on educating their peers about the impact menopause can have on a woman's quality of life and hormone replacement therapy options, benefits and risks. Academy participants held local educational sessions for healthcare professionals.
- ✓ Furthered education and awareness around menopause and hormone replacement therapy options by supporting a symposium at the International Congress of the European Menopause and Andropause Society.
- Launched new generation contraceptive products in the private market through distribution partners in the Philippines, Taiwan, Mauritius, Tanzania, Mongolia and Thailand to reduce discontinuation rate (happening due to adverse effects).



#### Dermatology

- ✓ Educated nurses from Belgium, France, Portugal and Spain on wound and infection care through a
  master class at the International Nurse College of Antimicrobials Management.
- Held educational workshops aimed at increasing knowledge about the treatment of eczema in Asia, Europe, the Middle East and South Africa.
- ✓ Sponsored the Interactive Derma Academy for the fourth year in a row to increase awareness and knowledge about dermatological diseases. Nearly 270 doctors from Austria, Belgium, Bulgaria, Croatia, Czech Republic, Germany, Greece, Italy, Lithuania, Malaysia, Netherlands, Philippines, Portugal, Romania, Russia, Saudi Arabia, Serbia, Slovakia, Slovenia, Spain, Sri Lanka, Turkey and Ukraine attended.
- ✓ Increased options for acne patients and their doctors in Australia through the launch of Acnatac, which was already widely available in Europe. In order to provide a complete disease management approach, a new line of dermo-cosmetics, called Acnacalm, was launched in Italy and Switzerland, along with a campaign highlighting the impact of acne in the quality of life of teenagers and providing information on proper treatment.
- ✓ Expanded the availability of our over-the-counter wart treatment EndWarts® beyond Europe to include patients in Thailand and Australia.





## A LEGACY OF IMPACT: **EMPLOYEES**

obsession with quality, a strong work ethic, a commitment to teamwork and

Employment increased from the original four to 25 people at the time Mylan launched its first manufacturing operations in Morgantown, West Virginia, in the mid-1960s. It was there that one of our company's signature traits emerged. When a problem arose at the plant, leaders wouldn't turn to just a single person to find a solution. Instead, they would hold small group discussions with supervisors, lab staff and line workers.

This approach resulted in better informed solutions. It also emphasized learning and raised employee morale, engagement and accountability. And it's credited as influencing Mylan's ability to advance our business through the development of more challenging formulations than a typical generics manufacturer might undertake.

"Do it right or don't do it at all" became a way of working, and employees took a growing sense of pride in the company's accomplishments. By the early 1970's our workforce had increased to about 250 people.

The effort that employees invested in Mylan was rewarded, including with new health and retirement benefits added in the early 1980s. Operations grew as well. In 1987 we diversified our manufacturing base by starting up a new plant in Puerto Rico and in 1988 opened a distribution center in Greensboro, North Carolina. Employment growth overall was limited; however, at the end of the decade, the workforce stood at a few hundred people.



## **EMPLOYEES**

Hiring increased dramatically in the 1990s as our product offerings and capabilities grew. The Morgantown operations doubled in size. A second factory launched in Puerto Rico. The Greensboro center moved to a larger local warehouse, and an additional distribution center opened in Reno, Nevada, to serve western U.S. markets. Acquisitions included Dow B. Hickam, Bertek, UDL Laboratories and Penederm.

These moves, together with other investments, resulted in a Mylan workforce that exceeded 2,000 employees as the 1990s came to a close.

In the first decade of the new century, Mylan set out to improve access to medicine by achieving the scale needed to succeed in an industry that had become increasingly competitive. Despite its influence and accomplishments, Mylan nonetheless was a mid-size company operating in a consolidating industry, and its leaders recognized the need to augment organic growth with acquisitions.

A major step was acquiring Matrix Laboratories, the Hyderabad, India, company that served as the world's second-largest producer of APIs. The 2007 acquisition created a "global startup" of 5,100 employees operating in 10 countries. Matrix increased Mylan's manufacturing base and provided access to new markets in India, China and Africa, as well as a platform for expansion in Europe. In addition to its key capabilities, Matrix possessed a corporate culture and work ethic that paralleled Mylan's own.

A collaborative spirit was among the shared qualities. In an early test of the Mylan-Matrix relationship, R&D teams in Morgantown and Hyderabad were individually assigned a complex product and challenged by management to develop it as fast as possible. The teams quickly transitioned to sharing information and experiences on their respective successes and failures – learning from each other. The experience laid the groundwork for a collaborative approach that yielded substantial benefits.

Close on the heels of the Matrix acquisition, Mylan's bold bid for Merck Generics transformed the company yet again by growing its portfolio, scale and people. Merck Generics increased Mylan's footprint with new leading positions in Australia, France, Japan, Portugal, Spain and the U.K., and created significant opportunities to advance our global product offerings. The expanded Mylan family became the world's third-largest generics company overnight, with more than 11,000 employees in 90-plus countries.

"We believe Mylan is very well positioned for continued growth given our vertically and horizontally integrated, global, diversified platform and the broad set of opportunities we have identified and are prepared to execute."

- Rajiv Malik, President, May 2013









## **EMPLOYEES**

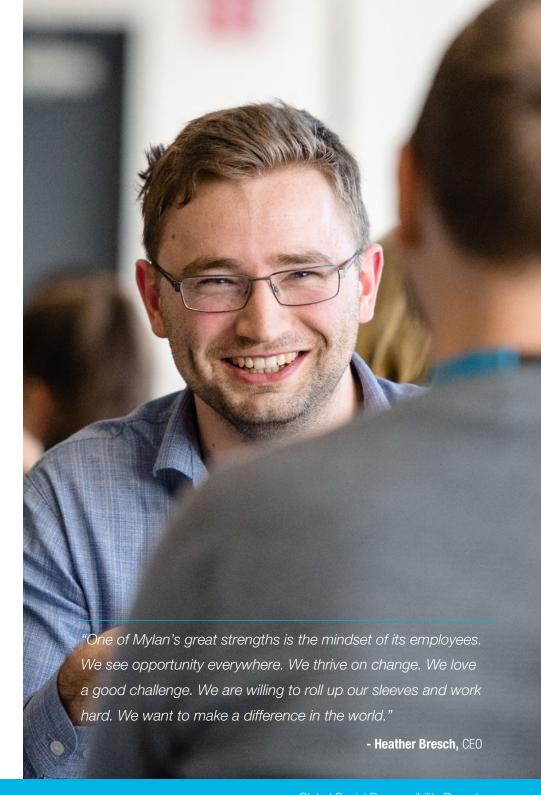
The two organizations proved to be a close cultural fit, with colleagues sharing values centered on quality, integrity, reliability and service. Rather than a collection of business units without a unifying culture, the new Mylan had the opportunity to become, and indeed became, a truly global enterprise.

Throughout our rapid growth, the employee experience was always a significant consideration – demonstrated in part by the 2009 decision by then-CEO Robert J. Coury to enhance all aspects of the Human Resources function under a new name, "Human Relations." The enhancements and associated name change reinforced the belief that our long-term success depended on the quality of our workforce, which remained a direct reflection of Mylan's strong and unique corporate culture.

The 2010s presented new opportunities to expand access to medicine by growing through acquisitions. Chief among those that further grew the Mylan employee family were the additions of Bioniche Pharma, Agila Specialties, Abbott's non-U.S. developed markets specialty and branded generics business, Famy Care's women's healthcare businesses, Renaissance Acquisition Holdings' topicals-focused business, and Meda. These acquisitions greatly enhanced Mylan's product portfolio and capabilities, while simultaneously increasing our reach across Europe, Canada, Japan, Australia and New Zealand, and accelerating our growth in markets including China, Southeast Asia, Russia and the Middle East.

Over the years, senior leaders focused on integrating these major acquisitions and utilizing the commitment and talents of colleagues across the world. As Mylan evolved, management had to think differently about our business by optimally leveraging our assets, restructuring and, in some cases, reducing our workforce. When it came to these difficult decisions, leaders made every attempt to minimize the impact to our people and care for impacted employees with the utmost respect and gratitude.

Through the strategic acquisitions, key partnerships and organic growth, our workforce has grown into the ~35,000-strong people at Mylan today. We are well-positioned for our next phase: our intended combination with Upjohn and creating a new company in Viatris.



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## **EMPLOYEES**

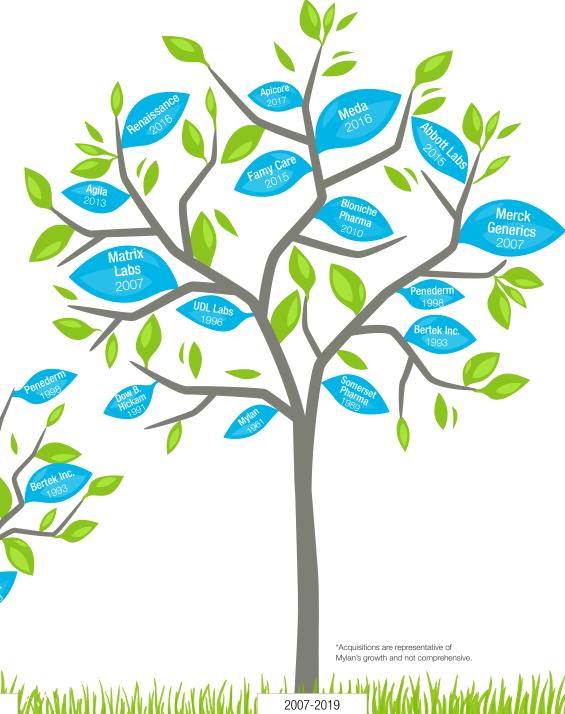
#### A Growing, Global Workforce

From the roots that were planted by our founders in 1961, Mylan has grown to become a world-leading pharmaceutical company.



"The reason our company has been so successful and is so well-positioned for a very bright future is because every one of our employees has made it a priority every day to live our values."

- Robert J. Coury, Executive Chairman, October 2009



Workforce: ~35,000

## **EMPLOYEES**

#### **Ensuring Employee Safety**

At Mylan, we actively promote and maintain a work environment in which each of us accepts personal responsibility for our own safety and that of our colleagues. Making safety personal and staying focused on a "think safe, work safe" mindset also helps us achieve our mission.

We applied that same proactive philosophy to many programs and processes, including machine guarding to ensure our employees were safe on the job and measures to reduce noise and dust in plants. In the 1990s, we invested in industry-leading lockout/tagout procedures that ensured machines were properly shut off during maintenance for the safety of our employees and nearby communities. The systems included controls to shut off power from outside of rooms housing equipment. These systems became standards of construction across our facilities in North America and, later, expanded globally as our operations grew.



#### **Implementing Standardization**

One of the Environment, Health and Safety (EHS) team's biggest contributions was bringing Mylan's global EHS standard across the new and larger company. Every time our business grew, Mylan's EHS employees were the first ones on the ground, learning from the teams in place, taking the best of the two systems, updating and enhancing our programs, and then implementing the same standard across the company. Whether we were opening plants or decommissioning others, we made sure EHS was our first priority. Recognizing and mitigating any risks posed by our operations is critical to our business.



#### **Sound Preparation Positioned Mylan Facility** to Weather Devastating Hurricane

Risk management habits begin at the top. At Mylan, we make it a priority to emphasize safety, quality, compliance and ethical behavior. Mylan and FM Global, a well-established property insurance company specializing in highly protected risk, share the belief that many losses can be prevented with forward-thinking investments.

When Hurricane Maria and its 150-mile-an-hour winds passed over Puerto Rico in 2017, it seemed to destroy nearly everything on the island. Yet, standing tall among the scattered trees and shattered buildings was Mylan's manufacturing site in Caguas. It had withstood the destruction thanks to years of planning and preparation to the facility.

As Mylan's plant expanded and renovations took place. it followed FM Global's latest recommendations on wall construction, dock doors and windows, and it reinforced its sprinkler system and added natural gas shutoffs to limit fire exposure in the aftermath of hurricanes and earthquakes.

Over the years, Mylan had made it a priority to protect our people, our products, our facilities and our environment. As a result, Mylan was able to resume operations much faster than its counterparts on the island and continue its pursuit of creating better health for a better world.

"Mylan is very committed to protecting its properties against risks, including threats from weather. They worked hard to make Caguas a well-protected facility, and it proved to be just that. It took a lot of dedication and foresight from both teams, but their joining goal was always safety."

- Diana Van Meter, Assistant Vice President, FM Global

# EMPLOYEE HEALTH: 2019 HIGHLIGHTS

#### **Mylan's Most Valuable Asset**

Our passionate and talented workforce is fundamental in bringing Mylan's mission to life. This is why we make it a priority to listen to – and act on – employees' feedback and to keep them informed about our business. It's their diverse perspectives that drive innovation, and we are certain that different views and experiences make our company stronger and more resilient. Throughout 2019, we embarked on a variety of talent programs and supported wellness activities around the globe in support of employees' professional and personal growth.

#### **Engaging Our Employees**

- ✓ Developed local action plans at more than 100 sites based on feedback from our 2018 global engagement survey. We also established a companywide focus on improving employee development, process efficiency and two-way communication.
- Achieved 86% employee participation in a pulse engagement survey in 2019 to track our progress toward our action plans, which found that 62% of employees have experienced positive changes as a result of the 2018 survey. Gained a slight increase in engagement with a global score of 71%, representing employees' willingness to go above and beyond in their roles to support the company.

71%

of employees have witnessed leaders' commitment to open and honest twoway communication with employees **67%** 

feel that recognition is a part of Mylan's culture

Held town hall-style meetings with more than 250 teams around the world on Mylan's business model, strategic priorities and transformation to ensure employees are informed of the company's progress.





✓ Introduced Celebrating You!, a global recognition program empowering employees to nominate colleagues who exemplify a commitment to quality, leadership, innovation, customer service, operational excellence and social responsibility. Received more than 3,400 nominations, with winners to be celebrated regionally and globally in 2020.

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# EMPLOYEE HEALTH: 2019 HIGHLIGHTS

#### **Talent Management and Development**

- ✓ Developed strategic plans for managing talent across all countries and segments with a focus on workforce planning in 40 areas that included capability enhancements, engagement and recruitment. Defined critical roles and established succession plans for the top 100 positions in the company.
- ✓ Simplified and raised the bar on our Leadership Expectations, which guide the behaviors employees should use to drive their own growth by Leading, Learning, Teaching and Performing with the right Attitude. Emphasized "how" work is accomplished through behaviors such as sound judgment, coaching, teamwork, empowerment, agility and humility. Supported managers in using the expectations to coach employees on their performance and development.
- ✓ Launched a formal career development planning process. Resulted in 69% of employees opting to set development goals and 73% defining Career & Development Plans to help them identify their goals and career aspirations.
- ✓ Strengthened the skills of people-managers worldwide through interactive training on continuous feedback and coaching skills. Developed our own coaching model focused on creating ownership, understanding motivations and inspiring change at its core all on a foundation of building trust and providing valuable feedback. Delivered training to ~2,000 managers and will continue to emphasize the value of coaching in 2020 to foster manager development and grow talent.

#### **Talent Principles**

We continued to integrate our Talent Principles for growing and managing people into our organizational practices and tools throughout 2019.

- Hiring with rigor is a must. We connect with the right talent every time.
   We look for internal talent and encourage unconventional career moves.
- Building talent is the responsibility of every leader.
- We invest management energy in assessing talent and potential.
- Employees own their careers.
- Professional development is required for everyone not just a select few.
- Successors are identified for critical roles.
- Diverse perspectives drive innovation.

#### **Cultivating and Acquiring Talent**

- ✓ Conducted our broadest global talent review to date, with managers assessing employees' potential to develop within their current roles and take on new roles or an increase in future responsibilities. Assessed 65% of employees globally at managerlevel and higher with an emphasis on retaining talent and planning for succession, which will continue in 2020.
- Encouraged employees to pursue internal career opportunities by formally identifying their interests in their Career & Development Plans and promoted key jobs internally on a monthly basis. Continued efforts planned for 2020 will seek to improve the candidate experience and internal mobility.
- ✓ Launched our employer brand The Power to Change the World in key markets to build awareness of the exciting career opportunities at Mylan and reflect employees' pride in their company.



- Reviewed our approach to sourcing candidates and refocused talent acquisition teams on key disciplines to extend our reach into defined markets. Standardized recruitment processes globally to create greater efficiencies and leverage specialized internal expertise, resulting in stronger hires.
- ✓ Hosted more than 300 interns and apprentices globally in 2019.
- Created online dashboard to measure the effectiveness of our people strategies and better manage our workforce through data analytics.

# EMPLOYEE HEALTH: 2019 HIGHLIGHTS

#### **Building Capabilities**

- ✓ Offered specialized leader development opportunities customized by region. Examples include a cross-functional executive development program for 30 leaders in our European operations and training on topics ranging from behavioral interviewing to disciplined execution for managers and formal team-building activities in India and Emerging Markets.
- ✓ Deployed several new online courses globally to enable employees to improve their skills in areas ranging from managing change to time management to supporting a positive workplace. Recorded more than 3,800 course completions in 2019 with an average 96% favorable feedback from participants. The courses will extend into 2020.
- Exceeded 3 million completed employee learning activities in MyUniversity, Mylan's learning management system, in 2019.

#### **Driving Performance**

- Implemented a new program that drove the company's top 300 leaders to set individual business objectives for transforming our organization and creating greater value over the next two years.
- ✓ Aligned employees' work with the company's business priorities by setting annual performance objectives. Our approach corresponds with our compensation framework, which is designed to effectively retain and reward talent. Career and development goals were established at the same time to help employees see the connection to their performance and build their careers.

82%

of employees discussed their career aspirations or development with their managers **76%** 

of employees received feedback they found helpful for improving their performance

#### **Culture of Diversity and Inclusion**

- Defined future strategies to promote increased diversity and inclusion. These strategies, established by senior leaders, include employee resource groups that foster a growing sense of belonging and fuel engagement.
- ✓ Conducted an extensive review of workforce data showing that career progression in 2019 occurred at a similar rate for men and women.
- Continued to educate employees on our equal employment opportunity and nondiscrimination policies as part of our Code of Business Conduct and Ethics mandatory annual training.
- Developed new Workplace Harassment Avoidance training to help ensure a safe, respectful work environment. Documented successful completion by 95% of North American employees in 2019.

#### **Employee Well-Being**

- ✓ Offered a variety of competitive benefits such as retirement plans, health insurance, education assistance, childcare incentives, preventive health screenings, immunizations and more to help employees take charge of their personal and financial well-being. For example, in India the Mylan Employees Welfare Fund provides grants to employees for unplanned circumstances and expenses such as healthcare, school tuition for employees' spouses and children, or marriage costs.
- Decided to add an Environmental, Social and Governance (ESG) fund to the Mylan U.S. 401(k) Plan to provide employees with more options for growing their savings while investing in socially responsible companies, planned for introduction in 2020.
- Hosted fairs at sites worldwide to help employees learn about their benefits, both health and financial, and how to use them to their fullest.
- Provided education throughout the year with webinars on topics ranging from retirement planning to educational benefits to nutrition and overall wellness.
- Sponsored activities to encourage employees to live healthier lifestyles, including vision screenings, flu shots, massages, fitness sessions and step challenges, among other health and wellness programming.
- Supplemented employee wellness initiatives with support ranging from fitness center discounts to employee assistance programs.
- Continued to collaborate with employees to assess site-specific opportunities to help balance work-life priorities and improve workplace flexibility. Implemented flexible work programs at select sites that will be evaluated for effectiveness for other locations.



#### **Employee Health and Safety**

Mylan is committed to providing a safe and healthy workplace for our employees, contractors and visitors. In addition to our rigorous safety programs and practices, we cultivate an environment that encourages our people to speak up and play an active role in making workplace safety a priority.

- ✓ Implemented Mylan Alerts, a global text notification program to ensure employees receive timely security updates and urgent company information. Enrolled more than 7,800 employees in the voluntary program in 2019, supporting greater business continuity.
- Launched new modules for our Safety Culture Program, which includes a new safety culture survey tool, leadership and employee workshops, and continuous improvement tracking for our sites.
- ✓ Received the 2019 National Member of the Year award from the National Safety Council of Australia (Foundation) for our Carole Park facility. The award is presented to an organization that has demonstrated commitment and leadership in Workplace Health and Safety (WHS) and is a result of the site's success in raising awareness of best practice WHS within the safety community and making a positive difference to WHS and culture.
- Achieved the British Safety Council (BSC) 5-Star Rating at India Unit 8 and Unit 9, bringing our total number of BSC-certified sites to four.
- ✓ Updated our EHS Management System to drive continuous improvement and incorporate current industry best practices and programs.



i READ MORE ON THIS TOPIC

## A LEGACY OF IMPACT: **ENVIRONMENT**

In the 1990s, Mylan was still a relatively small, U.S.-focused generics business, but our footprint was starting to expand with business acquisitions that added manufacturing plants in Vermont and Illinois, among others. Our biggest presence was still in our home state, though, so it was fitting that our first EHS hire was a native West Virginian.

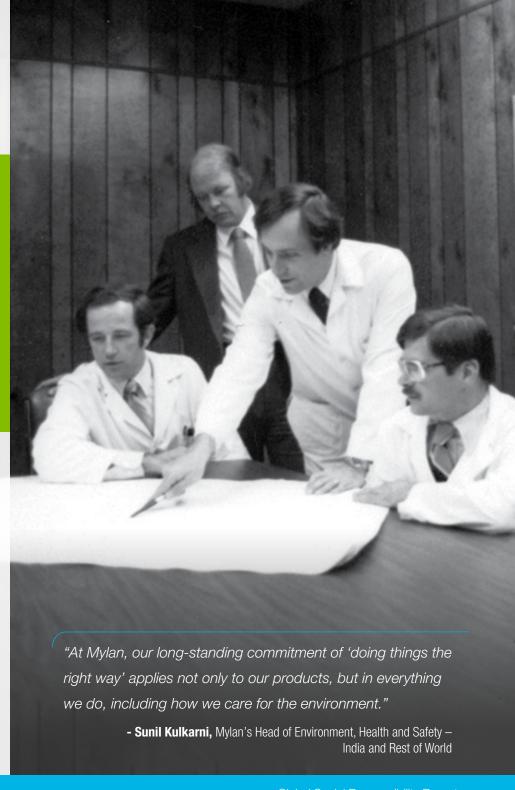
The team expanded slowly at first, adding a couple of technicians and a secretary who built on the work of previous contractors. Reporting into Human Resources, the team would eventually become a standalone department, with members sitting in locations around the world. Today, there are ~300 members of the EHS department who keep our workforce laser-focused on operating sustainably and safely.

#### **Setting High Standards**

One of the team's first accomplishments came in those early years when Mylan voluntarily changed the coating process in our Morgantown, West Virginia, facility from a solvent-based to a water-based formulation. The switch allowed us to eliminate a commonly used solvent from our Morgantown operations, reducing the risk of exposure to employees and the environment.

#### **Using Water Wisely**

Water is an important component for making medicines. It's also a precious resource that is in short supply in some parts of the world. That's why we have worked at our facilities around the world to ensure we use water wisely. From installing zero-liquid discharge



## **ENVIRONMENT**

(ZLD) technology at several of our facilities in India in 2009 to installing a state-of-the-art, expandable, full-scale wastewater treatment system featuring membrane technology at our plant in Galway, Ireland, we have made water conservation and wastewater treatment a priority.

Responsible wastewater treatment is a key topic for our industry, and it is our policy to comply fully with applicable legal requirements. Examples of our actions include advanced wastewater treatment technologies such as sequencing batch reactors, membrane technology, ZLD systems, carbon filtration and others. We use collection systems to capture water potentially containing high risk products and segregate wastewater streams for optimum treatment such as by-product recovery, sending incinerable waste for co-processing to save energy. We also have systems in place such as disk filters and water recovery systems to reduce the amount of wastewater generated.

#### **Promoting Clean Air**

We also have worked to promote clean air as we have promoted better health for a better world. A great example of this was in the early 1990s, when we installed a thermal-oxidization (TO) system at our plant in Vermont to control solvent compounds, including volatile organic compounds and hazardous air pollutants. Based on the positive experiences in Vermont, we went on to install similar systems elsewhere, including in 2010 when we added a regenerative thermal-oxidation (RTO) system in Morgantown, West Virginia. These technologies enabled Mylan to expand production while also decreasing emissions and protecting the environment. The RTO produces reusable heat that reduces operating costs and the system's overall energy consumption.

#### **Reducing Plastic in Packaging**

With a growing product portfolio through the years, we were always looking for opportunities to use our resources efficiently, not only in the making of our products but also in the packaging of them. For example, all of Mylan's blue bottles in North America are recyclable, and in Mérignac, France, we reduced plastic use through changes to the bottles of the liquid antiseptic Betadine®. In Confienza, Italy, we worked with a supplier to modify the design and reduce the use of plastic in the outer packaging of pump dispenser bottles for Saugella Girl and Babygella, a hygiene products line produced from natural plant extracts. And in Portugal, our Bebegel packaging is now a more sustainable and easier-to-use cardboard, instead of plastic.





#### **ENVIRONMENTAL HEALTH:**

#### 2019 HIGHLIGHTS

Responsible environmental stewardship and promoting safe, sustainable operations are priorities for Mylan. We work systematically and continuously to identify ways to protect the environment and minimize our impact through a comprehensive approach focused on managing our water, air emissions, waste and energy.

#### **Conserving Water and Managing Wastewater**

A high quality water supply is essential for our operations, and we are committed to working to protect and conserve this precious resource and improve our wastewater management.

- Continued to enhance our water purification processes across our operations, including efforts that reduced the amount of rejected water in our Warsaw, Poland, facility by 28%.
- ✓ Reduced water demands by 7% at our facilities in Bangalore and Nashik, India, by installing new advanced disk and glass media filtration systems, as well as initiated water conservation projects such as new spray nozzles on water taps, boiler condensate recycling, and recycling of purified water discharge which have decreased demand for fresh water supply.
- Supplied recycled water from our Bangalore Injectable units to a garment manufacturing facility so that freshwater demands can be reduced in their operations.



#### **Improving Air Emissions**

Mylan continues to focus on projects aimed at reducing particulate matter, sulfur oxides, nitrogen oxides, volatile organic compounds (VOC) and carbon dioxide (CO<sub>2</sub>) emissions to the air.

- Decreased the amount of particulate matter released into the air by 83% through the installation of new electrostatic precipitator control devices on boilers at our facility in Visakhapatnam, India.
- ✓ Reduced particulate matter, sulfur oxides, nitrogen oxides and CO₂ emissions at one of our sites in Bangalore, India, where the boilers were converted from fuel oil to natural gas. A second unit there is also in the process of being converted.
- ✓ Continued our efforts to reduce fugitive emission leaks of refrigerants and phase out the
  use of ozone-depleting substances in facility equipment across our operations. Globally
  we reduced refrigerant leaks by 35% compared to 2018 through enhanced prevention
  efforts at our manufacturing locations.

#### **Reducing Waste**

Throughout all of our operations, we continue to be committed to reducing waste through responsible use of resources, increased recycling, reuse of materials and initiatives dedicated to waste minimization. We strive to reduce our environmental impact by appropriately managing and reducing hazardous and non-hazardous waste generated from our processes and operations.

- ✓ Achieved zero landfill status at our Damastown, Ireland, oral solid dose facility, bringing the number of zero landfill sites to 11.
- Began a multi-year effort to evaluate projects at key locations that will decrease the amount of waste sent to landfills.
- √ Globally, increased the amount of waste we recycled from 14.1 tonnes to 17.8 tonnes –
  a 26% increase.



## **ENVIRONMENTAL HEALTH:**

## 2019 HIGHLIGHTS

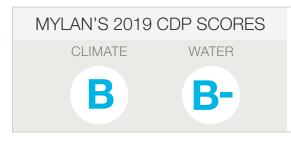
# **Encouraging Energy Efficiency and Mitigating Climate Change**

Responsible energy management is one important way that Mylan is reducing our impact on climate change.

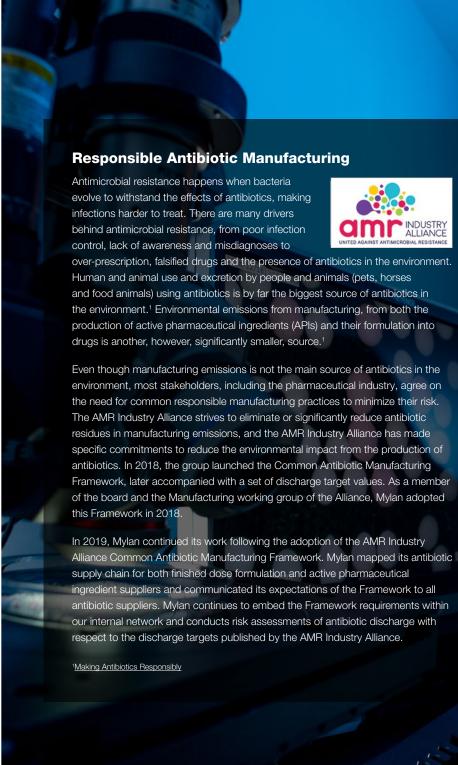
- ✓ Conducted energy assessments at key locations to evaluate opportunities to drive energy efficiencies and reduce emissions. We will use this information to establish additional metrics and goals over the next one to two years. We will also continue to conduct energy assessments at key locations in 2020.
- ✓ Installed a new cogeneration unit at our Caguas, Puerto Rico, facility.
- ✓ Completed several facility energy improvement projects that reduced the amount of steam required for operations.

amount of steam required for operations. For example, at two injectable locations in India the reverse osmosis (RO) plant recovery rate improved from 90% to 95% through desilication process, thereby reducing the hydraulic load on the evaporators treating the RO reject water and resulting in a decrease in energy and steam demand by 45%.

- ✓ Engaged with solar energy partners on a rooftop and ground-mounted solar energy project that is being evaluated at eight sites in India. Globally, we increased renewable energy 25% compared to 2018.
- Eight of our facilities are ISO 50001 certified and two additional facilities in India began sourcing energy from renewable resources in 2019.



One of our facilities in Vizag, India, was awarded the prestigious "National Energy Management Award" by the Confederation of Indian Industry.





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# **GLOBAL PUBLIC** HEALTH

- · Arguing against trade policies and intellectual property (IP) protections that extended exclusivity beyond national law for more expensive brand products, while restricting access to lower-cost generic medicines; and ensuring the appropriate balance between competition and innovation;
- Collaborating with health agencies across the world to ensure there were appropriate regulatory standards set across the generics industry, while also facilitating processes that would enable increased access and affordability to patients, such as quicker and increased approvals of generic and biosimilar medicines;
- Advancing industry viability by seeking to ensure a sustainable supply of medicines around the world and minimizing drug shortages;
- · Advocating for policies that promote antiretrovirals as prevention and not just treatment for those with HIV/AIDS: and
- Proactively shaping policies that would ensure the opportunity for patients to have access to biosimilar medicines that would reduce cost and increase access to these life-saving medicines.

In the 1980s, we co-founded the U.S. generic industry trade association that was instrumental in shaping the groundbreaking Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known by the names of its sponsors - Hatch-Waxman. In an effort to address the high cost of brand drugs, the legislation created incentives for U.S. generic drugmakers to challenge the patents of brand drugs. It struck a balance between innovation and competition and brought more affordable, high quality medicines more quickly to American consumers.



# **GLOBAL PUBLIC HEALTH**

Also in the 1980s, we found that many of our U.S. applications for generics had been delayed, while other companies were having no difficulty bringing similar products to market. We hired detectives who uncovered evidence of fraud and corruption in the FDA's generics division. The investigation discovered that certain companies were paying the agency to move their products up in the approval queue, while delaying their competitors. Congress took notice, and eventually several FDA officials and executives at other generics companies would face criminal charges. In the end, exposing these wrongdoings led to the restoration of a level playing field for manufacturers and the implementation of safeguards to ensure consumer safety.

## **Advocating for Quality Across Our Industry**

Part of ensuring safety for patients involved making sure we were committed to quality in everything we do. When Mylan went global in 2007, we were dismayed to learn that many manufacturers outside of the U.S. that supplied medicines to the U.S. market were seldom, if ever, inspected by the FDA. So we got to work and led the way in updating an outdated 1938 law to ensure that all prescription drugs dispensed in the U.S. are held to the same quality standards regardless of whether those medicines are made in facilities in the U.S. or abroad.

To ensure adequate resources for FDA to inspect facilities globally, Mylan also led the industry in the development, negotiation and passage of the Generic Drug User Fee Act (GDUFA) to help fund the needed inspections as well as to speed review of generic drug applications in the U.S. User fees from generic manufacturers would be used by the FDA to hire more agency experts to conduct and review applications for generic drugs, so the generic drugs could be approved faster and get to patients more quickly. It also enabled the FDA to continue to hire more inspectors to ensure that all manufacturing sites both domestically and internationally are inspected on a regular basis.

We partnered with other members of our industry to advocate for these important safeguards for patients. Mylan continues to be heavily involved with the discussions with the FDA when GDUFA is renegotiated and rewritten every five years. During the first update to GDUFA in 2017, Mylan worked with other generic companies to ensure that the FDA had the necessary funding from user fees to continue to approve generic drugs more quickly and that all plants are routinely inspected to ensure the continued supply of high quality generic drugs in the United States.



# **GLOBAL PUBLIC HEALTH**

#### Generic Savings Around the World

The use of generics saves money. Examples of these savings around the world include:

- In the U.S., the healthcare system saved \$293 billion in 2018 and about \$2 trillion in the last decade through the use of generic medicines. The savings in 2018 was the highest amount of savings attributed to generics over the years.
- In Australia, the generic medicines market for the year ended June 30, 2019 accounted for just over 86% of the volume of subsidized medicines but only 28.7% of the cost
- In Canada, for the 12 months ending June 2019, generic drugs filled 72.8% of prescriptions, but accounted for only 19.5% of the total cost of Canada's total annual prescription drug expenditure of CA\$29.6 billion.
- In Europe, generic medicines account for 67% of dispensed medicines and 29% of pharmaceutical expenditure at list prices, according to statistics for 2018.

Source: Association for Accessible Medicines, International Generic and Biosimilar Medicines Association

## **Leading Industry Associations Around the World**

One of the ways we help patients is through leading and participating in important industry associations around the world that are focused on solving the challenges of removing barriers to access for patients. In 1982, Mylan became a leading voice in the establishment of the



Mylan's Marcie McClintic Coates speaks on Capitol Hill to advocate for balanced trade policy to encourage generic and biosimilar medicines. Mylan played a leading role in helping to amend provisions of United States–Mexico–Canada Agreement (USCMA) to help address patient access barriers to generics and biosimilars in the U.S., Canada and Mexico.

Generic Pharmaceutical Industry Association (GPIA), the first U.S. association formed to give the generic industry a recognized voice. Through our determined focus on product quality and patient safety, Mylan helped to raise the bar for the entire generic industry.

Sparked by the urge to truly make a difference, Mylan today plays an active role in more than 60 similar associations around the world. Here are some examples of our work:

- In Europe, we were co-founders and continue to be active members of several prominent industry trade associations, including Medicines for Europe and Medicines for Ireland. We have worked with governments facing budget constraints to develop policies to expand access to and encourage the use of generics and have championed efforts to introduce paperless prescriptions, improve patient adherence and support early HIV diagnosis. In addition, we have advocated for the use of biosimilars so that patients could have access to high-cost biologic medicines. Finally, we have continued to work with our trade associations in Europe to ensure that the generic industry can remain sustainable for the long term and that requirements (e.g., serialization, responsible manufacturing and supply chain management) are being fairly defined for the generic industry.
- In Australia, we have consulted with the government to expedite patients' access to
  medicine, in some cases by up to two years. We have worked closely with Australia's
  trade association, the Generic and Biosimilar Medicines Association, to also ensure
  that the government-subsidized pharmaceuticals scheme encourages the uptake of
  generics and biosimilars and that any trade agreements do not hinder access to new
  generis and biosimilars for patients. Recently, we have been working closely with the
  trade association to ensure increased education and understanding of biosimilars.
- The Japanese government has set aggressive targets to continue to increase uptake of generic medicines and to be able to gain the savings from these medicines. To support that ambition, Mylan has shared the U.S. experience in increasing generic utilization and the impact on access.

Throughout our history, we have held leadership positions with trade associations around the world so that we can better advocate for patients. Many of our leaders have served as chair of the Association for Accessible Medicines (AAM) in the U.S., and currently Mylan leaders in Ireland and Australia head their respective industry groups, among others.

And just as importantly, we've also advocated for the generics industry as a whole to have a seat at the table in global issues affecting patients. We have continued to participate in – and at times lead – global organizations, such as the International Generic and Biosimilar Medicines Association (IGBA).

# **GLOBAL PUBLIC HEALTH**

#### **Forging International Partnerships to Help Patients**

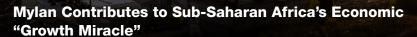
Since the global nature of the pharmaceutical industry requires significant geographic connectivity, we also work closely with international organizations. A great example is The Global Fund to Fight AIDS, Tuberculosis and Malaria, where we participate on or lead various committees. We also remain actively engaged with the World Trade Organization working group and are a signatory to the Davos Declaration on combating antimicrobial resistance (AMR) and a board member of the AMR Industry Alliance.

## Identifying Challenges to Patient Access in the U.S.

One of our most recent efforts involves working to address a new challenge to patient access in the U.S. Increasingly, generic medicines are being left off of generic formulary tiers, which provide lower out of pocket costs for patients, and instead are treated the same as brand-name drugs causing seniors to pay much higher out of pocket costs than necessary. In fact, a recent study from Avalere found that seniors could have saved nearly \$16 billion from 2016-2019 if generics were in fact treated as generics and included on generic formulary tiers. Research further demonstrated that in many cases generics were not even being placed on formulary tiers for up to three years after launching.

Historically, generic medicines were immediately included on a generic tier so that patients could get the benefit of lower priced generics by paying the lowest out-of-pocket cost. The result was a high utilization of generic medicines and a huge savings to the healthcare system. Additionally, patients should also get the benefit of lower cost specialty generics and biosimilars with lower out-of-pocket costs relative to brands. Specialty medicines represent some of the costliest and most frequently prescribed drugs in the U.S. but they continue to lack the dedicated formulary tiers that would ensure patients get the benefits of lower cost sharing.

We continue to work with lawmakers and the administration to find policy solutions to address these issues so patients can access more affordable generics and biosimilars and do so at an affordable cost.



Investment in health is not only a desirable, but also an essential priority for most societies. Health performance and economic performance are interlinked.

Sub-Saharan Africa's rapid economic expansion since 2001 has been called a "growth miracle" by Harvard professor Dani Rodrik.<sup>1</sup> A recent paper by Anna Tompsett of Stockholm University<sup>2</sup> estimates that improved access to HIV treatment, from essentially 0% at the start of the millennium to almost two-thirds of people living with HIV in that region today3, drove about onethird of this performance.

Mylan is the leading supplier of antiretrovirals to sub-Saharan Africa; since 2016, about 50% of people on treatment for HIV in the region have used a Mylan product. It is estimated that nearly 11.3 million HIV infections in sub-Saharan Africa have been averted since the beginning of the epidemic due to PEPFAR and the global HIV response.4 We are honored to have contributed to the health and well-being of millions of people in Africa and around the world, and look forward to continuing to do so for years to come.

<sup>1</sup>Journal of African Economies Advance Access: An African Growth Miracle? <sup>2</sup>Journal of Development Economics: The Lazarus drug: the impact of antiretroviral therapy on economic growth UNAIDS Data 2019

PEPFAR 2019 Annual Report to Congress

Mylan works closely with the ICH (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use), which includes regulatory authorities and representatives from the pharmaceutical



industry from around the globe that discuss the harmonization of the scientific and technical aspects of drug registration. Mylan has been a partner with ICH to achieve greater harmonization worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. Mylan was one of the first generic companies to have a leadership role in the various ICH teams. The company's role has increased with Mylan either leading or being involved in several of the ICH workstreams that promote science-based standards and set consistency to give patients peace of mind knowing they are taking high quality medicines.

# **GLOBAL PUBLIC HEALTH**

#### Fighting for Important Access in Europe

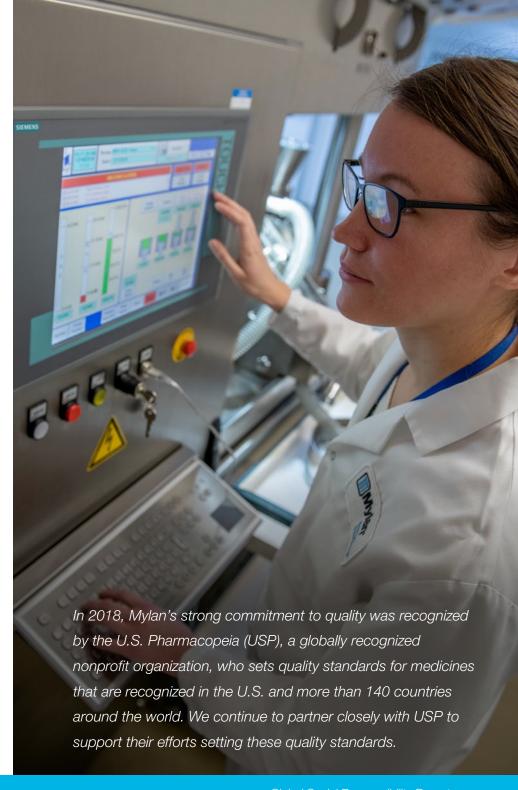
In most parts of the world, when brand medicine patents expire it opens the door for generic entrants into the market. The result is greater access created to more affordable medicines for patients. But in Europe, that wasn't necessarily the case. It was illegal to manufacture



medicines in preparation for a patent expiring, even when the final patent protection phase called "SPC" (Supplementary Protection Certificates) was in place. That intellectual property law meant patients couldn't get immediate access to more affordable versions of the medicines they needed. Instead, these newly allowed medicines had to be manufactured in other parts of the world and follow a long, expensive supply chain before getting to patients. The system limited access to patients and put Europe at an economic disadvantage by stifling manufacturing and job creation, making the EU as a whole less competitive.

In partnership with the industry association Medicines for Europe, which Mylan co-founded, we set out to change this through the approval of a SPC Manufacturing Waiver. Beginning in 2013, we played a critical role together with Medicines for Europe and later Medicines for Ireland, France's GEMME and other country trade organizations to develop policy and advocate to change this law. We built strong strategic stakeholder alliances in order to speak louder for patients and led media engagement in Brussels and other capital cities across Europe to spread awareness of this important issue.

In the summer of 2019, the European Commission granted the SPC Manufacturing Waiver. The move is expected to create 25,000 additional jobs and create billions of dollars in savings in pharmaceutical spending in the EU. Our hope is that the waiver can be quickly implemented to avoid further technology transfer of pharmaceutical production outside of Europe and boost R&D and manufacturing investment in the region, without shifting the balance between originator and competitive pharmaceutical sectors.



# Working Together to Fight AMR

Antimicrobial resistance (AMR) is a growing public health threat that is already impacting hundreds of thousands of patients each year and jeopardizing the level of care in health systems around the world. The effects of AMR threaten not only the application of modern medicine and ability to achieve good health but also have implications across society, from affecting agriculture and food security to economic development and beyond. Low- and middle-income countries are disproportionately burdened by factors such as limited access to antimicrobials, vulnerability of patients to invasive bacterial illness, limited diagnostic tools and overuse of antibiotics. Substandard and falsified medicines pose an additional challenge to mitigating the spread of AMR.

Addressing AMR requires a comprehensive approach and multi-stakeholder cooperation. An effective response to AMR will tackle challenges such as access to antimicrobials, stewardship measures – including appropriate use and surveillance – and responsible manufacturing. As a global healthcare company, Mylan considers the diverse needs and circumstances of patients and communities across the world by supporting and developing measures to address AMR while taking care to avoid unintended consequences.

Mylan is committed to supplying a diverse range of antimicrobial products including "forgotten antibiotics," those which are less widely produced and often effective against many resistant bacteria. Access to effective antimicrobials in low- and middle-income countries is a priority for Mylan, as evident in our collaborations with TB Alliance and Otsuka. These programs have allowed Mylan and our partners to increase access to affordable treatment for multidrugresistant forms of TB in high burden countries (see more on p. 22). Our supply chain supports reliable access to antimicrobials with mechanisms such as rapid-response advanced planning systems, dual sourcing systems and maintaining safety and strategic stocks. We have comprehensive processes to protect the security of products and safety of patients, including anticounterfeit serialization.

Our approach to stewardship includes healthcare professional (HCP) education, appropriate use packaging configurations, incorporating technology such as mobile apps and conducting AMR surveillance. Mylan supplies a broad portfolio of packaging configurations for various strengths and formulations, including pediatric formulations. Further, we work with pharmacies and support mobile applications, as well as other adaptations such as pictograms, to increase prescription adherence. Our HCP education programs meet the highest ethical standard and reach providers on the front lines of AMR. We monitor AMR through multiple surveillance programs which will be published in peer-reviewed journals. In India, Mylan supports a multicenter retrospective study of antimicrobial resistance in intensive care unit patients and operates the Revised National TB Control Programme (RNTCP).

4https://www.vinnova.se/en/p/platinea-a-collaboration-platform-for-innovating-existing-antibiotics/

We have adopted the AMR Industry Alliance Common Antibiotic Manufacturing Framework and have a global environmental program to conduct and promote responsible manufacturing. In addition, Mylan advances efforts on mitigating AMR and pharmaceuticals in the environment (PiE) through our national



and regional trade associations and collaborations with non-governmental organizations. Recently, we have engaged with the Ministry of Environment, Forest and Climate Change (MOEF) and other agencies in India regarding AMR, and in Sweden we are a founding member of PLATINEA<sup>1</sup>, a multi-stakeholder platform for innovation of existing antibiotics, supported by the Swedish Government which aims to optimize the use of these antibiotics and to increase the availability of important antibiotics which risk disappearing from Sweden.





## GLOBAL PUBLIC HEALTH:

## **2019 HIGHLIGHTS**

We work hard to give a voice to patients around the world and advocate for better health.

We do this through building relationships to advance the sustainability of our industry, helping shape policies that promote the use of lower-cost generics and biosimilars and fighting for fair regulatory expectations across all markets. By addressing these issues through direct and indirect advocacy and engaging with governments and other relevant external stakeholders, Mylan continues our work to provide patients around the world access to affordable medications.

#### **Advocating for Increased Use of Biosimilars**

One of the ways we did this was by driving a focus on building sustainable market environments to ensure access to biosimilars.

- Participated in the World Health Organization (WHO) prequalification pilot for cancer biologics on the Essential Medicines List and the first WHO implementation workshop on post-approval changes and continue to provide our feedback on the implementation.
- Supported the launch of British Columbia's Biosimilars Initiative in Canada to transition patients using originator biologic drugs for certain indications to their biosimilar versions.
- ✓ Completed activities to shape National and Local NHS commissioning policy toward switching to biosimilar insulin in the U.K.
- ✓ Worked closely with GBMA's (Australian Generics Trade Association) inaugural Biosimilars Week that was focused on increased education and awareness of biosimilars.
- Aligned with trade associations and other companies to change regulation that would have required the refiling of generic insulin applications and potentially delaying generic competition and access to a lower-cost insulin.



Mylan's Head of Global Biologics Commercial Chrys Kokino joined industry leaders in November 2019 to discuss ways to improve patient access and ensure a sustainable market for biosimilar drugs.

- Worked closely with trade associations to develop education materials and white papers to support increased understanding and usage of biosimilars.
- ✓ Engaged with the U.S. Centers for Medicare & Medicaid Services to receive a favorable coding decision and "pass-through" payment status, with both decisions enabling a better opportunity to gain biosimilar uptake.
- Continued to engage with various governments throughout the world by providing comments and submissions to possible government policy changes and rulings to continue to educate about the need for increased usage of biosimilars and savings for patients.

## **Educating About the Safety of Generics and Biosimilars**

Although they are equal in efficacy to their brand counterparts, generic medicines and biosimilars remain misunderstood in many parts of the world. Mylan takes seriously its responsibility to educate policymakers about the safety and effectiveness of these products, and we spent a lot of time in 2019 talking with governments and health authorities around the world. We have collaborated with trade associations and other companies to ensure that there is an increased awareness that patients can take a generic medicine or biosimilar and be assured that they are receiving a product as safe and effective as the brand counterpart.

## **Removing Barriers to Patient Access**

We advocated for policies and regulations to help patients get the medicines they need and not hinder access.

- Argued successfully along with Medicines for Europe for a SPC Waiver allowing generics manufacturers to make products in the EU in the months leading up to the originator product's patent expiration.
- Helped abolish mandatory arbitrations in Portugal between generic manufacturers and originators so that patients would have faster access to more affordable medicines.
- Continued to fight against the extension of patent protection and regulatory exclusivity periods that unfairly favor less affordable originator products and delay access for patients. These provisions have been included in free trade agreements and we have worked with policymakers to remove such increased exclusivity for the originator products. A recent success was the removal of the biologic exclusivity period of 12 years from the USCMA free trade agreement. We will continue to work with the negotiators of free trade agreements that are being updated throughout the world to hopefully achieve similar success.



## GLOBAL PUBLIC HEALTH:

## **2019 HIGHLIGHTS**

- Participated in discussions and planning to ensure a stable supply of medicines post-Brexit.
- Became the first generic company to have PrEP reimbursed in Portugal within less than one week after the originator's reimbursement.
- Deployed serialization across the globe to meet the timing and requirements from all authorities to ensure that all of our drugs can be tracked and traced through the supply chain.
- ✓ Played a strong leadership role on ICH with more experts on the various expert working groups than any other generic company. These working groups are focused
- ✓ Collaborated with other stakeholders to raise concerns about government changes in the manufacturing of oxytocin in India that could cause potential shortages and risk patient health during childbirth.

on harmonizing regulations in specific knowledge areas across the globe.

✓ Backed the use of a "ladder" policy by the Canadian pricing association, pCPA, which supported an increase in a drug price if competitors left the marketplace to ensure that the price was competitive to keep companies in the market and supply products without causing shortages. In 2019, the policy was implemented and the pCPA will consider tier price increase applications where one or more competitor marketed drugs are no longer marketed in Canada. If a product is deemed eligible for price increases, standard generic framework pricing rules will apply (number of drugs, proportion of brand reference price and brand reference determination).



Serialization ensures that medicines can be tracked and traced through the supply chain.

## **Promoting Affordability**

We communicated our concerns with policies and actions that would limit access to lower cost generic medicines.

- ✓ Advocated for fixing insurance formulary tiers in the U.S. that result in patients paying the brand out-of-pocket rate for lower-cost generics.
- Campaigned for a free HIV PrEP access program, which Ireland's Prime Minister and Health Minister officially announced the creation of in October 2019. Also worked with the government in Spain to have appropriate reimbursement for PrEP.

#### **Partnering to Advance Disease Awareness**

We're a partner with many like-minded organizations and government agencies around the world who share our passion to help patients.

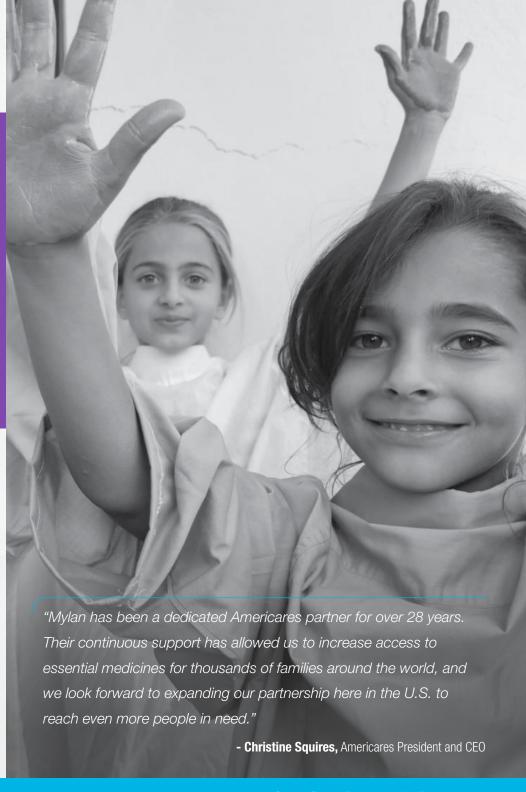
- Sponsored the Congressional Women's Softball Game to benefit the Young Survival Coalition, which supports thousands of young women diagnosed with breast cancer every year.
- ✓ Engaged with the Ministry of Commerce in India and provided feedback to the government on the alternate export scheme in place of the Merchandise Exports from India Scheme and draft Foreign Trade Policy 2012.
- 18 2 2
- ✓ Provided feedback to India's Ministry of Environment about addressing AMR issues.
- Engaged with the Indian Government to create and pilot a TB eradication program to meet the Prime Minister's goal of eradicating the disease by 2025 in India and ahead of the WHO target of 2030.
- Collaborated with the AMR Industry Alliance as they completed their progress report, including providing data and information as well as a case study of our work with the TB Alliance.

# A LEGACY OF IMPACT: COMMUNITIES

Giving back has been a core value at Mylan since the beginning. Our founders believed contributing to Mylan's community was a great way to stay connected to people and truly understand their needs. That simple principle of being of service would grow in importance and scope as the company grew, too – first across the U.S., and then across the world. Whether it has been helping residents recover from devastating floods in West Virginia or ensuring young Indian students had a safe water supply, Mylan has promoted better health through supporting our neighbors and strengthening our communities.

One of our earliest ways of giving back was through helping the people in the state where Mylan got its start. The Milan Puskar Health Right, founded in 1984, is a primary care clinic named after one of our founders that provides free healthcare to the uninsured or underinsured in North Central West Virginia. We've given generously to the clinic and since 2007 have donated more than 11 million doses of medicine. We have supported many other causes in the state over the years, including the United Way and others, culminating in 2018 with the announcement of a collaboration called STEMCARE® with West Virginia University. That initiative encourages a growth mindset through science, technology, engineering and math (STEM), with a goal of touching young lives in every corner of the state.

As we added to our portfolio and began reaching more patients around the world, our efforts to give back expanded, too. We began supporting groups like Americares, and as of today have provided ~353 million doses of medicine to the organization since 2007. Americares delivers our medicines to a network of 4,000 health centers worldwide, as well as health facilities treating disaster survivors. In recent years, we've supported Americares responses to the 2015 Nepal earthquake as well as several hurricanes in 2017. For Hurricanes Harvey, Irma and Maria alone, Mylan donated more than 6 million doses of essential medicines. We are extremely proud to be one of Americares' most dedicated and longstanding supporters.



## **COMMUNITIES**

We've also closely aligned with The Dispensary of Hope (DOH), a nonprofit, social enterprise that connects medication surplus from manufacturers and physicians with low-income and underinsured patients around the U.S. The group shares our mission of access, making our efforts a perfect match. In all, Mylan has donated 193 million doses of medicine spanning a variety of therapeutic areas to the Dispensary of Hope since our partnership began in 2012.

Our efforts to provide support are as diverse as the regions we serve and the people they help. For example, in India, we have a very robust program of corporate social responsibility initiatives. Mylan supports and encourages our employees in India and around the world to give back.

In the U.S., Mylan has a donations policy and committee that manages contributions. Elsewhere, our country managers oversee community initiatives in accordance with local and company policies.

Mylan also funds the Mylan Charitable Foundation, an independent U.S. 501(c)(3) organization. The Foundation provides financial support to help meet community education, social services and health needs, among other areas.

Some other ways Mylan has made an impact in communities around the world include:

- Creating access to healthcare by donating thousands of doses of flu vaccine in Greece and Italy
- Providing financial assistance to help eliminate mother-to-child transmission of HIV in Nigeria
- Facilitating ongoing education and research in pediatric oncology through a
   €1 million donation to the Princess Maxima Center in the Netherlands that was
   used to construct a new auditorium
- Supporting students studying pharmacy and medicine with scholarships in South Africa

Working together with our partners and other stakeholders, we are making an impact in the communities where we live and work around the world.



Mylan sponsors Positive Athlete
Pittsburgh because student-athletes in
Western Pennsylvania, home to our U.S.
headquarters, share many of our core
values – including passion, leadership
and perseverance. As a result, Mylan has
supported the Positive Athlete program
since 2014, providing more than \$150,000
for scholarships to local students and
overall event support.



The Mylan-sponsored auditorium at the Princess Maxima Center for Pediatric Oncology.

# **Some Examples of Doses of Medicine Donated**

Catholic Mission Medical Board:

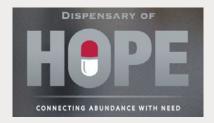
**1 billion** since 2012

Americares:

**353 million** since 2007

Dispensary of Hope:

**193 million** since 2012



"Mylan's donations have helped patients in more than 33 states plus the District of Columbia. In fact, in 2019 alone, the company's donations have equated to more than 92,000 daily doses, distributed to support America's low income, uninsured population."

 Scott Cornwell, Dispensary of Hope Chief Supply Chain Officer

# Community Highlight: Making a Lasting Impact in India

Mylan's presence in India has allowed us to touch millions of lives across 18 states over the years through our commitment to social responsibility. Our efforts have included everything from constructing healthcare infrastructure, donating medical equipment, creating access to clean water and spreading disease awareness to desilting water bodies, constructing check dams, building community halls and improving road safety measures. All of our efforts have helped to promote better health, well-being and productivity in communities throughout the country.

Our health outreach programs have impacted the lives of more than 1 million people over the past five years, including through our multi-specialty health camps that provide education and help identify gaps in care. One example is Mylan's partnership with the Institute of Liver and Biliary Sciences (ILBS) in India for the "Healthy Liver, Healthy Delhi" initiative which serves to create awareness of liver health and facilitate screening of hepatitis B and C. Mylan has funded a state-of-the-art mobile diagnostic unit for detection of liver-related disorders, and so far more than 16,000 people have received free screenings through the program's mobile clinics; 6,000 were screened in 2019 alone. Based on the success of the initiative, Mylan and ILBS are working to increase the number of mobile clinics to reach more patients.

One of the most significant and successful impacts we have made has been through the Affordable Cancer Care program. Doctors, nurses and supporting staff in western India were trained to screen for and treat cancer at district-level hospitals and improve care given to cancer patients. As a result, patients were not required to travel to larger cities for screening and treatment but instead can stay in their own districts. Under this program, over 6 million people have been screened for oral cancer.

## >6 million

people have been screened for oral cancer with Mylan's support under the Affordable Cancer Care Program

Additionally, in northern India, more than **1 million people were screened for TB** in a screening camp sponsored by Mylan as part of a national mission to eradicate the disease by training health workers and providing ease of access to medicines.

We have also made an impact in India in the following ways:

- Implemented a comprehensive sanitation and hygiene program in schools across the states of Tamil Nadu, Karnataka, Telangana, Andhra Pradesh and Madhya Pradesh. Constructed 26 toilet facilities in schools in these states over the last five years under the Swachh Vidyalaya program, benefiting around 6,800 students a year.
- Equipped 24 schools in South India with RO purification water systems. This
  initiative will benefit over 6,000 students every year by providing them with clean,
  safe drinking water.
- Established over 30 community drinking water facilities which provide clean and safe drinking water to over 100,000 people.
- Donated funds to help rebuild the lives and homes of those affected by floods in Kerala.
- Partnered with medical schools in India to educate residents on the rational use of antimicrobial agents in managing infections.
- Donated garbage disposal trucks to seven villages in India to help support the management of solid waste for more than 100,000 residents.





## **COMMUNITY HEALTH:**

## 2019 HIGHLIGHTS

Because many factors can affect someone's ability to live a healthy life, we are always looking for ways to help strengthen the communities where we live and work. Here are some of the highlights from 2019:

✓ Raised disease awareness and funding for patient groups by participating in runs, walks and biking events around the world, including the Run Lyon for the eighth consecutive year in France to benefit the Association Petit Princes and runs in Italy to benefit patients with HIV and cystic fibrosis. We also participated in events in Finland, Belgium, Bulgaria and the U.S., among others.



✓ Supported children with life-limiting conditions and their families by donating to the only children's hospice in Queensland, Australia, through a series of employee fundraisers.



Supported mothers and children in Mardin, Turkey, through the establishment of a new toy library at the Cumhuriyet Neighborhood Women-Children Center. Mylan's team donated toys as well as manpower to clean and paint the space and celebrated the library's opening with local families.



✓ Supported families suffering pregnancy loss in the U.K. to have continued access to East Kent Hospital's Ocean Suite, which is a special room used by grieving families so that they can be separate from the maternity suite.



Promoted better health for children with autism and their families in Ireland through the support of the Galway Autism Partnership (GAP) and the Snowflakes organization in Dublin. Our Galway team raised money through a variety of events including the "Sky Diver, Hell & Back" obstacle race.



✓ Worked to help Serbia's most vulnerable young people by donating clothes, toys, books and other items to the Children's Shelter in Belgrade. Many of the children who benefit are victims of violence, abuse and neglect, trafficking and are homeless.



Contributed funding to help Greece's Athens Checkpoint, the country's most prominent community-based HIV testing and counseling facility, rebuild after the facility was targeted by arsonists.



✓ Funded an awareness campaign in South Africa on the importance of knowing one's HIV status, getting onto a treatment regimen and adhering to that course of treatment.



✓ Provided about 800 students in Bollaram, India, access to develop skills that will help them succeed in work and life through the construction of a skill development center. The facility for 10th grade and intermediate students will focus on soft skills such as leadership, teamwork and communication, among others.



✓ Supported children at the Indira Gandhi Institute of Child Health in Bangalore, India, through the construction of a play zone near the hospital's outpatient center that is expected to serve as many as 10,000 children a year. Donated a high-definition medical grade camera system that will allow doctors to safely perform minimally invasive surgeries on ~1,000 infants a year.



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## **Restoring Hope in Partnership with SBP**

All too often, natural disasters leave many of our friends and neighbors in need in the communities where we operate around the world. In those times, we're proud to step up and help not just immediately following a crisis, but for the months and years of recovery that often lie ahead.

In the spring of 2019, Mylan attended a welcome home ceremony after the Mylan Charitable Foundation (MCF) pledged \$1 million to rebuild communities in Puerto Rico in partnership with SBP, a national disaster recovery organization. This donation helped jumpstart the rebuild and repair of devastated homes, adding to SBP's recovery efforts since Hurricane Maria devastated the island in 2017.

This commitment was on top of what we did after the storm violently struck: We immediately shipped 36,000 pounds of essential items needed by local residents in a chartered aircraft; opened the doors of our manufacturing plant to provide food, water and other assistance to those in the surrounding area.

We first came together with SBP in 2016, when Mylan and the MCF contributed \$1 million to SBP to rebuild homes and help residents in southern West Virginia recover from devastating floods. Mylan and its employees also contributed to SBP's relief efforts in Texas following the heavy flooding left by Hurricane Harvey.

"We are grateful for the Mylan Charitable Foundation's support in establishing a long-term recovery operation here in Puerto Rico. This partnership has enabled SBP to help establish on-the-ground recovery operations and provide a predictable path home for disaster-impacted families in several communities across the island."

- Zack Rosenburg, SBP Co-Founder and CEO



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## **Impacting Young Lives** in the U.S.

2019 was a busy year for our STEMCARE® initiative with West Virginia University. We introduced a new curriculum for kids and continued to raise awareness of the program, which is designed to help encourage a growth mindset through science, technology, engineering and math (STEM) programming and transform the state's youth to reimagine their futures.



The program was announced by CEO Heather Bresch and West Virginia University President Gordon Gee in May 2018. Mylan committed a \$5 million charitable contribution over 10 years to help empower West Virginia children to be Curious, Active, Resilient and Engaged - putting the CARE in STEMCARE.

In the summer of 2019, we debuted the Mylan-sponsored Innovation Station curriculum to 4-H campers to encourage kids to challenge themselves and develop important critical thinking skills. In the fall, we started introducing that curriculum into schools across West Virginia.

One part of the Innovation Station, an activity called "Sky's the Limit," was also on display at the 2019 WV State Fair, attended by thousands. During the lesson, children used the engineering design process to build their own flying machine to hover in a wind tunnel. The fun activity promotes creativity and problem solving - two aspects that make up a growth mindset, which helps kids understand that they can keep working and growing even if they don't succeed on their first try.

At the fair, the STEMCARE booth also featured DIY marshmallow catapults and "drop copter" templates for kids to take home. Parents and educators could find a brochure that explained the program, why Mylan is involved and how they can incorporate STEMCARE ideas in their own curricula at home or in classrooms.

We took every opportunity in 2019 to spread awareness about the program, including speaking to educators and 4-H leaders from around the country at the annual meeting of the National Association of Extension 4-H Agents. Many participants from around the country were interested in replicating the program in their home states, and we are hopeful the program will have an opportunity to expand beyond West Virginia.

#### STEMCARE BY THE NUMBERS

May-November 2019

~500 young campers have participated in STEMCARE programming through 4-H camps in West Virginia.

~300 students have been educated through STEMCARE programming offered at West Virginia schools.

#### 20 WVU Extension Agents & 21 WVU STEM Ambassadors

have been trained to deliver STEMCARE's "Sky's the Limit" program that focuses on a growth mindset and design-based learning in schools and at 4-H camps.



Children at 4-H camp participate in the "Sky's the Limit" activity sponsored by Mylan during the summer of 2019.

# **GSR MANAGEMENT DISCLOSURE AND** PERFORMANCE DATA

In this section of Mylan's 2019 GSR Report, we present a comprehensive description of Mylan's management, governance and organization of important social responsibility and ESG matters. We will also provide performance data across Mylan's impact areas. The information presented herein complements the information presented in the preceding chapters. Our intention is to provide a balanced and complete description of Mylan's work and performance to enable informed decisions about Mylan by our key stakeholders.

This report has been prepared in accordance with the Global Reporting Initiative (GRI) Standards: Core option and references the Sustainability Accounting Standards Board (SASB) disclosures. Mylan's GRI Content Index and SASB Reference Table are presented on p. 88-96.



#### **Our Vision for Global Social Responsibility**

Global social responsibility (GSR) is intrinsically woven within Mylan's commitment to achieve our mission and deliver better health for a better world. It is what drives our enduring passion to improve access and serve unmet needs across all geographies, while respecting the environment and positively impacting our stakeholders.

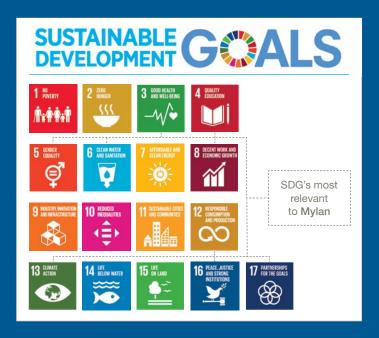
As a signatory to the U.N. Global Compact, Mylan is committed to the Compact's ten principles related to human rights, labor, environment, and anti-corruption.

Mylan supports the U.N.'s agenda and believes that companies can play a central role in helping to achieve these development goals. The Sustainable Development Goal that is most relevant to our mission and impact is No. 3: Good Health and Well-Being. Our broad and diverse portfolio across 10 therapeutic categories – combined with our long-standing commitment to increasing access to high quality medicine through innovation and partnerships – strongly positions Mylan to make continued contributions toward this goal.

As a global healthcare company, we know our influence and actions impact other goals as well. From ensuring a fair, diverse and safe workplace and upholding a culture of integrity and ethical business practices to supporting local communities and reducing our environmental impact, we are committed to helping lead positive, sustained change.

#### **GSR Governance**

Mylan's Board of Directors oversees management's efforts with respect to GSR through its Risk Oversight Committee. At the end of 2019, Mylan's Head of Global Sustainability was promoted to oversee a newly organized Corporate Affairs function within Mylan. This function now encompasses not only Mylan's global social responsibility efforts, but the company's global communications, global policy, U.S. government relations and global brand activities. It also collaborates closely with Mylan's investor relations team. The Head of Corporate Affairs reports directly to the CEO and communicates regularly with Mylan's Board of Directors through the Risk Oversight Committee. This reorganization only served to amplify the importance of Mylan's commitment to sustainability across all of its stakeholder



## **United Nation Global Compact (UNGC) 10 Principles**

#### **Human Rights**

- 1: Businesses should support and respect the protection of internationally proclaimed human rights; and
- 2: make sure that they are not complicit in human rights abuses.

#### Labor

- 3: Businesses should uphold the freedom of association and the effective recognition of the right to collective bargaining;
- 4: the elimination of all forms of forced and compulsory labor;
- 5: the effective abolition of child labor; and
- 6: the elimination of discrimination in respect of employment and occupation.

#### **Environment**

- 7: Businesses should support a precautionary approach to environmental challenges;
- 8: undertake initiatives to promote greater environmental responsibility; and
- 9: encourage the development and diffusion of environmentally friendly technologies.

#### **Anti-corruption**

 Businesses should work against corruption in all its forms, including extortion and bribery.

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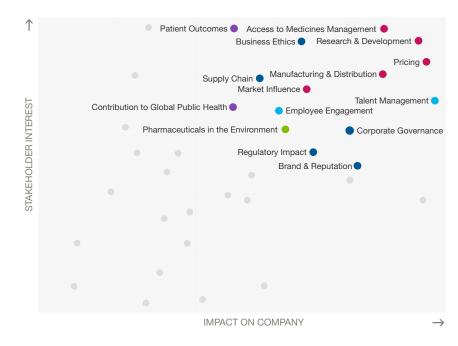
communication efforts under the leadership of an executive with meaningful ESG knowledge and experience. The office of Corporate Affairs oversees the development and implementation of Mylan's strategic focus and efforts around GSR matters and philanthropy and provides regular updates to Mylan's Risk Oversight Committee on GSR matters. A multifunctional GSR Advisory Committee comprised of crossfunctional leaders convenes monthly and supports the progress and integration of relevant GSR topics across the organization.

#### **GSR** Assessment and Priorities

In 2018, Mylan conducted a priority assessment in coordination with external ESG advisors, capturing external and internal perspectives on important GSR topics. We considered GSR-related input from external stakeholder engagements, as well as viewpoints, concerns and priorities of a broad range of stakeholders, including customers, partners, investors, NGOs, employees, community groups and policy makers. We also engaged senior leaders at Mylan, representing key business units and cross-functional areas of our company, spanning Mylan's geographic footprint.

Five issues – pricing, manufacturing and distribution (including product quality and safety), research and development, access to medicines management and talent management – were identified as GSR priorities based on their overall stakeholder interest and potential impact on Mylan's business and mission.

However, all topics included in the assessment are relevant and important to manage diligently and effectively. These topics, and the broader findings of our GSR analysis, formed the basis for and are addressed throughout this report and have also been used to inform Mylan's strategic planning and enterprise risk management efforts.



COMPLETE LIST OF ISSUES ASSESSED				
Access to Medicine Access to Medicines Access to Medicines Management* Compliance Local Capacity Building Manufacturing and Distribution (including product quality & safety)* Market Influence Patents and Licensing Pricing* Product Donations Research and Development*  Societal Impact Community Engagement and Impact Patient Outcomes Contribution to Global Public Health	Being a Responsible Employer Diversity and Inclusion Employee Engagement Talent Management*  Environmental Stewardship Air Climate Change and Energy Environmental Protection Pharmaceuticals in the Environment Product Stewardship Waste Water Workplace Health and Safety	Operating a Responsible Business Brand and Reputation Business Ethics Corporate Governance Customer Satisfaction Data Privacy and Protection Ethical Marketing and Promotion Global Competitiveness Human Rights Regulatory Impact R&D Impacts Risk Management Supply Chain Transparency  "Denotes top 5 priority based upon assessment results		

#### **Mylan's Commitment to Access**

Throughout our history, Mylan's foundation and core business model have been focused on providing access to medicine. Given the significance of patient needs across the globe and across all income levels, we are convinced that meeting this challenge requires a consistent and sustainable commitment. Our access objectives and key performance indicators (KPIs), that flow from our mission statement, seek to describe how we have and will continue to operate universally to fulfill our aim of providing high quality medicines to billions of patients around the world.

## **OUR MISSION**

At Mylan, we are committed to setting new standards in healthcare.

Working together around the world to provide 7 billion people access to high quality medicine, we:

- Innovate to satisfy unmet needs
- Make reliability and service excellence a habit .......
- Do what's right, not what's easy.....

## **OUR ACCESS OBJECTIVES:**

Continuously leverage the breadth, depth and capability of our business model to consistently provide high quality medicine and related services to meet the needs of patients in low-, middle- and high-income countries

Research and develop new dosage forms that will improve effective adherence; alternative product

options that will provide more affordable access; a

 options that will provide more affordable access; and opportunities to bring our existing portfolio to additional countries and regions

Cultivate quality-focused internal and external manufacturing capabilities and services along with pricing approaches that allow for both affordable patient access and sustainable supply

Apply the same commercial and operational focus as well as commitment to quality and safety while supplying products to patients and countries with varying degrees of income level and resources

 Seek out opportunities to provide access-related industry and global public health leadership

#### **OUR ACCESS KPIs:**

- Doses sold
- Number of products
- Number of countries and territories reached
- Therapeutic categories
- Coverage percentage of the top ten causes of death globally
- Coverage percentage of the top ten causes of death across low- and lower-middle income countries
- Products in development by region
- Products pending approval by region
- Types of products
- Average selling price of Mylan's medicines
- Customer service levels globally and by region
- Percentage of low- and lower-middle income countries reached
- Doses sold in low- and lower-middle income countries
- Number of products on the World Health Organization's (WHO) Essential Medicines List
- Number of products on the WHO list of prequalified products (including cross-listed approvals)
- Active partnerships or organizational memberships related to increasing access to medicines

At Mylan, we invest in science and believe that innovation is key to expanding access to medicine. In the pharmaceutical industry, R&D is often assumed to reference only the development of new, brand-name drugs. However, there are many other components of R&D that are just as critical to providing the world's population with access to needed medicines. At Mylan, in addition to working on new chemical entities and focusing on developing new delivery devices, we also constantly look for ways to improve patient convenience, prescription compliance, safety, experience and access. We continually review our product portfolio, manufacturing network and supply chain to ensure our products help address unmet needs while supporting our mission. For these reasons, it is not uncommon for us to be among the first to manufacture difficult-to-make generic versions of drugs.

#### In 2019 we:

- ✓ Received over 600 global product approvals.
- √ Completed 139 market submissions in more than 120 different countries, including 89 products in emerging and expansion markets.
- √ Filed over 650 individual market submissions, including over 300 individual market submissions for emerging and expansion markets for the total number of regulatory filings.
- √ Completed 14 drug master filings. A drug master file (DMF) contains detailed information on a new API molecule that will be used in a new Mylan medicine.

Patients in more than 165 countries and territories rely on our products today, and we are committed to ensuring the continued sustainability and availability of our portfolio to the extent possible, which may periodically mean rationalizing products not earning their cost of capital. Throughout this process, Mylan pays special attention to the availability of single source medications critical to patient health. Portfolio sustainability also means focusing our R&D investments on medicines that are more difficult to manufacture in an effort to meet unmet patient needs. As we move our portfolio up that value chain, we are focused on making improvements to existing products and expanding formulations to make them more widely available to those who may not have previously had access.

Our Access Key Performance Indicators	2017	2018	2019
Doses sold	~69 billion	~59 billion	~62 billion
Number of products	>7,500	>7,500	>7,500
Number of countries and territories reached	>165	>165	>165
Major therapeutic categories	10	10	10

Our Access Key Performance Indicators	2017	2018	2019
Coverage percentage of the top 10 causes of death globally <sup>1,2</sup>	N/A	90%	90%
Coverage percentage of the top 10 causes of death across low- and lower-middle income countries <sup>3</sup>	N/A	77%	77%
Total investments in R&D	From 2013- 2017, we invested more than \$3 billion in cumulative R&D spend	\$704.5M	\$639.9M
Products in development by region <sup>4</sup>			
North America	359	340	190
Europe	174	200	90
Rest of World	4915	600	250
Products pending approval by region <sup>4</sup>			
North America	267	200	190
Europe	528	700	690
Rest of World	9885	1,600	1,600
Types of products		See page <u>87</u>	
Average selling price of Mylan's medicines	17¢ per dose	19¢ per dose	18¢ per dose
Customer service levels globally and by region			
North America	N/A	82.3%	84.8%
Europe	N/A	90.3%	89.3%
Rest of World	N/A	95.7%	95.8%
Global	N/A	90.3%	89.5%

<sup>&</sup>lt;sup>1</sup>The remaining cause of death is road injury

<sup>&</sup>lt;sup>2</sup>Source: Global Health Estimates 2016: Deaths by Cause, Age, Sex, by Country and by Region. 2000-2016 Geneva, World Health Organization: 2018

<sup>&</sup>lt;sup>3</sup>Income groups from the World Bank list of economies (Published July 2019)

<sup>&</sup>lt;sup>4</sup>Change in year over year numbers is a focus of product mix; products taken from internal data and rounded

In the 2017 GSR Report, Mylan reported per RoW split into: Japan, Australia & New Zealand and Expansion Markets

Our Access Key Performance Indicators	2017	2018	2019
Percentage of low- and lower-middle income countries reached <sup>1</sup>	N/A	90%	88.5%
Doses sold in low- and lower-middle income countries <sup>1</sup>	N/A	>5 billion	~6.5 billion
Number of medicines on the WHO's Essential Medicines List	N/A	>150	>200
Number of medicines on the WHO list of prequalified products (including cross-listed approvals)	63	HIV/AIDS: 46 Reproductive Health: 9 Tuberculosis: 8 Influenza: 3 Malaria: 1 Hepatitis: 1 Total: 68	HIV/AIDS: 45 Reproductive Health: 9 Tuberculosis:7 Influenza: 2 Malaria: 3 Hepatitis: 3 Total: 69 <sup>2</sup>

<sup>1</sup>Income groups from the World Bank list of economies (Published July 2019)

<sup>&</sup>lt;sup>2</sup>As per 2/2/20

Additional Data	2017	2018	2019
Number of patents filed to date	~4,000	>4,500	>5,000¹
Licenses via the Medicines Patent Pool	N/A	5	5 <sup>2</sup>
Number of women and girls that Mylan provided contraceptives to <sup>3,4</sup>	>13 million	>13 million	>14 million

<sup>1</sup>Including active patents and pending applications

# **Ensuring Quality and Patient Safety in Processes and Products**

Protecting patients and consumer health by ensuring the quality and safety of our products is at the heart of how we operate across our network. Every step of our development, manufacturing and monitoring processes - from product development to sourcing of raw materials to producing finished dosage forms - is grounded in this commitment.

All of Mylan's sites are regulated and inspected by national health authorities from the markets where we sell. The health authority inspections provide extensive external certification and authorization of Mylan sites for further production and marketing.

In 2019, global health authorities conducted over 92 regulatory inspections of our over 40 manufacturing facilities. Additionally, we completed 656 quality and Good Manufacturing Practice (GMP), 83 Good Clinical Practice (GCP), and 16 Pharmacovigilance (PV) audits at our facilities and suppliers.

#### **Quality Management**

Mylan maintains a quality infrastructure at the global level that includes Global Quality Policies which set a uniform expectation for fundamental topics within the Quality Management System, as well as Global Quality IT systems which are implemented and designed to establish industry best practice and consistency throughout our global network.

All our operational facilities have management systems, standards and processes in place which are designed to ensure product quality and safety across our operations and to be in compliance with the quality guidelines and practices applicable to the markets in which our products are provided, such as current Good Manufacturing Practice (cGMP), Good Pharmacovigilance Practice and Good Clinical Practice.

In addition to these guidelines, we apply relevant quality guidelines and practices, including: Eudralex, Falsified Medicines Directive, ICH Quality Guidelines, WHO GMP, Food and Drug Administration Safety and Innovation Act (FDASIA) and the EU Excipient Risk Assessment for ascertaining GMP for excipients of medicinal products for human use. We use a Regulatory Intelligence and Knowledge Management Dissemination Program to better inform, evaluate and implement regulatory updates, industry trends and internal knowledge.

Mylan's Quality Management System (QMS) and Product Safety and Risk Management System maintain standard operating procedures for core components including but not limited to:

- Managerial responsibility
- Regular training
- Regular audits

- Products risk assessment
- Regular compliance monitoring
- Regular testing
- Incident investigation, corrective and preventative action

<sup>&</sup>lt;sup>2</sup>As per 3/9/20

<sup>&</sup>lt;sup>3</sup>Data per 2017 and 2018 has been restated due to modifications in methodology.

<sup>&</sup>lt;sup>4</sup>Based on internal sales records and IQVIA IMS data for third party manufactured products (sales in Europe). IQVIA IMS 2019 data was available up to Q3, for full year data the average of 3 quarters is measured as 4th quarter.

#### Quality Governance and Organization

Mylan's Head of Global Quality reports to the President and the following functions are within the overall Global Quality structure:

- Global Operations Audit
- Global Learning and Development
- Global Quality Compliance
- Global OSD and API Quality
- Global Injectables Quality
- Global Dermatologics Quality
- Global Biologics Quality

- Global Respiratory Quality
- Global Quality Systems/QA IT Technical Quality
- Global Quality Investigations
- Global Quality Operations, Affiliates
- Global Quality Integration/Surveillance
- Global Clinical and Bioanalytical Quality

Mylan continuously evolves its quality organization to ensure alignment with the business operations and to enhance compliance with applicable standards. We enhanced our overall operations and quality organizations to further improve connectivity and oversight throughout the global network. Quality leadership was expanded to facilitate broader surveillance functions and to continue to optimize compliance. Existing global quality resources are embedded within the operational verticals to align closely with the business units and drive consistency across the sites. These enhancements promote closer connectivity among operational leaders and leads to improved product quality, supply continuity and patient access.

As part of the continual work to assess and adapt quality management, in 2019 Mylan further enhanced its global policies and procedures on data governance, corrective and preventative action, training, auditing, incident investigation, critical event management and field alert reporting to further drive consistency in practice and allow more efficient trending and life-cycle management.

## **Training for Continuous Improvement**

Our Global Operations Training program provides consistent and effective training to assure access to and delivery of knowledge to global Mylan operations personnel. This program coordinates and standardizes training requirements, content, techniques and training delivery methods to continually strengthen our corporate learning culture. Employees are provided training on quality culture to ensure personnel have a clear understanding of Mylan's commitment to quality. Mylan also provides a regulatory intelligence program that provides all Mylan personnel access to current global regulations, publications, and industry trends.

Mylan provides procedural and GMP training for all personnel whose duties are in any way associated with the manufacturing, packaging, processing, holding, or testing of products or whose duties require them to enter manufacturing areas or laboratories, as well as any other personnel whose activities could affect the quality of the product. Personnel working in areas where contamination is a hazard, such as clean areas, sterile areas or areas where highly active, toxic, infectious, or sensitizing materials are handled, are given additional specific training.

Training in cGMP is conducted by qualified individuals to assure that employees remain familiar with the specific cGMP requirements applicable to them.

 Our Global Operations Training program ensures that role-specific and periodic cGMP training programs are compliant with regulatory requirements both regionally and globally. cGMP training is conducted on an annual basis in accordance with regulatory requirements. In addition to training on the theory and practice of cGMP, Mylan utilizes a curriculum-based approach to ensure all analysts, operators, and other personnel are fully trained based upon their defined job descriptions and assigned duties. The curricula are specifically designed for each job description.

Supplier quality training is reviewed as part of the supplier selection due diligence process. In addition, throughout the business relationship, supplier employee quality training is reviewed as part of the routine GMP audits.

#### Quality Monitoring in Our Operations

Our program relies primarily on oversight by a specially trained team of internal global experts, augmented and supported by independent third parties. Mylan's global internal audit program is a key component of Mylan's oversight and monitoring of the quality performance across our network. The internal audits are designed to proactively evaluate compliance against the GQM/ GQP and global cGMP regulations.

- Internal sites are required to provide appropriate corrective and preventative actions in response to any observations with agreed upon timelines for implementation.
- Dedicated audit leads are assigned to quality operations within each vertical to participate in all internal audits within that vertical. There is collaboration with site and vertical leadership to develop more robust processes and re-evaluate existing processes from risk stand point and develop appropriate risk mitigation mechanisms. Internal audits are performed on an annual basis for each production site.
- Quality Council programs at each site oversee and monitor key performance indicators, track quality incidents, identify trends and have the authority to escalate incidents to senior quality leadership.

In 2019, we streamlined the global internal audit program to include expedited timelines for issuance of observations and increased site leadership engagement to ensure immediate remediation of identified observations. We further increased focus on global investigations oversight, third-party management, and surveillance across Mylan sites.

- We have expedited the internal audit process by augmenting the program to mimic the U.S. FDA 483 process. Our stringent policy requires internal sites to develop mandated corrective actions within 15 business days and to implement them within 90 days. These CAPA are submitted to Mylan's Global CAPA Management team for review and approval. Furthermore, any CAPA from critical and/or major observations are verified by the Global Operations Audit Team.
- In 2019, Mylan worked with global industry experts to further develop competency in deviations and corrective and preventive action (CAPA) management, focusing on triage<sup>1</sup>, procedures and root cause analysis techniques.

#### **Quality Risk Assessment**

Proactive risk assessment is central to our approach to ensuring quality. We apply the principles outlined in the Quality Management and Quality Risk Management guidelines<sup>2</sup> by the ICH: the ICH Q9 Quality Risk Management, as well as those in ICH Q10 Pharmaceutical Quality System.

## **Ensuring a High Quality Supply Chain**

To help ensure the integrity of our supply chain, external suppliers and third parties are taken through a rigorous Business Contract Review and Approval/Supply Network Committee (BCRA/SNC) approval process prior to being engaged for the supply of an active pharmaceutical ingredient (API) or a drug product. As part of this process, a contractual agreement called a Quality Technical Agreement (QTA) may be implemented that specifically details Mylan's expectations and the right to perform regular on-site audits to ensure compliance with regulations and Mylan's expectations, notification of health authority inspections and outcomes, and access to all records related to the supplied products.

- Mylan's Global Operations Audit program for supplier management includes risk-based assessment scoring of external suppliers based upon current health authority regulatory compliance, dosage form, supplier type, date of last Mylan conducted audit, audit history and severity of observations. The risk scores further facilitate audit prioritization and the supply chain decision-making process.
- To support some external suppliers in meeting quality standards, Mylan has
  implemented a program that places Mylan Quality personnel in person at the
  site of a supplier to engage, monitor, and mentor the site team and foster quality
  compliance. Improvements are assessed as part of the review of manufacturing
  and packaging of each batch prior to release. This program has been successful in
  educating and improving compliance of our external manufacturers and ensuring
  quality product is produced and released.

- Mylan conducts routine audits to assess the strength and performance of the QMS.
   Frequency is based upon cyclical audit requirement by facility type, historical regulatory inspection performance, and key product launches.
  - In 2019, 656 GMP, 83 GCP audits as well as 16 PV audits were conducted by Mylan's global Quality team at our facilities and suppliers.

External contractors and suppliers approved for business with Mylan are recorded in an internal global database which encompasses a mixture of third-party manufacturers (sterile and non-sterile), third-party packagers, third-party laboratories, distribution centers, miscellaneous service providers, API Suppliers (sterile and non-sterile), excipient suppliers, and packaging component suppliers.

#### **Working with Health Authorities**

We constantly review our products, processes and facilities throughout our network and work closely with external health authorities to ensure transparency with emerging information, including shortages, adverse event reporting of other manufacturers' products, development of new scientific and testing criteria and evolving regulatory and manufacturing expectations everywhere we operate. We continuously learn from these interactions as scientific, technology and regulatory expectations continue to evolve.

- The health authority inspections provide extensive external certification of Mylan sites and Mylan's suppliers and provide authorization for further production and marketing.
- Regarding Mylan's active FDA Warning Letters from 2018 and 2019, we are making progress according to plan to resolve the identified non-conformities.
- In 2019, 92 health authority inspections were conducted across Mylan's facilities.

Notable International Health Authority Inspections in 2019 include:			
AGES – Austria	ANSM - France	ANVISA – Brazil	
ASL – Italy	CDSCO – India	Danish Medicines Agency (DKMA) – Denmark	
DQS-MED - Germany	Drug Control Administration (DCA) – India	Drug Enforcement Administration (DEA) – USA	
FAMPH – Belgium	FDA – Ghana	FDA – USA	
Finnish Medicines Agency (FMA/Fimea) – Finland	Fukui Prefecture Health Authority – Japan	GIF – Poland	
Health Canada - Canada	HPRA – Ireland	Infarmed (NAMHP) – Portugal	

<sup>1</sup>A process used by companies to speed up workflows for projects under tight deadlines. <sup>2</sup>ICH Quality Guidelines

Notable International Health Authority Inspections in 2019 include:				
Kanton Zug Health Authority – Switzerland	Medicine Control Authority (MCAZ) – Zimbabwe	MHRA – United Kingdom		
Ministry of Food and Drug Safety (MFDS/KFDA) – South Korea	Ministry of Health – Belarus	Ministry of Industry and Trade of the Russian Federation – Russia		
National Agency for Medicines and Medical Devices (NAMMA/ ANMDM) – Romania	National Drug Authority (NDA)  – Uganda	National Organization for Medicines (NOM/EOF) – Greece		
Pharmaceuticals and Medical Devices Agency (PMDA) – Japan	Pharmacy and Poisons Board (PPB) – Kenya	Regierungspräsidium Darmstadt – Germany		
SOLNA STAD - Sweden	TFDA – Taiwan	TMDA – Tanzania		
World Health Organization (WHO				

#### **Patient and Product Safety**

Our PV system, coupled with a global policy on product safety, guides Mylan's approach to ensure patient care and safety in relation to the use of our marketed products. In line with applicable global legislation, we have a cross functional team of medical and scientific professionals that support a global PV system that reports our risk and benefit assessments to global health authorities. Mylan's Corporate Product Safety Committee, chaired by the Global Head of Product Safety & Risk Management and the European Economic Area-Qualified Person for PV provides a forum for the periodic and ad hoc evaluation of newly emerging safety information regarding our products.

 In 2019, Mylan submitted about 250,000 individual case safety reports and more than 1,600 aggregate reports.

As part of developing Mylan's PV system and being compliant with evolving regulations, we began implementing the new international standard for transmitting adverse event reports, as per the ICH E2B R3 reporting requirements. This entailed upgrading the existing Global Safety Database followed by full validations against the global PV safety reporting requirements. Our standard operating procedures were updated to reflect the newly implemented processes and all personnel involved in these processes have now been fully trained.

Potential safety signals are assessed and evaluated through our corporate safety governance structure and new information is communicated in a timely manner to healthcare professionals, patients and health authorities. Mylan currently has more than 300 risk management plans and associated interventional measures designed, where required, to ensure all of Mylan's products are used safely and effectively. As part of Mylan's PV system, the benefit risk profile of all products are monitored and assessed for safety impact on an ongoing basis.

Mylan's PV System includes standard operating procedures for managerial responsibility and standardized processing for all activities. Key activities are monitored for performance and compliance against standards, targets and thresholds. The system is subject to both internal and external audits and inspections by regulatory authorities from around the world. Mylan's compliance and deviation monitoring mechanisms are in place for any observations resulting from audits and inspections to ensure they are thoroughly analyzed for root cause and impact addressed. As appropriate, corrective and preventive actions which are tracked until their effective implementation for compliance with worldwide pharmacovigilance obligations are implemented. All processes are compliant with the EU Good Pharmacovigilance Practices (GVP) or, if applicable, stricter regulations anywhere in the world.

Our Product Safety & Risk department is a key component of our PV system and participates in all internal and external audits which are conducted regularly, along with ensuring that the personal health information of those participating in our clinical trials is carefully safeguarded.

In 2019, in addition to the 16 PV audits conducted by Mylan's global Quality team, there were 4 external audits by business partners and 4 PV inspections by national health authorities conducted at Mylan's facilities.

The internal audit schedule is based on a robust risk assessment with all PV system
processes and all stakeholders in scope. The frequency of the audits is normally 1 year
for global process service providers and around 3 years or shorter for affiliates based
on risk assessment.

We conduct training that complements Mylan's policy on PV Training Standards, which defines training curriculum, frequency, effectiveness measurements and documentation and other requirements. Employees who are part of Mylan's PV systems are assigned professional development training courses based on individual experience.

#### **Product Testing**

All ingredients used in Mylan products undergo testing to assure they meet registered specifications, and those that do not are rejected. For all products, as regulated by GMP, Mylan conducts extensive testing throughout the product lifecycle including raw material, intermediate, and finished product and post-distribution stability testing in compliance with the registered specifications as approved in each marketing authorization for the markets in which those products are provided.

#### **Product Recall Management**

Effective quality and product safety management systems are designed to detect potential risks and may result in product recalls as part of their design. These recalls are largely initiated by a pharmaceutical company as a precautionary measure in cases of possible or actual risk to the quality and safety of the product and/or risk to the patient. Though there is no harmonized international standard between countries on what constitutes a recall, Mylan has a global requirement that each Mylan site must maintain a written procedure to govern the recall of products based upon health authority regulatory requirements in the territories in which our products are provided. Additionally, a recall may often be performed out of an abundance of caution and therefore, can be a positive metric as it relates to the health of a Quality Management System (QMS).

## **Conducting Responsible Clinical Development**

Mylan is committed to conducting clinical trials in an ethical way and to promoting patient safety and protection of patient rights throughout the study lifecycle. The company's global program for clinical research and applicable standard operating procedures are designed to adhere to international best practice and GCP as defined in the Declaration of Helsinki and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) framework.

## Management and Oversight

Mylan's Head of Global Clinical Operations reports to the Head of Global Clinical Research & Medical Operations, who reports to Mylan's Chief Operating Officer (COO). The COO reports to Mylan's President and is part of the company's executive governance committee. Mylan's Global Quality Management System (QMS) is at the core of our clinical investigations. It includes procedures on internal processes associated with drug development as well as

processes for overseeing and auditing outsourced activities completed by our vendor partners. Dedicated independent members of Mylan's quality team conduct periodic assessments and audits. Any potential or actual incidents are managed through clear processes and escalated to senior management as appropriate.

In 2019, Mylan continued clinical research activities in the U.S., EU and Asia-Pacific region in diverse therapeutic areas such as oncology, diabetes and cystic fibrosis, to name a few. Mylan conducts clinical trials in many regions of the world as part of the process to eventually make treatments available to patients. To support the geographic expansion of Mylan's products and bring more products to more patients, the number of trials in new settings have increased. Regardless of where the trials are conducted and whether they are performed inhouse or by a qualified vendor party, Mylan's global standard operating procedures apply which aims to ensure the safety of the participants and the trial.

Mylan develops clinical study protocols for every clinical trial, which contain criteria and procedures for the conduct of each trial. The procedures for clinical site assessment are developed prior to the selection of investigators. Mylan maintains procedures that require ongoing evaluation of a clinical site's conduct of clinical studies from study initiation through study closeout. Mylan works with our partners to ensure that clinical investigators are carefully screened prior to being selected to participate in a clinical study and requires that clinical investigators conduct careful screening and selection of patients.

Mylan requires that all clinical studies receive review and approval with the institutional review board/independent Ethics Committee (IRB/EC). The review of each clinical study must be properly documented for every clinical site participating in a Mylan clinical study. Mylan reviews IRB/EC documentation for clinical sites that participate in a clinical study, ensuring that initial IRB/EC approval is thoroughly documented, and that ongoing review of each clinical site is underway.

Mylan's governance councils and quality committees oversee the conduct of clinical trials, including regular monitoring of ongoing trials, and partner with internal and external experts and investigational sites to promote patient safety and data integrity across our clinical development programs. In addition, we use quality councils, governance boards and independent data monitoring committees when appropriate to support quality, safety and protection of participants in our clinical development programs.

Mylan's standard operating procedures specifically address the requirements associated with the development of Investigator Brochures, Clinical Protocols and Informed Consent Forms

in order to adhere to global regulations. A cross-functional development and review process is incorporated into the procedures to ensure that experts in various functions have input into the design and approval of these documents. These documents provide clinical investigators with sufficient background on the investigational product to ensure the safety of research participants, that the clinical study is scientifically rigorous and that participants are wellinformed of the potential risks and benefits, study goals, procedures, and their critical role in clinical research. All employees that are involved in this aspect of a clinical trial undergo training for this purpose.

#### Informed Consent

Mylan's standard operating procedure governing the informed consent process is part of Mylan's QMS. It includes detailed procedures regarding the development, review, approval, implementation and confirmation of the accent/informed consent process for adult and pediatric trails. Informed consent documents are written in a manner that allows potential trial participants, regardless of reading skills and local language, the ability to make an informed decision that considers the potential risks and benefits of trial participation. Local independent ethics committees review and approve informed consent forms prior to patient participation in a clinical study. The clinical investigator ensures that patients understand the informed consent document prior to participation in the clinical study. As part of adhering to GCP, Mylan provides a direct contact line for the trial participants and information on how to escalate a report.

## Risk Management in Clinical Development

The QMS provides procedures on assessing risks associated with the various aspects of clinical development, such as study design, vendor selection, site selection and patient populations. The application of data analytics and access to increasingly better data enable more efficient management and oversight of clinical trials, focusing efforts on trials that are regarded as higher risk.

## **Trial Data Transparency**

Mylan's QMS addresses the publishing of Mylan clinical trial data in publicly accessible registries, as required by global regulations to promote transparency. Mylan publishes results of applicable clinical trials in publicly accessible registries such as www.clinicaltrials.gov. https://eudract.ema.europa.eu, and others.

As part of complying with the GCP, Mylan follows the FDAAA 801 and the Final Rule requirements for disclosure and results posting in the US and currently are following the EU Clinical Trial Directive (EC) No. 001/20/EC in the EU. When the Clinical Trial Regulation EU No. 536/2014 goes into effect, Mylan will comply with that regulation as well.

Mylan also maintains procedures that describe a scientifically rigorous process for the preparation and dissemination of scientific articles addressing the results of clinical trials in order to ensure that Health Care Providers (HCPs) and patients have access to information on the results of clinical trials.

#### **Animal Studies**

We do not conduct animal testing unless it is required by national regulation. Mylan is committed to the "3 R" approach (Replacement, Reduction and Refinement) with respect to ethical animal testing. Facilities performing animal testing on our behalf are required to comply with regional scientific procedures for laboratory animal science. These facilities use and/ or are approved by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC). Mylan's Global Operations Audit team performs regular audits on all parties to ensure compliance.

## **Promoting Product Security and Fighting Falsified** Medicine

To mitigate the risks from counterfeit products and protect the security of products and safety of patients, Mylan has a formal infrastructure to support oversight of product security and guide applicable efforts. Mylan's Product Integrity Coordination Committee consists of leaders from Compliance, Quality, Regulatory, Medical Affairs and Security. Mylan's Product Security team conducts an annual risk assessment of Mylan's portfolio to determine those products which may be at a higher risk for counterfeiting or diversion activity. This assessment takes into consideration several aspects including therapeutic category, dosage type, regulatory concerns, medical affairs concerns, and previous incident history. Products with higher levels of risk are given priority attention when it comes to analysis and market monitoring. We also use intelligence gathered from open market analysis to prioritize risk.

Mylan conducts internal investigations when there is suspicion of counterfeit or at-risk products and to support health authorities and law enforcement investigations. In addition to internal resources, we are also collaborating with external stakeholders such as online sales platforms, to ensure that counterfeit products avoid reaching the hands of our patients.

Mylan has a legal obligation to provide effective controls to guard against theft and diversion of controlled substances, and to design and operate a system to identify suspicious orders of controlled substances. At the same time, it is just as important to ensure an uninterrupted flow of medicine to the patient.

We have a cross-functional team including members from Compliance, Customer Relations, Controlled Substance Monitoring, Global Security, Distribution Center, Regulatory Legal, Regulatory Affairs, State Licensing and DEA that works to maintain and continuously enhance our strong programs designed to detect and prevent diversion within the supply chain, while assuring there is an uninterrupted flow of medication to our customers and patients across the globe.

Our suspicious order monitoring program holds some key components, including but not limited to:

- Experienced compliance team
- Data and analytical programs
- Know Your Customer (Due diligence) process
- · Education and training
- · On-going state and federal collaboration efforts

In addition, we also have a concentrated product diversion program, which encompass anonymous reporting mechanisms. Together with our suspicious order monitoring systems, it enables risk mitigation.

Quality and product safety expectations are intensifying globally from a variety of stakeholders. There is now a greater emphasis on companies taking responsibility for their supply chains, data integrity and quality assurance, priorities Mylan has embraced for many years.

Falsified medicine – medicine that is sold as authorized, authentic medicine but in fact contains ingredients of bad or toxic quality or dosage – continues to be an issue for the pharmaceutical industry. We have made significant investments in packaging and information technology to enhance product safety. By lowering the likelihood that falsified products will enter our supply chain, we are helping to ensure that the integrity of the product is not impacted and to enhance product safety as well as ensure access to high quality medicine. Mylan has global policies to govern validation, operations, serialization and product security. New and updated procedures have also been implemented across all manufacturing sites to drive consistency in packaging, management, master data and distribution of serialized product. Among these are processes to track and trace serialized products. An internal product safety group helps monitor the supply chain to help ensure it is not breached.

#### Serialization

Serialization is a process that helps companies obtain valuable information about the products they sell, and where they are made and shipped. It is fueled by myriad government regulations that require pharmaceutical companies to track their products along the supply chain and verify their authenticity. The goal of serialization is to ensure that medicines reaching consumers are not counterfeit, stolen or contaminated. Our quality, regulatory and serialization teams are also ensuring that serialization requirements for all countries are met. In doing so, Mylan works closely with industry groups such as the RxGPS Alliance, a group of multinational pharmaceutical supply chain stakeholders who have a common interest in advancing global alignment of drug serialization and tracing requirements to harmonize various standards among countries.

Serialization efforts include technology that uniquely numbers each pack and places a serialization mark, known as a 2D data matrix, on products. Mylan works internally and externally (with contract manufacturers) to ensure the products made for patients include these identifying marks. Eventually, this serialization process will leverage aggregation, which places a unique code on shippers of our products. This code will associate data for each individual product packaged within it, creating a parent-child relationship. Aggregation will facilitate the efficient flow of product in the supply chain. Once products are serialized, our work continues. Large amounts of data created by serialization must be managed, maintained and reported to authorities or trading partners. Before serialization, Mylan delivered quality products; in the future with serialization, quality products must be delivered with serialization data. This new way of doing business is driving a digital supply chain with emphasis on data integrity.

Our serialization project has involved installation of new equipment on our nearly 200 internal packaging lines, as well as work with hundreds of other manufacturers who are part of our supply chain.

Overall, 2019 was a stabilization year for serialization. With go-live dates of November 2018 for the U.S. Drug Supply Chain Security Act for product serialization and February 2019 for full implementation of the EU Falsified Medicine Directive (FMD), most of 2019 was focused on ramping up to full volume and stabilization of data flows from packaging to agency reporting. Master data cleansing was also a part of these stabilization efforts. In the EU, in addition to stabilization, the industry is also focusing on alerts. The Mylan alert team has developed analytic tools to filter alerts allowing the team to focus on root causes. The alert team works in collaboration with EU and national verification organizations, Medicines for Europe and solution providers to improve the alert management and reporting process.

## GSR MANAGEMENT DISCLOSURE & PERFORMANCE DATA

## **PATIENT HEALTH**

In 2020, Mylan will upgrade our serialization technology and continue to build out aggregation capabilities. In the EU, Mylan will focus on EU FMD alerts by engaging with various working groups, national agencies and applying additional advanced analytics with the goal of eliminating false positives. Mylan is working actively with national authorities and trade organizations on alerts within the EU system so that counterfeit and suspect products are properly identified. In the U.S., Mylan is focused on wholesaler returns verification and will commence testing in early 2020, in preparation for the end of enforcement discretion in November 2020.

Rest of World markets are also a focus as several key markets will enact serialization regulations in 2020.

Mylan actively monitors serialization regulations. In some instances, Mylan actively contributes in working groups to properly advance regulations that leverage global standards and requirements.

Examples of partners Mylan is working with to prevent counterfeiting include:

- Pharmaceutical Distribution Security Alliance (PDSA)
- The Alliance for Global Pharmaceutical Serialization (RxGPS)
- Association of Accessible Medicines (AAM) Supply Chain Taskforce
- Medicines for Europe EFPIA FMD Implementation Workshop
- Medicines for Europe FMD Alerts Working Group
- Medicines for Europe Anticounterfeit Steering Committee
- World Health Organization (WHO) Policy on Traceability Drafting Group
- Ireland Medicines Verification Organization (IMVO) Ireland Working Group

# Alerting stakeholders of potential or known risks associated with counterfeit products

In the U.S. and EU, suspect and counterfeit reporting systems are integral to the serialization regulations. Mylan is a member of the Pharmaceutical Security Institute (PSI), an organization of pharmaceutical manufacturers who collaborate and work together to share intelligence and information related to counterfeit and diverted pharmaceuticals. As part of the requirements to join PSI, Mylan is required to share information with PSI when counterfeit or diverted drugs are identified in the marketplace. This is in addition to any standard regulatory requirements that may be required.

We have also worked with our IP legal team to register trademarks with U.S. customs on products which may pose a risk to product security. Therefore, we will be notified in the event a questionable product is seized and could assist and respond appropriately.



## **Tackling Medicine Shortages**

Drug shortages are a challenge across the globe, with several causes that are in some instances very complex. Mylan is partnering with industry and governments to mitigate the impact on patients and to find solutions.

A fundamental factor is that the global demand for medicine is increasing significantly, putting extra pressure on manufacturers and supply chains to produce and supply products around the globe. At the same time, governments all over the world are facing the urgent need to manage spending amid increasingly tight budget constraints. Generic medicines have proven to be important in addressing both challenges: Generics lower the cost of medicine through increased competition in the marketplace with increased availability of treatments.

However, manufacturers are facing increasing regulatory complexity and costs, as well as, volatile demand and procurement models that often only look at lowest price. The combination can be difficult for industry to manage while pursuing the mission of access.

Tackling medicine shortages in a multi-source context requires a holistic approach that addresses both the root causes of the problem while also mitigating the impact when a shortage occurs. This includes addressing the economic causes of shortages to ensure market predictability and healthy competition and also improving regulatory efficiency and managing supply chain information.

Mylan has been actively engaged in drug shortage task forces initiated by health authorities to provide context of the supply chain dynamic that can be causing increased drug shortages and potential solutions to minimize shortages. We are also working with a variety of stakeholders to find a holistic and long-term solution to ensure continued supply and access to medicines.

Our supply chain security program has achieved Tier III status, the U.S. Customs and Border Protection's vision for the highest level of Customs - Trade Partnership Against Terrorism (C -TPAT). Tier III consists of those fully certified, validated C-TPAT partners who exceed the minimum standards and who have adopted C-TPAT best practices. Certified, validated C-TPAT importers using C-TPAT best security practices will be subject to relatively infrequent random inspections. Also, in the past (2014-2015), Mylan participated in the FDA Secure Supply Chain Pilot Program to contribute to the infrastructure and knowhow of secure supply chains.

## **Working for a Stable Supply of Medicine**

Our more than 40 manufacturing sites, combined with our global supply chain network and the facilities of the many partners with whom we collaborate on manufacturing, development, supply and logistics offer a worldwide, strategically located network of robust size and scope. Designed to reach more patients with more solutions when and where they need them, our regional supply sites are often in close proximity to our key markets and utilize real-time demand and supply data to leverage capabilities and create efficiency and flexibility across our operations.

Mylan's global supply chain is strategically designed to support the continued growth of our business and to protect the quality and safety of our diverse and increasingly complex products. Mylan has a Rapid Response Advanced Planning system, a state-of-the-art technology for supply chain planning and management. The program enables Mylan's many stakeholders to be closely connected across our global operations. It enables us to update and share information in real time, allowing us to leverage capacities and resources across key functions such as commercial, supply chain, warehousing and manufacturing. We look out over a 24-month horizon and plan supply to meet both the forecast and safety stock requirements to buffer against any potential fluctuations in demand or supply.

#### Distribution

Mylan's products make their way to patients through a variety of distribution channels and intermediaries, and local laws and customs give rise to different types of pharmaceutical markets (distribution, tender, substitution and prescription). As a result, the customers we work with to distribute our medications to patients number in the tens of thousands and include retail pharmacies; specialty pharmacies; wholesalers and distributors; payers, insurers and governments; and institutions such as hospitals, among others. We work closely with them and other important collaborators including NGOs, to help create better health for a better world by making our products available to patients in countries with varying degrees of income and resources.

#### **Examples of customers we serve**

Retail and Pharmacy



Institutions



Wholesalers/ Distributors



Payers. Insurers 8 Governments



Mail-Order/ E-commerce **Pharmacies** 



## **Supporting Appropriate Use of Medications**

Helping patients use medicines appropriately and adhere to prescriptions are crucial factors in improving health and well-being around the world. Mylan promotes the appropriate use of medicines and has several initiatives aimed at educating patients on medical conditions and ways to better manage them. We support online portals, websites and mobile applications that offer features ranging from tracking symptoms to reminding patients about refilling prescriptions. In addition, some digital solutions provide real-time guidance for healthcare providers to help them understand a patient's overall status.

Mylan supports individual dose dispensing across several European countries to increase therapeutic adherence and reduce medication errors, which is particularly important for elderly patients taking multiple medications. Dose dispensing not only helps an individual patient use medication correctly, it also assists caretakers and healthcare professionals in managing medications more effectively. In addition, Mylan continues to adapt its packaging to include symbols and pictograms that illustrate dosage schedules to make it easier for patients to take the right doses of medicines at the right time.

In 2019, Mylan introduced a special digital dosage calculator in Serbia for the pain medicine Brufen to assist with more accurately administering the suspension to children and launched several websites across Europe with comprehensive and consumer-friendly information about the product.

## **Human Relations Organization and Governance**

Mylan Human Relations supports the success of our employees and our business by being closely integrated at all levels of the organization. The HR function focuses on the priority areas of talent, organizational effectiveness and engagement. This framework allows for HR to deliver solutions with specificity at the regional and local levels, while still operating as a global community as it executes on its strategy.

The company's Chief Human Relations Officer reports to the CEO and is a member of the executive governance team. The function provides quarterly



updates to the Compensation Committee of the board and as needed to the full board. Global centers of excellence for Talent and Total Rewards actively define strategies and processes to support local markets. Regional HR leaders are accountable for helping to deploy global and local programs, working closely with our commercial and operational functions. Actionable insight and guidance is provided by HR Business Partners who are aligned at all levels by site and business.

HR support for employee services is provided through channels that include online portals and regional shared service centers. This results in high quality service center support as evidenced by an average employee satisfaction score of 4.7 on a five-point scale for 2019.

Mylan's workforce operates under one integrated HR information system, making it easier to review data holistically so we can make informed decisions that benefit the business and people everywhere. Efforts to further improve and standardize the employee experience are ongoing.

Our People	2017	2018	2019
Mylan's workforce			
Total workers	35,560	35,260	34,240
Employees	31,828	31,207	31,180
Temporary workers	3,732	4,053	3,060
Workforce by region			
North America	21.2%	19.0%	17.8%
Europe	27.4%	28.8%	27.6%
Rest of World	51.4%	52.2%	54.6%
Full-time equivalent employees by region			
North America	N/A	97.9%	99.9%
Europe	N/A	93.2%	93.8%
Rest of World	N/A	99.7%	99.8%
Globally	N/A	97.4%	98.2%
Workforce by function			
Operations	58.0%	57.1%	60.1%
Sales & Marketing	19.7%	21.0%	21.8%
General & Administrative	13.7%	13.7%	10.2%
Scientific Affairs	8.6%	8.2%	7.9%
Employees by age group			
Under 25	4.2%	4.0%	3.0%
25-34	37.4%	36.9%	35.5%
35-44	30.4%	30.8%	31.6%
45-54	19.1%	19.3%	20.1%
55-64	8.6%	8.6%	9.3%
65 and over	0.3%	0.4%	0.5%
Average age		39.4	34.6

All references to "workers" and "workforce" include employees and temporary workers.

Our People	20	017	20	)18	20	019
Employee gender by region <sup>1</sup>	Female	Male	Female	Male	Female	Male
North America	38.2%	61.8%	40.7%	59.3%	40.3%	59.7%
Europe	55.3%	44.7%	54.9%	45.1%	55.9%	44.1%
Rest of World <sup>2</sup>	11.9%	88.1%	13.8%	86.2%	15.9%	84.1%
Globally	28.3%	71.7%	29.8%	70.2%	31.3%	68.7%
Board diversity <sup>3</sup>	36.0%	64.0%	33.3%	66.7%	30.8%	69.2%
People managers by gender <sup>1</sup>	26.0%	74.0%	26.8%	73.2%	29.0%	71.0%
% of female employees responsible for managing people as a percentage of total female population <sup>1,4</sup>	14.0%		13.1%		14.6%	
% of male employees responsible for managing people as a percentage of total male population <sup>1,4</sup>	16.0%		15.8%		16.3%	
% of senior management that is female <sup>1</sup>	N/A		19.1%		18.0%	
Career progression by gender <sup>1</sup>						
% of female employees with career progression	N/A		N/A		22.8%	
% of male employees with career progression	N/A		N/A		22.3%	

<sup>&</sup>lt;sup>1</sup>Based on Mylan's HR information system.

#### **Diversity and Inclusion**

Mylan is committed to providing a positive, productive work environment that fosters inclusion, integrity, dignity and mutual respect for all. Embracing diverse viewpoints, thinking differently and challenging the status quo all support our ability to understand and meet patients' needs and set new standards in healthcare.

We are an equal opportunity employer that embraces what makes our people unique including, but not limited to, gender, sexual orientation, age, race/ethnicity, color, religion, national origin, physical or mental disability, or any other characteristic protected by law. Our global policy prohibiting discrimination, harassment and retaliation is reflected in our practices for managing talent, recruitment and hiring, transfers and promotions, training and compensation.

All employees are trained on Mylan's global Code of Business Conduct and Ethics that articulates Mylan's prohibitions against discrimination, harassment and retaliation. Employees who believe they have been subject to discrimination, harassment or retaliation can contact their supervisor or Human Relations representative, the Legal department or the Compliance department. They can also anonymously report any concerns using Mylan's Compliance Line.

## **Compensation and Benefits**

Mylan has a competitive compensation framework that provides salaries, wages and benefits aligned with the market. We also maintain short- and long-term incentive programs to effectively retain and reward talent. Incentive programs include performance-based annual cash bonuses, sales incentive compensation programs and equity grants, each designed to drive the continued development of our business, recognize achievements, create shareholder value and encourage behaviors expected of leaders. We actively manage our incentive programs to ensure they are dynamic enough to attract key talent, motivate people to accomplish our stated goals and objectives, and retain our employees, our most important asset.

During the annual compensation review process, Mylan managers evaluate employee performance and total compensation. We also overlay a review of gender to ensure employees in the same job and performance level are aligned to the same compensation package. We continue to ensure our compensation programs are competitive, consistent and incentivize the continued growth of our business.

<sup>&</sup>lt;sup>2</sup>64.2% made up of manufacturing employees in India.

<sup>&</sup>lt;sup>3</sup>Includes CEO Heather Bresch.

<sup>&</sup>lt;sup>4</sup>As a percentage of total female and male population, respectively.

All references to "workers" and "workforce" include employees and temporary workers.

## **Commitment to Managing Reorganizations Responsibly**

We are committed to managing reorganizations responsibly and communicating with employees to support them in times of change. We carefully assess employee expertise and skill sets to best position employees for the future. In 2019, Mylan enhanced its severance plan and global guidelines for impacted employees; this may include pay and benefit continuation as well as outplacement services and, where applicable, tuition assistance, retraining, job search allowances, moving allowances and other support.

Our People	2017	2018	2019
Employee turnover rate overall	17.8%	16.7%	10.7%
Voluntary overall			7.4%
Voluntary male <sup>1</sup>	N/A	8.3%	6.8%
Voluntary female <sup>1</sup>	N/A	8.9%	8.3%
Involuntary overall			2.2%
Involuntary male <sup>1</sup>	N/A	5.9%	1.6%
Involuntary female <sup>1</sup>	N/A	4.5%	2.0%
Other overall			1.1%
Other male <sup>1,2</sup>	N/A	2.3%	0.9%
Other female <sup>1,2</sup>	N/A	1.7%	1.3%
New hire rate overall	N/A	15.3%	11.2%
By male <sup>1</sup>	N/A	14.1%	10.2%
By female <sup>1</sup>	N/A	16.3%	12.6%
Average male employee tenure <sup>1</sup>	N/A	7.5 years	7.4 years
Average female employee tenure <sup>1</sup>	N/A	8.4 years	7.6 years
% employee engagement <sup>3</sup>	N/A	70%	71%

<sup>&</sup>lt;sup>1</sup>Based on Mylan's HR information system.

#### **Recognizing Freedom of Association**

Mylan recognizes and respects the rights of employees to have access to representation and collective bargaining. Around the world, we have a significant number of employees in manufacturing, commercial and corporate functions who are represented and covered by collective agreements. We engage with employee representatives globally and strive to maintain productive relationships with them as we do with all employees.

#### **Involving Employee Representatives**

We are committed to informing and consulting with employee representatives and routinely obtain their input, particularly regarding the work environment, employee safety and providing wages, benefits, and terms and conditions of employment aligned with the market.

## **Health and Safety Management Information**

## Management System and Governance

Our Global Health and Safety Policy and Global EHS Management System along with our technical standards provide a foundation for our work to create a safe and healthy workplace for Mylan employees, contractors and visitors. They guide us in our efforts to implement industry best practices and are key in ensuring we meet health and safety compliance requirements.

The Global EHS Management System is implemented at all operational sites worldwide. Our technical standards establish global minimum operating requirements for a variety of safety and environmental activities and topics including emergency response, work at height, bloodborne pathogens, electrical safety, hazardous energy, fire prevention, personal protective equipment, machine guarding and chemical storage, among others. Our technical standards program includes a five-year continuous improvement strategy that began in 2015. Each year, we conduct self-assessments on the standards to ensure alignment with the five-year plan.

Implementing these standards helps ensure compliance with applicable regulations in the countries where we operate, in addition to filling gaps where certain regulations may not exist.

<sup>&</sup>lt;sup>2</sup>Reasons include retirement, mutual agreement and others.

<sup>&</sup>lt;sup>3</sup>See Employee Health: 2019 Highlights.

The Global EHS Function is integrated across the organization and reports into the Chief Operating Officer (COO), who oversees EHS performance and initiatives. These efforts include health and safety programs such as industrial hygiene, occupational toxicology, emergency preparedness, facility design guidance, risk assessment, incident management, personal protective equipment, confined space, chemical management and serious and fatal incident prevention. Vertical leadership are also key members of our EHS Governance Committee. Their commitment and drive within their respected businesses is a key component of our EHS programs and performance. The COO reports to the president and is a member of Mylan's executive governance committee.

We aim to continuously improve our safety programs and to keep safety at front of mind. One way we do this is through Safety Excellence programs that we have launched at many of our facilities in Europe, India and North America. These programs include safety leadership workshops with site senior leaders and supervisors where topics such as the role of leadership and safety excellence leadership behaviors are discussed.

We are committed to being transparent on Mylan's health and safety efforts and performance. We report externally on an annual basis and communicate both internally and externally throughout the year to promote general awareness on health and safety issues as well as to inform about Mylan's work.

We strive to keep our facilities resilient and secure, especially those vulnerable to natural disaster. Risk engineering and emergency response planning are vital components of our EHS programs and across our operations we have well-trained emergency response teams and technology to respond quickly should an incident occur. When a natural disaster strikes, Mylan and its partners will endeavor to protect our sites and resume production as soon as possible, always keeping safety top of mind.

Health and Safety*	2017	2018	2019
Number of sites certified to OHSAS 18001	5	12	12
Number of sites certified to the British Safety Council	N/A	2	4

\*Data as of January 2020. Information may be restated due to the availability of additional data. Includes data for manufacturing, packaging, research and development, and distribution sites based on direct operational control.

#### Internal and External Audits

We routinely conduct assessments and internal and external on-site audits, including reviews of our data, systems and programs. The frequency of assessments and audits is established per a risk-based approach which incorporates EHS performance trends, facility design, regulatory compliance and other EHS program requirements.

For more details on Mylan's EHS management and governance, please see p. 52-53 and 70.

#### Proactive Incident Prevention

Our Incident Prevention Opportunity (IPO) program promotes the identification and correction of potential hazards. It enables employees to report safety concerns and encourages every employee to participate by setting site and department specific targets and goals each year that are monitored monthly.

Our Serious and Fatal Incident Prevention (SFIP) Program further identifies the potential for incidents to be more severe and ensures that we proactively address these possible conditions and outcomes with effective controls.

Health and Safety*	2017	2018	2019
Total Recordable Incident Rate (Recordable cases per 200,000 hours worked)	0.51	0.52	0.67
Total DART Incident Rate <sup>1</sup> (DART cases per 200,000 hours worked)	0.39	0.39	0.47
Total Lost Time Incident Rate (Lost time cases per 200,000 hours worked)	0.29	0.34	0.41
Work-related fatalities	0	0	0

<sup>1</sup>Annual incident rates are calculated per 100 employees. Assuming the average employee works 2,000 hours per year, 100 employees equals 200,000 hours worked.

<sup>\*</sup>Data as of January 2020. Information may be restated due to the availability of additional data. Includes data for manufacturing, packaging, research & development, and distribution sites based on direct operational control.

## GSR MANAGEMENT DISCLOSURE & PERFORMANCE DATA

## **EMPLOYEE HEALTH**

#### Safety Training

Through extensive training, Mylan's employees and contractors receive information and knowledge to assist them in performing activities safely and without harm to themselves or others. We require employees to take safety courses based on job responsibilities and regulatory requirements including topics such as emergency response, hazardous energy, confined space, powered industrial trucks, personal protective equipment and many others. Global or regional training campaigns are also conducted and have included topics such as fall prevention, incident prevention opportunities and situational awareness. Training is administered through our online MyUniversity platform as electronic learning, classroom training or practical training and are translated to local or native languages.

## **Contractor Safety**

Our commitment to safety extends beyond our employees. Across all locations, protecting the safety of our contractors and visitors is part of our EHS management system. Contractors and visitors are covered by EHS policies and procedures applicable at their specific sites. We have established guidelines and expectations for contractor safety management, prescreening and training. Contractor safety performance is tracked and included in our contractor safety metrics. We have not experienced any work-related fatalities among contractors since 2017.



## **ENVIRONMENTAL HEALTH**

#### **Management System and Governance**

Mylan's Global Environmental Stewardship Policy and Global Environmental, Health and Safety (EHS) Management System provide the foundation of Mylan's comprehensive work to reduce our environmental impact and help ensure that we meet environmental compliance requirements.

The EHS Management System builds on a four step cycle for continuous improvement: PLAN: IMPLEMENT: CHECK: IMPROVE: **Identify how we** Close the gaps. Measure or **Decide how** confirm that we can get can close gaps between where we we have better. are versus where succeeded. we should be.

The Global EHS Management System supports systematic identification of continuous improvement opportunities and industry best practices. Mylan's technical standards establish global minimum operating requirements for a variety of environmental and safety activities. Implementing these standards helps ensure compliance with applicable regulations in the countries and locations where we operate, in addition to filling gaps where certain regulations may not exist.

Our environmental programs, guidelines and technical standards cover waste management, wastewater management and discharge, incident management, chemical management, facility design, ozone depleting substances, air emissions, pharmaceuticals in the environment and environmental hazard assessments of products. Forty-five percent of Mylan's manufacturing sites are ISO 14001 certified for environmental management systems.

External Certifications	2017	2018	2019
Number of sites certified to ISO 14001	12	20	20
Number of sites certified to ISO 50001	7	8	8

#### Governance, Monitoring and Reporting

The Global EHS function is integrated across the organization and reports into the chief operating officer (COO). The COO reports to the president and chairs Mylan's EHS Governance Committee, overseeing programs, performance and initiatives, including environmental programs on energy, climate change and water management. The Global EHS team oversees the data collection, management and monitoring of climate-related activities through a global database and system. The team also monitors relevant environmental issues and opportunities - including climate change impacts - and reports relevant information to the COO and the Global Social Responsibility Advisory Committee.

Working collaboratively with operations and business unit leaders, the Global EHS team leverages technical expertise across multiple disciplines, including environmental management, health and safety, industrial hygiene, occupational toxicology, training, process safety and information technology (IT) systems.

We monitor and track many elements of our environmental performance allowing us to manage data, oversee results and identify risks and opportunities. Our IT systems include custom built databases, tools, dashboards and reports that drive EHS compliance and identification of key trends, opportunities and information.

We are committed to being transparent regarding Mylan's environmental efforts and performance. We report externally on an annual basis and communicate throughout the year to contribute to general awareness on environmental issues as well as to inform internal and external stakeholders about Mylan's work.

90% of Mylan's API manufacturing facilities<sup>1</sup> are ISO 14001 certified for environmental management systems.



<sup>1</sup>All API manufacturing facilities in India are certified.

## **ENVIRONMENTAL HEALTH**

#### **Internal and External EHS Audits**

Internal assessment and audit are core components of our EHS management approach and serve several purposes, including identifying risks to employees, the environment and the company; fostering continuous improvement; and promoting knowledge transfer. We routinely conduct assessments and on-site audits, including reviews of our systems, procedures, programs and data. Every Mylan site has a 1- to 5-year auditing frequency, with the actual schedule established per a risk-based approach which incorporates EHS performance trends, facility design, regulatory compliance and other EHS program requirements. In case of observations, the audited facility develops and implements action plans, which are tracked by the EHS function.

#### **Environmental Risk Management**

Environmental risks are evaluated for our products, processes and facilities. Through Mylan policies, the Global EHS Management System and technical standards, each site is required to utilize EHS risk assessments using a formal process to analyze environmental, health and safety risks and maintain continuous improvement plans. These plans include improving water management, increasing recycling efforts, mitigating climate change risks including management of ozone depleting substances, GHG emission, improving energy efficiencies and data management.

Other environmental risk management areas of focus include:

- Waste
- Water scarcity analysis using World Resource Institute Aqueduct tool
- · Wastewater treatment and discharge
- · Regulated air emissions
- GHG emissions and climate change
- Pharmaceuticals in the environment including antimicrobial resistance

We have completed more than 683 environmental hazard assessments of our products since implementing the program in 2016. The evaluation criteria were based on sources such as the U.S. Environmental Protection Agency, the Stockholm County Council, European Medicines Agency, the European Union's CLP (classification, labeling and packaging) standards and third-party experts. Products and compounds are compared to the criteria and classified as representing low, moderate or high risk. Assessments then are compared to internal guidance documents to determine appropriate levels of control within our manufacturing processes.

#### **GHG Emissions and Climate Change**

Protecting our employees, our products, our facilities and the environment has always been a long-standing priority for Mylan. As part of those efforts, we also evaluate regulatory and physical risks and opportunities associated with the effect of climate change across our operations. Mylan's ability to maintain operations and support the local community in Puerto Rico when Hurricane Maria hit in 2017 is a relevant example of effective planning, risk mitigation, and building resilience from the impact of extreme weather.

We are committed to responsible energy and greenhouse gas (GHG) emissions management through strategic energy sourcing and on-going improvement of our energy management systems. We continuously evaluate and identify opportunities to lower our energy demand usage and decrease GHG emissions. Examples of efforts undertaken are the phase out of ozone depleting substances and energy sourcing and reliability for manufacturing.

Individual operation sites have set various shortterm strategies that support Mylan's overall commitment and several initiatives have been implemented throughout the organization. These include: increasing the purchase of renewable energy, utilizing alternative fuel sources and fugitive emission reductions, and phasing out

Our renewable energy consumption grew by **25% in 2019** 

ozone depleting substances (as required). Several of our operations sites are systematically looking for ways to improve energy management and efficiencies by implementing energy efficiency and emissions reduction projects.

We performed energy assessments at key operational locations in 2019 to identify energy efficiency and emission reduction opportunities to help drive additional targets and initiatives with respect to energy and climate change. Mylan will continue to evaluate its baseline data outlined herein to identify potential opportunities and strategies that may have a direct or indirect impact on climate change. We will continue to conduct energy assessments at key locations in 2020.

We recognize the need for relevant information on management of risks and opportunities related to climate change through the enhanced disclosure recommendations from the Task Force on Climate-related Financial Disclosures (TCFD). We have begun incorporating its recommendations into our energy and climate change strategies and disclosures. We have reported to the CDP climate program since 2017. Our current CDP climate change score is B. Mylan's climate data as reported to the CDP is subject to third party verification.

# **ENVIRONMENTAL HEALTH**

Energy Purchased (GWh)	2015	2016	2017	2018	2019
Total energy use	548	559	572	592	611
Renewable energy sources	16	36	56	72	90
Non-renewable energy sources	532	522	516	520	521
Energy Intensity Ratio (GWh / million USD revenue)	0.05	0.05	0.05	0.06	0.05

Greenhouse Gas Emissions (thousand tonnes CO <sub>2</sub> e)	2015	2016	2017	2018	2019
Total GHG Emissions	653	661	670	676	670
Scope 1 GHG emissions	299	315	326	325	316
Scope 2 GHG emissions (market-based)	354	346	344	351	354
Total GHG Emissions Intensity Ratio (tonnes CO₂e / million USD revenue)	69	60	56	59	58

- . 2015 is base year for total GHG emissions.
- Scope 2 emissions are based on market-based method.
- Includes data for manufacturing, packaging, research and development, and distribution sites based on direct operational control.
- Data from 2015–2019 have been adjusted to account for acquisitions and divestitures, in accordance with the methodology prescribed in the WRI Greenhouse Gas Protocol.
- Excludes data and sources from commercial, employee travel and commutes, small administrative/lab sites, small warehouses and other business transportation.
- Data do not include process emissions from manufacturing or emissions from insignificant sources such as welding
  gases, lab gases, fire extinguishers, dry ice, etc.
- All solvent combustion in air pollution control devices in Scope 1 emissions is treated as ethanol.
- 2019 GHG emissions data has been verified by a third-party to a reasonable level of assurance using the methodology of
  the GHG Protocol issued by the World Business Council for Sustainable Development and the World Resources Institute.
   The 2017 and 2018 data was previously verified by a third-party but has since been restated due to acquisitions and new
  and more accurate emission factors and has not been reverified at this time.
- Where applicable, prior year data have been restated due to improved data quality.
- Some data include estimates and may be updated at a later time when more accurate data are available.

### **Waste Management**

Mylan's companywide EHS waste management standards, along with industry regulations, govern specific handling, treatment, storage and disposal of all waste. Each waste stream is reviewed and evaluated to determine the best treatment method. Waste treatment methods are selected based on the type of waste treatment requirements and internal standards. We strive to use recycling, reuse and energy recovery options, including waste-to-energy facilities, cement kilns and fuel-blending facilities where possible to treat waste. Converting waste to energy contributes to the substitution of fossil fuel at these facilities. We strive to reduce or eliminate the amount of waste sent to landfills and are looking to continue to increase our number of zero landfill sites.

Waste Management (thousand tonnes)	2017	2018	2019	
Total waste generated	56	58	69	
Hazardous waste	36	39	45	
Non-hazardous waste	19	19	24	
Percentage of waste recycled or sent to energy recovery	68%	70%	74%	
Significant spills	0	0	0	

- Where applicable, prior year data have been restated due to improved data quality.
- Includes data for manufacturing, packaging, research and development, and distribution sites based on direct operational control
- Some data include estimates and may be updated at a later time when more accurate data is available.

# **ENVIRONMENTAL HEALTH**

#### **Water and Wastewater Management**

Responsible wastewater treatment is a key topic for our industry and Mylan is committed to leading by example. We recognize that water is a scarce resource in some of the communities where we live and work and are committed to working proactively to protect water resources and continue to improve our water management practices and systems. We perform water risk assessments and all operations sites are periodically audited to ensure compliance with local regulatory and internal standards.

Our teams work to identify opportunities to improve water management within our highly regulated industry, which often presents many restrictions and limitations related to items such as reuse of water in production.

The production requirements of our operations, coupled with local regulations and infrastructure, guide the type of water and wastewater management applied. We implement appropriate controls, technologies and containment strategies to minimize the amount of potential pharmaceutical ingredients that could enter the wastewater.

All wastewater streams are then treated to ensure compliance with local regulatory and internal standards. In India, multiple sites apply zero liquid discharge (ZLD) technology that eliminates wastewater discharge. To ensure our ZLD-equipped plants continue to operate effectively, we conducted independent, third-party assessments on some ZLD facilities and will continue to conduct additional evaluations. Mylan maintains all applicable permits and authorizations for wastewater discharge with governing authorities and complies with all local discharge limits.

Water Use & Discharge Summary (thousand m³)	2015	2016	2017	2018	2019
Total water supply	3,130	3,162	3,270	3,306	3,263
Total water recycled and reused	133	370	424	467	475
Total water discharged	1,717	1,650	1,650	1,592	1,573
Sites with zero liquid discharge (ZLD) systems	6	7	9	10	10

- Where applicable, prior year data have been restated due to improved data quality.
- Includes data for manufacturing, packaging, research and development, and distribution sites based on direct operational control.
- · Total wastewater discharge includes sanitary/domestic sewage.
- Some data include estimates and may be updated at a later time when more accurate data is available.

Water Use by Sources (thousand m³)	2015	2016	2017	2018	2019
Municipal / Third party	3,050	3,082	3,174	3,186	3,155
On-site borewell	73	73	89	112	100
Rainwater	2	2	2	2	1
Other	5	5	5	5	3

- Where applicable, prior year data have been restated due to improved data quality.
- Includes data for manufacturing, packaging, research and development, and distribution sites based on direct operational control.
- Some data include estimates and may be updated at a later time when more accurate data is available.
- 2019 Water Supply and Wastewater Discharge were verified by a third-party to a reasonable level of assurance.

# **ENVIRONMENTAL HEALTH**

#### **Air Emissions**

Mylan is committed to reducing emissions to the air and we use the companywide EHS program to identify, track, monitor and control relevant emissions, per industry standards and regulatory guidelines. Our facilities are equipped with air emission control devices as required to manage regulated air pollutants. Examples include high-efficiency dust collection, HEPA filtration, electrostatic precipitation, primary and secondary condensers, multi-stage filtration and recirculation systems, process scrubber technology and regenerative thermal oxidizers.

#### **Pharmaceuticals in the Environment**

The primary pathways for pharmaceuticals entering the environment from human use are by normal patient excretion and improper disposal of medicine by consumers¹ in addition to the use of pharmaceuticals in agriculture. A significantly smaller contribution stems from emissions resulting from the pharmaceutical manufacturing process, which is attributed to less than 2% of the overall contribution.²

While gaps remain in the scientific link between pharmaceuticals in the environment and human health risk, we are committed to reducing pharmaceuticals discharged from our manufacturing operations. Mylan's approach to addressing and minimizing the potential impact of pharmaceuticals in the environment (PiE) from our own manufacturing is based on a wide range of activities and governance:

- · Risk and Impact Evaluation
- Risk Reduction and Control
- Engagement and Policy

Mylan is an active participant in the Eco-Pharmaco-Stewardship Inter-Association Initiative, a cross-industry collaboration on environmental issues such as responsible effluent management and appropriate disposal of unused medicine.

#### **Mitigating Antimicrobial Resistance**

Antimicrobial resistance (AMR) continues to be a major global public health problem negatively impacting the lives of hundreds of thousands each year. Mitigating AMR requires a holistic approach and multi-stakeholder cooperation to address issues such as universal access to antimicrobials, appropriate use, surveillance, stewardship and responsible manufacturing.

Mylan is a signatory to the Davos Declaration on combating AMR and a founding board member of the AMR Industry Alliance. Mylan has adopted the AMR Industry Alliance Common Antibiotic Manufacturing Framework and is an active member of its manufacturing working group.

The Common Antibiotic Manufacturing Framework provides a common methodology to assess potential risk from antibiotic discharges and take appropriate action when necessary.<sup>3</sup>

As part of this commitment, the AMR Industry Alliance developed a unified approach to establishing discharge targets for antibiotic manufacturing, referred to as Predicted No Effect Concentrations (PNECs) for use in environmental risk assessments of antibiotics. Mylan conducts risk assessments using the discharge target values published by the AMR Industry Alliance to assess potential risk of release of antibiotics from production, and if needed, takes corrective action.

More information on Mylan's efforts to mitigate AMR are presented on p. 37 and 43.

External initiatives that Mylan engages on regarding manufacturing and the environment:

- CDP
- AMR Industry Alliance
  - Board Member
  - Manufacturing Work Group
- Medicines for Europe
  - Environment, Health and Safety Work Group
- Inter Association Initiative on Pharmaceutical in the Environment (IAI PiE) Task Force
- BDMA

# **Risk Governance and Management**

Mylan is committed to operating ethically and with integrity and seeks to apply a holistic, enterprise-wide approach to risk management. We are subject to a number of risks inherent in the complex and rapidly changing environment in which we operate including, but not limited to, global operations, environment and social responsibility. Mylan's management and employees implement and administer risk management processes to identify material risks to our business.¹ Management assesses, monitors and manages those risks, all while maintaining flexibility in how we operate. To further embed risk management and compliance into our culture, Mylan implements policies and procedures and trains employees on how to comply with them. Mylan's board and its committees rigorously review key risks with management.

Mylan's enterprise risk management (ERM) and business continuity process and associated programs are supported by multiple functional areas including Global Internal Audit, Global Information Technology, Global Compliance, Global EHS, Global Security, Finance, Quality and Product Safety. Global Internal Audit and Global Compliance report into the Audit and Compliance Committees of the Board of Directors, respectively. Other stakeholders support the company's ERM activities as needed. These programs are designed to ensure that Mylan is prepared to respond to a variety of events that may adversely impact the business, such as legal or regulatory matters, supply disruptions, environmental events, including those related to climate change (e.g., flooding, drought, extreme temperatures, severe storms) or other significant business interruptions.

By embedding our ERM processes into the company's strategic planning process, we optimize our ability to identify and manage risks, while also identifying and leveraging opportunities. We conduct a periodic enterprise risk assessment, which is a significant component of the company's ERM program, to identify key and emerging risks. Our GSR priority assessment informs the periodic enterprise risk assessment and ultimately the company's risk profile.

As we continue to expand into new geographies — potentially with increased risk profiles — safeguarding integrity in business conduct and our assets is critical. Mylan has well-established procedures to identify, manage and monitor risks as part of expanding our business. More specifically, risks associated with expansion into new geographies is an element of our ERM program which is leveraged by Global Internal Audit in determining areas over which it will perform audits.

### **Mylan's Balanced Pricing Model**

Given our long history of providing high quality, low-cost generic pharmaceuticals, we are uniquely situated to work with customers, payors, non-governmental organizations (NGOs) and other partners to find solutions and meet the needs of the patients and families we serve. We also have a strong track record of developing new products, particularly complex and difficult-to-formulate medicines, and are committed to making safe, high quality products accessible to patients across all income levels.

With respect to Mylan's generic portfolio, we offer thousands of affordable products at a fraction of the price of the equivalent innovator medicine. The prices of these drugs often decrease every year. As negotiations occur with our customers or as we participate in tender programs or public-private partnerships around the globe, we will continue to do so based on an assessment of supply, demand, patient need and the affordability of our products, especially as it relates to the equivalent brand name drug.

As it pertains to our brand portfolio, Mylan is committed to pricing its products in a way that reflects their value to patients and providers. Mylan will endeavor to not raise the prices of our branded products more than once per calendar year; however, we will assess the prices of our products on a regular basis. Our aim is for any price increases to be reasonable in light of relevant factors, including current economic indicators and the state of the overall business marketplace. The socioeconomic conditions within each market where Mylan does business are inherently considered as part of our generic and brand pricing assessments, as is the importance of sustaining our ability to consistently provide patients in each market with the quality products needed. This is reflected in our ability to provide ~62 billion doses of medicine in 2019 to more than 165 countries and territories around the world at an average price of 18 cents per dose.

In connection with its oversight responsibilities, the Compliance Committee of Mylan's Board of Directors reviews global compliance-related policies relating to pricing and commercialization of the company's products and services.

<sup>&</sup>lt;sup>1</sup>For more detailed information about the risks and uncertainties associated with our business activities, see our <u>Annual Report</u> on Form 10-K for the year ended Dec. 31, 2019.

#### **Responsible Marketing and Promotion**

Mylan employees often interact with members of the healthcare community as part of their efforts to educate on the appropriate use and efficacy of Mylan's products. These interactions are important and fundamental to increasing patient access but may bring elevated risk. Mylan's Standards for Interactions with Healthcare Professionals (HCPs) instruct employees on proper behavior when engaging with HCPs. The guidelines are grounded in Mylan's companywide standards and take into consideration local laws and regulations. Any member of Mylan's workforce who interacts with HCPs are trained on the standards and are required to comply with them. Additionally, employees are trained in Mylan's Code of Business Conduct and Ethics, which also addresses interactions with healthcare professionals. A summary of Mylan's Standards for Interactions with Healthcare Professionals is provided on Mylan.com.

We have well established global, regional and local policies and procedures that inform employees on appropriate interactions with the healthcare community and requirements

pertaining to drug promotion and ethical marketing. Risk assessments and employee training are key components of each. We strive to comply with regulations and adhere to ethical standards set forth by Mylan and industry associations.

Mylan's Global Policy for the Marketing and Advertising Review Council requires the establishment of local procedures to ensure that all promotional materials and other commercial communications are reviewed and approved internally by appropriate subject matter experts. Promotional activities and materials must never involve promotion of drugs for off-label indications, uses, doses or populations.

- The goal of the local review procedures implemented under the policy is to ensure that all materials and communications intended for promotional or commercial purposes are accurate, truthful, medically and scientifically sound, not misleading, and compliant with all applicable marketing, legal, regulatory and medical requirements and company policies.
- These local procedures include clear review processes, risk assessments and compliance monitoring as part of Mylan's compliance program and enterprise risk management.

#### **Cultivating Good Conduct and Compliance**

Everyone at Mylan – and those acting on our behalf – is personally responsible and accountable for the company's reputation and dedication to doing business with integrity. Mylan works to provide the adequate procedures and guidance to support that individual responsibility. Mylan's Chief Administrative and Compliance Officer has the operational responsibility to ensure Mylan's Corporate Compliance Program is effective and robust and directs its day-to-day implementation. To ensure broad perspectives and independence in the Compliance Office, Mylan's Chief Administrative and Compliance Officer reports to the board's Compliance Committee and the Chief Executive Officer.

Mylan's Compliance department is organized by operating regions and Global Centers of Excellence (CoE) to efficiently support the organization. The Compliance department and Mylan's Global Compliance Program are structured in a manner consistent with the Office of Inspector General of the U.S. Department of Health and Human Services (OIG) Resource Guide for Measuring Compliance Program Effectiveness. The Chief Administrative and Compliance Officer leads three global CoE that support Mylan's global operating regions and business. A senior leader manages each respective CoE, which focuses on policies, training and communications, global compliance risk, audit and due diligence, and investigations. The Compliance department oversees the development, maintenance and recordkeeping of global policies and procedures, and performs various periodic and needs-based operational audits throughout the year, often in conjunction with Internal Audit.

#### In 2019, Mylan:

- ✓ Updated our:
  - o Global Policy on Records and Information Management, as well as implemented a unified, companywide records retention schedule;
  - o Insider Trading Policy;
  - o Privacy Policies (Data Protection Policy, Fair Processing Notice, and the Privacy Shield Policy) to ensure Brexit readiness.
- Continued to review the definition of compliance-related matters in consideration of relevant guidance to assess risk more effectively.
- ✓ Continued to enhance Mylan's employee data protection and privacy policies, processes and training to ensure compliance with the evolving Global Data Protection Regulation (GDPR) and other privacy regulatory requirements.
- Evaluated the U.S. Department of Justice (DOJ) Criminal Division's updated guidance against Mylan's Program elements using a risk-based approach to clarify and streamline requirements wherever possible.
- ✓ Successfully completed all year-two requirements under Mylan Inc. and Mylan Specialty L.P.'s Corporate Integrity Agreement with the OIG and submitted our annual report.

Mylan's Code of Business Conduct and Ethics outlines guiding principles on how employees and those working on our behalf should conduct themselves. It also informs on policies and standards while providing high-level guidance on critical areas of the company's business operations. We require and provide dedicated training on anti-corruption, fair competition and Mylan's Standards for Interactions with Healthcare Providers (for employees with relevant job responsibilities). Vendors that may interact with government officials on our behalf also receive anti-corruption training. Depending on their role, part-time employees and contractors are required to take subsets of the trainings listed above.

We require employees to certify that they have read, understand and agree to comply with Mylan's Code of Business Conduct and Ethics.

**GOAL**: Maintain and communicate Mylan's Code of Business Conduct and Ethics and train at least 90% of employees on the Code of Business Conduct and Ethics



**GOAL**: Maintain and communicate Mylan's Anti-Corruption Policy and train at least 90% of Mylan's applicable employees on the company's Anti-Corruption Policy and related laws



**GOAL**: Maintain and communicate Mylan's Fair Competition Policy and train at least 90% of Mylan's applicable employees on the company's Fair Competition Policy





# GSR MANAGEMENT DISCLOSURE & PERFORMANCE DATA

#### RESPONDING TO THE U.S. OPIOID EPIDEMIC

Throughout our history, Mylan has worked to help address some of the world's most pressing public health issues, and the opioid crisis facing Americans is no exception. Mylan recognizes the scope of this issue and is committed to doing its part to help in the nationwide fight against opioid addiction, abuse and misuse.

Mylan's opioid products in the U.S. are almost exclusively generics, which typically are automatically substituted for branded products by pharmacies. Mylan's generic opioid products consist of pain relievers that provide important therapeutic benefits for appropriate patient populations when prescribed and used responsibly, and products indicated for the treatment of opioid dependence (such as generic suboxone). Mylan also has a single branded opioid product, ULTIVA™, an intravenous anesthesia medication administered exclusively and directly by healthcare providers in surgery-center, in-patient settings.

Mylan has a very limited role in the U.S. opioid market and is not promoting or marketing these products. We supply on average approximately 1% of opioid-containing drug products sold, according to IQVIA data for 2016-2019. Furthermore, Mylan's total net sales of opioid-containing drugs in the U.S. made up only 2.5% of its sales in 2019. Excluding Mylan's generic suboxone and its branded Ultiva product, Mylan's sales of opioid-containing products only make up approximately 1% of Mylan's sales in the U.S.

Despite its limited role in the United States opioid market, Mylan - given its leadership position within the generic pharmaceutical industry and its extensive scientific capabilities – is committed to finding ways to be part of the long-term solution to this challenge. Indeed – as noted above – Mylan offers products that are used to treat opioid dependence. Moreover, in 2014, Mylan launched a generic, injectable, single-vial version of naloxone, a product that is indicated for the complete or partial reversal of opioid depression induced by natural and synthetic opioids, as well as for diagnosis of suspected or known acute opioid overdosage. In the summer of 2016, the Company expanded its offerings of this important therapy by launching a multiple-vial version of naloxone.

The <u>U.S. Surgeon General</u>, the <u>Department of Health and Human Services</u>, and the <u>Food and Drug Administration</u> have each publicly recognized naloxone as a critical tool for individuals, families, first responders and communities to help reduce opioid overdose deaths. Mylan stands ready to continue to provide reliable supply of and access to naloxone, including through a commitment to develop an auto-injector drug-device combination naloxone product.

In 2019, Mylan launched a generic, combination product of buprenorphine and naloxone (generic suboxone) - which is indicated for the treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support. When the FDA announced its approval of Mylan's generic suboxone sublingual film product, then-FDA Commissioner Gottlieb stated: "The FDA is taking new steps to advance the development of improved treatments for opioid use disorder, and to make sure these medicines are accessible to patients who need them. That includes . . . facilitating market entry of generic versions of approved drugs to help ensure broader access." (See press release here).

Mylan's commitment to being part of the long-term solution to the opioids crisis goes beyond the product offerings described above. As yet another example of Mylan's commitment, Mylan's Board of Directors published a report in 2019 to provide Mylan's stakeholders with additional information regarding, among other things, the steps that Mylan has taken and will continue to take to ensure the safe and approved use of its opioid-based medications. The full report can be accessed on Mylan's website.

### **Fighting Corruption and Promoting Fair Competition**

Mylan's anti-corruption program is based on the elements of the U.S. Department of Justice (DOJ) and Securities and Exchange Commission (SEC) Resource Guide to the U.S. Foreign Corrupt Practices Act; the U.K. Ministry of Justice Bribery Act 2010 Guidance; and the Organisation for Economic Cooperation and Development's Good Practice Guidance on Internal Controls, Ethics and Compliance, as well as the local laws where we operate.

Our Global Anti-Corruption Policy strictly forbids bribery and corruption in any form anywhere we do business. The policy defines bribery and corruption, including facilitation payments, which are strictly prohibited even where permitted under law. Mylan has monitoring and auditing procedures in place to identify and deter such payments. We reassess our anti-corruption program periodically and make updates as warranted. Training is provided for employees as applicable to educate them on what constitutes bribery, corruption and facilitation payments as well as where the risk exposure may be elevated. The training also guides employees on what constitutes acceptable behavior and how to seek support when questions arise. Mylan provides several options for personnel to submit concerns or seek guidance: either online or via telephone, mail, or email. They are very welcome to reach out to their manager, specific departments, their local Compliance Officer, or use the Compliance Line.

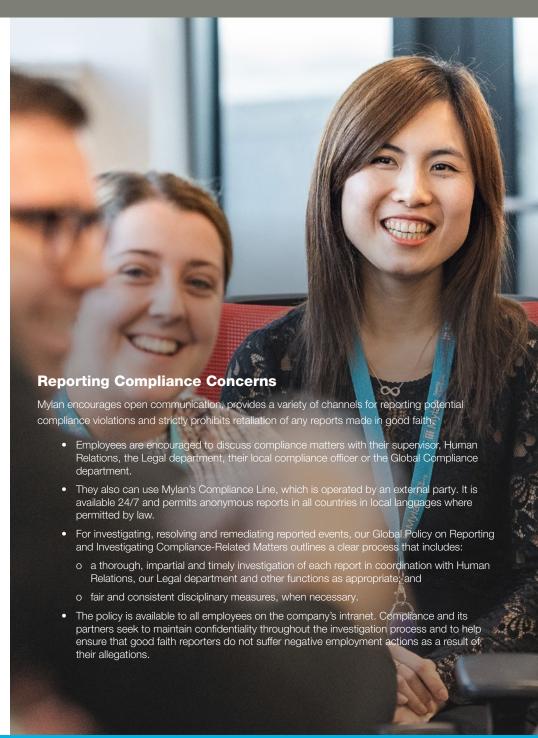
As part of these procedures, Mylan monitors any case of suspected conflict of interest. Each identified case is investigated and if concerns remain after investigation, actions are taken as appropriate.

As part of Mylan's ERM program, Internal Audit assesses anti-corruption and anti-fraud management over entities throughout the world from a corruption risk perspective. Size (the number of people and sales volume) and a country's ranking in the Transparency International Corruption Perception Index (CPI) are key to informing the risk profile of an entity. Entities identified as higher risk along with those of strategic importance to Mylan are a particular focus.

Further, we monitor business activities that are deemed an elevated risk – such as HCP interactions – through established internal processes and controls. Our procedures also address our business partners.

# **Ensuring Good Conduct in External Partnerships**

External partners sometimes act as intermediaries on our behalf or in settings where special skills or expertise are required. Given their role, it's essential these partners comply with Mylan's ethical and anti-corruption standards and act with good judgment.



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The Compliance department identifies business partner categories that may carry higher inherent corruption and/or reputational risk. These partners, noted during the business contract drafting and approval process, are subject to a risk review depending on the aggregated risk factors assigned, as well as other Mylan compliance standards. Those identified as having an elevated risk are subject to a due diligence process including investigation and clarification of discovered legal, civil and reputational allegations or convictions. Anti-corruption language, right-to-audit clauses and ethical expectations are included in Mylan contracts. Any potentially high-risk business partners undergo a due diligence review and annual monitoring. Mylan also has a process to train business partners who interact with government officials on Mylan's behalf on our Anti-Corruption Policy and procedures.

#### **Building Sustainable Supplier Relations**

Mylan relies on its suppliers to deliver high quality, affordable and accessible products to our customers and ultimately to patients. Keeping good relationships helps not only to reduce risk and ensure a high quality and reliable supply but also helps us partner on our sustainability practices.

### Mitigating Supply Chain Risk

We have a robust due diligence process to better understand supplier capabilities and ensure their ability to comply with regulatory and compliance requirements. Our source selection process is governed by a Source Review Committee (SRC), comprised of a cross-functional internal team from science, legal and sourcing.

This team also manages the selection of API suppliers. Mylan has a proactive risk mitigation program to protect the supply chain by strengthening supply agreements with current suppliers and qualifying alternate suppliers. We monitor performance through reporting, trend analysis and consistent business review meetings. Mylan has established escalation and cross-functional issue management processes. Sourcing teams routinely meet with suppliers to review the performance of supply and create action plans to address identified risks. For our third-party finished dose formulation suppliers, we maintain an end-to-end product management approach.

# Advancing Sustainable Sourcing

Mylan's vision for sustainable sourcing is to identify, evaluate and select goods and services across the globe that are strategically aligned with Mylan's commitment to social and environmental responsibilities by fostering long-term relationships with suppliers that embrace sustainability practices.

In 2019, we expanded Mylan's Council for Sustainable Sourcing to include members from Global Environmental Health and Safety, Commercial and Global Social Responsibility - in addition to the members of Mylan's sourcing leadership team. This group will continue to:

- Provide guidance and direction for sustainable sourcing;
- · Develop policy, practice and reporting of sustainable sourcing;
- Instill the culture of sustainable sourcing within sourcing teams;
- · Set annual sustainable sourcing goals and objectives;
- Develop, implement and monitor compliance of sustainable sourcing policies and metrics: and
- · Continue to expand our focus on Green Procurement.

This year the sourcing team also executed on commitments to support Mylan's larger GSR efforts by continuing to build-out our sustainable sourcing program focused on the following areas:

- Supplier Code of Conduct
- Source selection
- Partnerships and communication
- Supplier diversity
- Monitoring, reporting and continues improvements

The Supplier Code of Conduct provides guidance for doing business with Mylan and supports our efforts to inspire, engage in and foster better health for a better world. Further, it aims to enhance supplier relationships and helps mitigate supply chain risks. We are committed to continually working to improve our operations and expect our business partners to promote similar principles throughout their supply chain. In 2019 we:

- Inhanced internal training on the Supplier Code of Conduct which is required to be completed on a biannual basis and relaunched training for employees with purchasing, supply chain and sourcing roles.
- ✓ Continued to build-out our Supplier Relationship Management program focusing on preferred suppliers to mitigate risk and enhance long term strategic partnerships. Our Supplier Relationship Management program aims to minimize risks by consolidating our supply base with preferred suppliers.
- ✓ Promoted Mylan's Supplier Code of Conduct and reiterated Mylan's commitment to sustainability in supplier meetings.
- Enhanced our standard Supply Agreement template to include sustainability language and clearer language on the right to request supporting documentation, the right to audit and implementation of corrective action plans as needed. These templates are expected to be rolled out in 2020 and apply to new agreements.

✓ As part of our commitment to the AMR Industry Alliance Common Antibiotic Manufacturing Framework to promote responsible practices, we have notified our active antibiotic suppliers of our alignment with this Framework and expectations of our suppliers.

Source selection is a key sourcing process to ensure vendors meet Mylan's minimum standards for quality, cost and compliance. In 2019, we expanded our focus in this area to include:

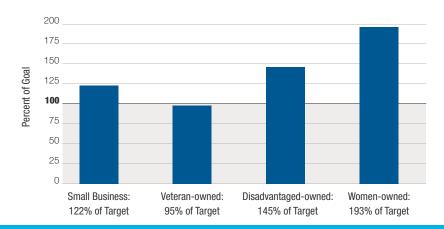
- ✓ Implementing an enhanced practice to consider sustainability as part of the source selection process for direct materials. The new practice aims to verify that the supplier has established a sustainability program and has set sustainability goals.
- ✓ Requiring vendor acknowledgement of Mylan's Supplier Code of Conduct prior to new source selection or renewal of existing Supply Agreements for Direct Materials.

~100% of direct material suppliers received Mylan's Supplier Code of Conduct and ~70% of indirect suppliers received Mylan's Supplier Code of Conduct.

#### Promoting Supplier Diversity in the U.S.

Our U.S. Supplier Diversity Program supports small businesses and businesses owned by minorities, women and veterans. We have worked to build relationships with small and diverse businesses. Mylan's senior management meets guarterly to review goals and achievements related to supplier diversity and when necessary, recommend corrective action. We train our sourcing employees on this initiative, monitor spending and provide access to databases featuring diverse suppliers to promote these businesses.

✓ Achieved our overall 2019 target for small business spend, with most areas exceeding expectations:



# **Respecting Human Rights** As a signatory to the U.N. Global Compact, we recognize our responsibility to respect a opportunity to support and promote the protection of human rights within and beyond our own operations. We do so through our core business, how we conduct ourselves and in our dealings with partners. Mylan is committed to the 10 principles of the U.N. Global Compact and respects the International Bill of Human Rights and the Fundamental Conventions of the International Labour Organization. Mylan's global policies and associated procedures, employee and partner training and due diligence are the foundation of our work to mitigate the risk of human rights violations. Topics critical to addressing human rights are addressed through a variety of Mylan policies including our Code of Business Conduct and Ethics, Supplier Code of Conduct, Mylan's Policy Statement Regarding Slavery and Human Trafficking, Global Policy on Combatting Human Trafficking in Persons and our companywide EHS program. Examples include: • freedom of association: • legal compliance; prohibition of trafficking of persons; prohibition of forced and child labor; handling of identity and immigration documents; wages; working hours; safety in the workplace; · preventing harassment; and · recruitment practices.

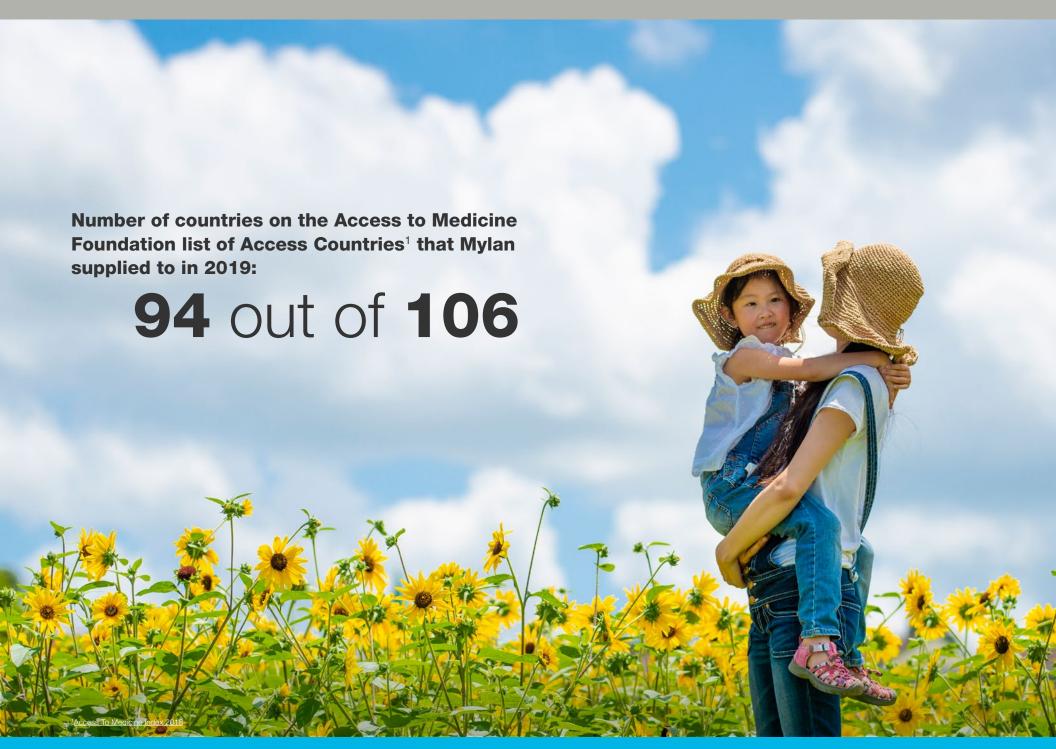
# PRODUCTS ON THE WHO PREQUALIFICATION LIST

Int	ernational nonproprietary name (INN)	Dosage form & strength
	Daclatasvir (dihydrochloride)	Tablet, Film-coated 30mg
	Daclatasvir (dihydrochloride)	Tablet, Film-coated 60mg
	Sofosbuvir	Tablet, Film-coated 400mg
	Abacavir (sulfate)	Tablet 300mg
	Abacavir (sulfate)	Tablet 60mg
	Abacavir (sulfate)/Lamivudine	Tablet, Film-coated 600mg/300mg
	Abacavir (sulfate)/Lamivudine	Tablet 60mg/30mg
	Abacavir (sulfate)/Lamivudine/ Zidovudine	Tablet 300mg/150mg/300mg
	Atazanavir (sulfate)	Capsules, hard 150mg
	Atazanavir (sulfate)	Capsules, hard 300mg
	Atazanavir (sulfate)/Ritonavir	Tablet, Film-coated 300mg/100mg
	Darunavir (ethanolate)	Tablet, Film-coated 800mg
	Darunavir (ethanolate)	Tablet, Film-coated 600mg
	Dolutegravir (Sodium)	Tablet, Film-coated 50mg
	Dolutegravir (Sodium)/Lamivudine/ Tenofovir disoproxil fumarate	Tablet, Film-coated 50mg/300mg/300mg
	Dolutegravir (Sodium)/Lamivudine/ Tenofovir disoproxil fumarate	Tablet, Film-coated 50mg/300mg/300mg
	Efavirenz	Tablet, Film-coated 600mg
	Efavirenz	Tablet 50mg
	Efavirenz	Tablet, Film-coated 100mg
	Efavirenz	Tablet 200mg
	Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate	Tablet 600mg/200mg/300mg
	Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate	Tablet, Film-coated 600mg/200mg/300mg
	Efavirenz/Lamivudine/Tenofovir disoproxil fumarate	Tablet, Film-coated 600mg/300mg/300mg
	Efavirenz/Lamivudine/Tenofovir disoproxil fumarate	Tablet, Film-coated 400mg/300mg/300mg

Intern	ational nonproprietary name (INN)	Dosage form & strength		
_	favirenz/Lamivudine/Tenofovir isoproxil fumarate	Tablet, Film-coated 400mg/300mg/300mg		
E	mtricitabine	Capsules, hard 200mg		
	mtricitabine/Tenofovir disoproxil ımarate	Tablet, Film-coated 200mg/300mg		
F	lucytosine	Tablet 500mg		
Li	amivudine	Tablet 300mg		
Li	amivudine/Nevirapine/Zidovudine	Tablet, Film-coated 150mg/200mg/300mg		
L	amivudine/Nevirapine/Zidovudine	Tablet, Dispersible 30mg/50mg/60mg		
L	amivudine/Stavudine	Tablet 150mg/30mg		
L	amivudine/Stavudine	Tablet 150mg/40mg		
	amivudine/Tenofovir disoproxil ımarate	Tablet, Film-coated 300mg/300mg		
	amivudine/Tenofovir disoproxil ımarate	Tablet 300mg/300mg		
L	amivudine/Zidovudine	Tablet, Film-coated 150mg/300mg		
Li	amivudine/Zidovudine	Tablet, Film-coated 30mg/60mg		
L	amivudine/Zidovudine	Tablet, Dispersible 30mg/60mg		
L	opinavir/Ritonavir	Tablet, Film-coated 200mg/50mg		
L	opinavir/Ritonavir	Tablet, Film-coated 100mg/25mg		
N	evirapine	Tablet 200mg		
R	itonavir	Tablet, Film-coated 100mg		
R	itonavir	Tablet, Film-coated 25mg		
S	ulfamethoxazole/Trimethoprim	Tablet 400mg/80mg		
S	ulfamethoxazole/Trimethoprim	Tablet 800mg/160mg		
Te	enofovir disoproxil fumarate	Tablet, Film-coated 300mg		
Z	idovudine	Tablet 300mg		
Z	idovudine	Tablet, Film-coated 100mg		

Int	ernational nonproprietary	name (INN)	Dosage form & strength		
	Oseltamivir (phosphate)		Capsules,	hard	d 30mg
	Oseltamivir (phosphate)		Capsules, hard 45mg		d 45mg
	Oseltamivir (phosphate)		Capsules,	hard	d 75mg
	Artemether/Lumefantrin	ne	Tablet 20r	mg/1	20mg
	Artemether/Lumefantrin	ne	Tablet 40r	mg/2	240mg
	Desogestrel/Ethinylestra	adiol	Tablet 0.1	50m	ng/0.030mg
	Desogestrel/Ethinylestra Placebo	adiol +			thinylestradiol Tablet let 150mcg/30mcg
	Ethinylestradiol/Levono	rgestrel	Tablet, Su 30mcg/15	0	
	Ethinylestradiol/Levonorgestrel + Ferrous Fumarate		Ethinylestradiol/Levonorgestrel Tablet + Placebo (Ferrous Fumarate Tablet) 30mcg/150mcg + 75mg		bo (Ferrous Fumarate
	Ethinylestradiol/Levonorgestrel + Placebo		Tablet, Sugar coated 30mcg/150mcg + 0mg		
	Levonorgestrel		Tablet 1.5mg		
	Levonorgestrel		Tablet 750mcg		
	Levonorgestrel		Tablet, Film-coated 0.03mg		
	Medroxyprogesterone a	icetate	Suspension for injection 150mg		
	Capreomycin (sulfate)		Powder for solution for injection 1g		
	Cycloserine		Capsules, hard 250mg		
	Isoniazid		Tablet 300mg		
	Isoniazid		Tablet 100mg		
	Kanamycin (sulfate)		Solution for	or inj	ection 500mg/2ml
	Kanamycin (sulfate)		Solution for	or inj	ection 1000mg/3ml
	Moxifloxacin (hydrochlo	ride)	Tablet, Fili	m-cc	pated 400mg
		Hepatitis			Malaria
	Therapeutic Area Legend	HIV/AIDS			Reproductive Health
	Alea Leyellu	Influenze			Tuberculosis

Source: WHO Pre-Qualification list as per 2/26/20



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# COLLABORATING TO IMPROVE ACCESS

Below are examples of our collaborations. This list is not all-inclusive.

COM	MERCE	ORGANIZ	ATIONS

AMCHAM (American Chamber of Commerce in India)

BCIU (Business Council for International Understanding)

FICCI (Federation of Indian Chambers of Commerce & Industry)

PHARMEXICIL (Pharmaceutical Export Promotion Council)

USIBC (US-India Business Council)

USISPF (US India Strategic Partnership Forum)

U.S. Chamber of Commerce

#### GLOBAL PUBLIC HEALTH ORGANIZATIONS

U.N. Global Compact

WHO (World Health Organization)

#### INDUSTRY ASSOCIATIONS

Association for Accessible Medicines (AAM)

AESEG (Spanish Generic Medicines Association)

APOGEN (Portuguese Association of Generic Medicines and Biosimilars)

AssoGenerici (Italy Association of Generic Medicines and Biosimilars)

BAH (German Medicines Manufacturers' Association)

BG Pharma (Bulgarian Generic Pharmaceutical Association)

BGMA (British Generic Manufacturers Association)

Biosimilars Canada

**BioWV** 

BOGIN (Netherlands Association for Biosimilars and Generic Medicines)

CGPA (Canadian Generic Pharmaceutical Association)

Council for Healthcare and Pharma Front

EFPIA (European Federation of Pharmaceutical Industries and Associations)

FGL (The Association for Generic Pharmaceuticals and Biosimilar.Sweden)

FOPE (Federation of Pharma Entrepreneurs)

GEMME (French Generics-maker Association)

GBMA (Australia Generic and Biosimilar Medicines Association)

GENAS (Slovak Association of Generic producers)

IDMA (Indian Drug manufacturers Association)

IGBA (International Generic and Biosimilar

IGL (Danish Generic and Biosimilars Medicines Industry Association)

Ihoken (Medical Insurance System Study Conference)

Medicines Association)

JBSA (Japan Biosimilar Association)

JGA (Japan Generic Medicines Association)

KPIA (Kansai Pharmaceutical Industries Association)

Läkemedelsindustriföreningen (Trade association for the research-based pharmaceutical industry, Sweden)

Medaxes (Belgian Association of Pharmaceutical Companies)

Medicines for Europe

Medicines for Ireland

Neprofarm (Dutch association representing manufacturers of self-care products)

NZSMI - New Zealand Self-Medication Industry

Pharmig (Austrian Pharmaceutical Industry Association)

Prognerika (German Generic Association)

SINFAR (Union of Pharmacists)

SINDUSFARMA (Industry Syndicate of Pharmaceutical Products in the State of São Paulo)

Yueki (The Intravenous Solutions Society)

# COLLABORATING TO IMPROVE ACCESS

#### INFECTIOUS DISEASE PARTNERS

Bill & Melinda Gates Foundation

Clinton Health Access Initiative

GBCHealth

Gilead Sciences

Global Fund to Fight AIDS, TB, and Malaria

International AIDS Society

**OPTIMIZE** Consortium

Otsuka

**UNAIDS** 

President's Emergency Plan for AIDS Relief (PEPFAR)

St. Stephen's AIDS Trust

TB Alliance

UNITAID

ViiV Healthcare

#### MANUFACTURING ASSOCIATIONS

Alliance for Global Pharmaceutical Serialization

AMR Industry Alliance

CII (Confederation of Indian Industries)

FPMAJ (Federation of Pharmaceutical Manufacturer's Association of Japan)

Global Pharmaceutical Manufacturing Leadership Forum

ISPE (International Society for Pharmaceutical Engineering)

JPMA (Japan Pharmaceutical Manufacturers Association)

Pharmaceutical Manufacturers Association of Tokyo (PMAT)

#### PRODUCT ASSOCIATIONS

AESGP (Association of the European Self Medication Industry)

Consumer Healthcare Products Association

Consumer Health Products Canada

WSMI (World Self Medication Industry)

#### PROFESSIONAL ORGANIZATIONS

Canadian Association of Professionals in Regulatory Affairs (CAPRA)

Regulatory Affairs Professional Society (RAPS)

PPSWG (Pharmaceutical Product Stewardship Working Group)

#### **QUALITY AND REGULATORY AUTHORITIES**

Drug Information Association (DIA)

FDA Alumni Association and Alliance for Stronger FDA

FDA Drug Shortage Committee

GDUFA/BSUFA Implementation/Negotiation Teams

ICH (International Council for Harmonisation)

IPAC-RS (International Pharmaceutical Aerosol Consortium on Regulation & Science)

Pharmaceutical Science Group (PSG)

PDA (Parenteral Drug Association)

USP (United States Pharmacopeia)

#### WOMEN'S HEALTH

United Nations Population Fund

U.N. Every Woman Every Child initiative

# Mylan has more than **40 manufacturing sites** in various locations around the world.<sup>1</sup>

REST OF WORLD	EUROPE	NORTH AMERICA
INDIA: Ahmedabad Aurangabad Bangalore Hosur Hyderabad Indore Jadcherla Jaggiahpeta Mumbai Nashik Sarigam Vizag  OTHER: Carole Park, Australia Johannesburg, South Africa Katsuyama, Japan Zambia, Africa	Chatillon, France Confienza, Italy Damastown, Ireland Dublin, Ireland Galway, Ireland Komarom, Hungary Merignac, France Meyzieu, France Troisdorf, Germany Warsaw, Poland	Somerset, N.J. Caguas, Puerto Rico Morgantown, W.Va. Rockford, III. San Antonio, Texas St. Albans, Vermont Sugar Land, Texas



# **Types of Mylan Products**

Biosimilar and insulin analogs
Respiratory
Complex sterile products
Dermatological and transdermals
Complex OSD
Modified-release dosage forms
OTC/parapharmaceuticals
High potency
Traditional generics

'As of publication, this report does not include one site already announced for closure. Some locations have more than one manufacturing site. Also represents packaging facilities.

# Participation in relevant patient assistance and government-sponsored healthcare or tender programs

Mylan provided patient assistance for 20 products in the U.S. in 2019; operates the Ashray program for Hep C and breast cancer patients in India and participates in various government-sponsored healthcare or tender programs around the world.

# **Managing Political Contributions Responsibly**

Mylan's Global Political Contributions and Activity Policy guides our approach to political contributions. It is overseen by the Compliance committee of the Mylan Board of Directors and applies to all company personnel. Only to the extent allowed by law, the company may directly contribute to political candidates and political organizations. This is relevant primarily for Mylan's U.S. subsidiaries and Mylan's Political Action Committee, a voluntary, nonpartisan, employeerun committee. Political contributions are made in accordance with U.S. campaign finance laws.

Mylan files a quarterly report of expenses associated with lobbying the federal government in accordance with the U.S. Lobbying Disclosure Act. That report can be found on the U.S. Senate Office of Public Records website or the U.S. House of Representatives Office of the Clerk website. Mylan's Political Action Committee also files monthly political contribution reports (FEC) with the U.S. government. Mylan relies on outside legal counsel to support these filings. Mylan's semiannual Political Contribution & Trade Association Memberships report is reviewed by the Board of Directors and made available on our website.

# **Honoring Our Commitment as a Publicly Traded Company**

Mylan N.V. is listed on the NASDAQ stock exchange in New York. Its corporate seat is Amsterdam, Netherlands, with its principal executive office located in Hatfield, Hertfordshire, England.

The global headquarters of the Mylan group is Canonsburg, Pennsylvania, U.S. It is at this location where the CEO and other executive officers of the group carry out the day-to-day conduct of our worldwide business

Mylan N.V. is managed and controlled under the oversight of the company's Board of Directors. Each director is elected annually by the company's shareholders pursuant to Dutch law and the company's Articles of Association. Certain of the directors' duties, rights and responsibilities are detailed in the company's Articles of Association, Board Rules and Corporate Governance Principles, among other governance documents. Mylan is subject to applicable rules, regulations and/or listing standards of the U.S. Securities and Exchange Commission, NASDAQ and the Dutch Corporate Governance Code, among other requirements.

# GRI 102: GENERAL DISCLOSURES\*

Disclosure	Description	Cross-Reference or Answer	SDG	UNGC Principle
Organizational Pro	file			
102-1	Name of the organization	Mylan N.V.		
102-2	Activities, brands, products, and services	2019 Form 10-K		
102-3	Location of headquarters	p. 87		
102-4	Location of operations	p. 87 2019 Form 10-K	8	
102-5	Ownership and legal form	p. 87 2019 Form 10-K		
102-6	Markets served	p. 16-24, 55-57 2019 Form 10-K	3	
102-7	Scale of the organization.	p. 5-7, 55-56, 66 2019 Form 10-K		
102-8	Information on employees and other workers	p. 66-67 A significant portion of Mylan's activities are performed by workers who are employees, and there are no significant variations in our employee figures annually.		6
102-9	Supply chain	p. 55-66, 81-82 2019 Form 10-K		
102-10	Significant changes to the organization and its supply chain	2019 Form 10-K		
102-11	Precautionary Principle or approach	p. 34-37, 53-54, 57-64, 71-75, 81-82		
102-12	External initiatives	p. 4, 9, 18-24, 37, 41-45, 47-51, 64, 75, 85-86		
102-13	Membership of associations	p. 37, 40, 42-45, 75, 85-86		

<sup>\*</sup>Mylan's 2019 Global Social Responsibility Progress Report applies the 2016 version of the GRI Standards; "2016" refers to the Standards issue date, not the date of information presented in this report.

Disclosure	Description	Cross-Reference or Answer	SDG	UNGC Principle
Strategy				
102-14	Statement from senior decision-maker	p. 8-9		
102-15	Key impacts, risks and opportunities	p. 8-11, 13-65, 68-82		
Ethics and Integri	ity			
102-16	Values, principles, standards, and norms of behavior	p. 2 Mylan Values	16	2, 5 & 10
102-17	Mechanisms for advice and concerns about ethics	p. 66, 77-78, 80		
Governance				
102-18	Governance structure	2019 Form 10-K		
102-20	Executive-level responsibility for economic, environmental and social topics	p. 8-11, 53-54, 68, 71, 76-77		
102-21	Consulting stakeholders on economic, environmental and social topics	p. 8-11, 30, 37, 39-45, 48, 51, 54, 58-59, 64, 75, 81-82		
102-22	Composition of the highest governance body and its committees	p. 53-54, 76 2019 Form 10-K Mylan.com/Leadership Mylan.com/corporategovernance		
Stakeholder Enga	agement			
102-40	List of stakeholder groups	Community Customers Employees Partners Patients Shareholders	8	
102-41	Collective bargaining agreements	p. 68 Mylan recognizes and respects the rights of employees to representation and collective bargaining. We currently do not keep company-wide records on the percentage of employees covered by collective bargaining agreements."		3
102-42	Identifying and selecting stakeholders	p. 10-11, 38-45, 54, 75-76		
102-43	Approach to stakeholder engagement	p. 10-11, 38-45, 54, 75-76		
102-44	Key topics and concerns raised	p. 10-11, 38-45, 54, 75-76		

<sup>\*</sup>Mylan's 2019 Global Social Responsibility Progress Report applies the 2016 version of the GRI Standards; "2016" refers to the Standards issue date, not the date of information presented in this report.

Disclosure	Description	Cross-Reference or Answer	SDG	UNGC Principle
Reporting Practic	ee			
102-45	Entities included in the consolidated financial statements	<u>2019 Form 10-K</u>		
102-46	Defining report content and topic Boundaries	We completed our first formal priority topic analysis in 2018 to confirm our GSR priorities based on the topics of highest importance to the company and key stakeholders. We identify where impacts occur for each priority topic in the Topic Boundary section (GRI 103) of the GRI Index.		
102-47	List of material topics	Topic Boundary section (GRI 103) of the GRI Index		
102-48	Restatements of information	Women with access to Mylan's contraceptives in 2017-2018, p. 57 GHG data per 2015-2018, p. 73		
102-49	Changes in reporting	None		
102-50	Reporting period	Calendar year 2019, Jan. 1 - Dec. 31		
102-51	Date of most recent report	4/3/19		
102-52	Reporting cycle	Annual		
102-53	Contact point for questions regarding the report	Should you have questions or feedback, please contact us at GSR@Mylan.com.		
102-54	Claims of reporting in accordance with the GRI Standards	Mylan's 2019 GSR Report is prepared in accordance with Global Reporting Initiative (GRI) Standards, core level.		
102-55	GRI content index	p. 88-96		
102-56	External assurance	Mylan's 2019 Global Social Responsibility Progress Report has not been assured by a third party. Mylan's reporting to the 2019 CDP Climate Change and Water Security Programs was verified by an external party.		

<sup>\*</sup>Mylan's 2019 Global Social Responsibility Report applies the 2016 version of the GRI Standards; "2016" refers to the Standards issue date, not the date of information presented in this report.

# GRI 103: TOPICS AND TOPIC BOUNDARIES\*

Mylan's Priority (Material) Topics	Management Approach Cross-Reference	Relevant External Entities
Economic		
GRI 203: Indirect Economic Impacts 2016	18-24, 38-45, 47-51, 55-65, 76	Communities, Customers, Patients
Environment		
GRI 301: Materials 2016	Environmental Stewardship Oversight and Compliance p. 57-62, 73-75, 81-82	Communities, Customers, Governments, Patients, Suppliers
Social		
GRI 402: Labor/Management Relations 2016	Oversight and Compliance p. 66, 68-70	Communities, Governments, Shareholders
GRI 404: Training and Education 2016	p. 31, 65	N/A
GRI 416: Customer Health and Safety 2016	p. 55-65	Communities, Customers, Governments, Patients, Shareholders

<sup>\*</sup> Mylan's 2019 Global Social Responsibility Report applies the 2016 version of the GRI Standards; "2016" refers to the Standards issue date, not the date of information presented in this report.

# GRI 200-400: TOPIC-SPECIFIC DISCLOSURES\*

Topics	Disclosure	Description	Cross-Reference or Answer	SDG	UNGC Principle
Economic					
GRI 201: Economic Performance 2016**	201-1	Direct economic value generated and distributed	2019 Form 10-K		
GRI 203: Indirect Economic Impacts 2016	203-1	Infrastructure investments and services supported	p. 46-51		1
·	203-2	Indirect economic impacts	p. 18-24, 38-51, 55-65, 76	3	
GRI 205: Anti-corruption 2016**	205-2	Communication and training about anti- corruption policies and procedures	p. 78, 80-81	16	10
GRI 206: Anti-competitive Behavior 2016	206-1	Legal actions for anti-competitive behavior, anti-trust, and monopoly practices	2019 Form 10-K	16	10
Environmental					
GRI 301: Materials 2016	301-1	Materials used by weight or volume	Details on material types, sources and percentage of renewable content, in addition to the information on energy, water and waste is not provided.	12	
GRI 302: Energy 2016**	302-4	Reduction of energy consumption	p. 36-37, 72-73	12 13	8, 9
	303-1	Interactions with water as a shared resource	p. 36, 74-75	6 12	8
GRI 303: Water and Effluents 2018**	303-2	Management of water discharge-related impacts	p. 36, 74-75	6 12	8
GHI 303: Water and Ellidents 2018	303-3	Water withdrawal	p. 74	6 12	8
	303-4	Water discharge	p. 74	6 12	8
	305-1	Scope 1 GHG emissions	p. 72-73	12 13	7, 8
GRI 305: Emissions 2016**	305-2	Scope 2 GHG emissions	p. 72-73	12 13	7, 8
	305-5	Reduction of GHG emissions	p. 37, 72-73	12	7, 8, 9
	306-2	Waste by type and disposal method	p. 73-74	12	8
GRI 306: Effluents and Waste 2016**	306-3	Significant spill	No significant spills occurred at Mylan's facilities in 2019.	12	
GRI 307: Environmental Compliance 2016**	307-1	Non-compliance with environmental laws and regulations	No significant fines and nonmonetary sanctions for noncompliance with environmental laws and/or regulations in 2019.	12	

<sup>\*</sup>Mylan's 2019 Global Social Responsibility Progress Report applies the 2016 version of the GRI Standards; "2016" refers to the Standards issue date, not the date of information presented in this report.

<sup>\*\*</sup>Additional disclosures not related to material GRI topics

Topics	Disclosure	Description	Cross-Reference or Answer	SDG	UNGC Principle
Social					
001.01.5	401-1	New employee hires and employee turnover	p. 68	8	6
GRI 401: Employment 2016**	401-2	Full-time benefits not provided to temporary/ part-time employees	Mylan Careers		
GRI 402: Labor/Management Relations 2016	402-1	Minimum notice periods regarding operational changes	p. 68 Minimum notice periods regarding operational changes impacting employees, including continued employment, vary across the company, as determined by legislation, local and regional policies and practices, individual employment contracts, and collective bargaining agreements, as applicable.	8	
	403-1	Occupational health and safety management system	p. 29, 33, 68-70 Global Health Safety Policy	3 8	
GRI 403: Occupational Health and Safety	403-2	Hazard identification, risk assessment and incident investigation	p. 68-70 Global Health Safety Policy	3 8	
2018**	403-6	Promotion of worker health	p. 32-33, 68-70 Mylan Values	3 8	
	403-9	Work-related injuries	p. 69	8	
	404-1	Average hours of training per year per employee	p. 32, 78		
GRI 404: Training and Education 2016**	404-2	Programs for upgrading employee skills and transition assistance programs	p. 31-32 Mylan Careers	8	
	404-3	Percentage of employees receiving regular performance and career development reviews	p. 32		6
GRI 405: Diversity and Equal Opportunity 2016**	405-1	Diversity of governance bodies and employees	p. 67	5	6
GRI 412: Human Rights Assessment 2016**	412-2	Employee training on HR policies or procedures	p. 67, 77-78, 80-82		1, 2, 3, 4, 5
GRI 413: Local Communities 2016**	413-1	Operations with local community engagement, impact assessments, and development programs	p. 18-24, 47-51		1

<sup>\*</sup>Mylan's 2019 Global Social Responsibility Progress Report applies the 2016 version of the GRI Standards; "2016" refers to the Standards issue date, not the date of information presented in this report.

<sup>\*\*</sup>Additional disclosures not related to material GRI topics

Topics	Disclosure	Description	Cross-Reference or Answer	SDG	UNGC Principle
GRI 415: Public Policy 2016	415-1	Political contributions	p. 87	16	10
GRI 416: Customer Health and Safety 2016	416-1	Assessment of the health and safety impacts of product and service categories	p. 57-65 As part of Mylan's PV program, all products are monitored and assessed for safety impact on an ongoing basis.	3 12	
GRI 417: Marketing and Labeling 2016**	417-1	Requirements for product and service information and labeling	p. 57-65, 77	3 12	

<sup>\*</sup> Mylan's 2019 Global Social Responsibility Report applies the 2016 version of the GRI Standards; "2016" refers to the Standards issue date, not the date of information presented in this report.

<sup>\*\*</sup>Additional disclosures not related to material GRI topics

# Sustainability Accounting Standards Board: Biotechnology & Pharmaceuticals Sustainability Accounting Standard

As part of Mylan's efforts to evolve our disclosure regarding our approach and performance around topics that are important to key stakeholders and recognizing the growing integration of ESG information in investor decision-making, Mylan considered the SASB indicators when developing this report. In the below table we point to relevant content per a set of SASB topics and metrics, selected with consideration to Mylan's priority assessment in 2018.

SASB code	Metric details	Relevant information
HC-BP-210a.1	Discussion, by world region, of management process for ensuring quality and patient safety during clinical trials	p. 61-62
Topic: Access to	Medicine Medicine	
SASB code	Metric details	Relevant information
HBP-240a.1	Description of actions and initiatives to promote access to health care products for priority diseases and in priority countries as defined by the Access to Medicine Index	P. 16-24, 55-57, 84
HC-BP-240a.2	List of products on the WHO List of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP)	p. 57, 83
Topic: Affordabil	ty and Pricing	
SASB code	Metric details	Relevant information
HC-BP-240b.2	Percentage change in: (1) average list price (2) average net price across U.S. product portfolio compared to previous year	p. 40, 56, 76
HC-BP-240b.3	Percentage change in: (1) list price (2) net price of product with largest increase compared to previous year	p. 40, 56, 76
Topic: Drug Safe	ty	
SASB code	Metric details	Relevant information
HC-BP-250a.3	Number of recalls issued, total units recalled	p. 61
Topic: Counterfe	it Drugs	
SASB code	Metric details	Relevant information
HC-BP-260a.1	Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting	p. 62-65
Topic: Employee	Recruitment, Development & Retention	
SASB code	Metric details	Relevant information
HC-BP-330a.1	Discussion of talent recruitment and retention efforts for scientists and research and development personnel	p. 30-32, 66-67
HC-BP-330a.2	(1) Voluntary and (2) involuntary turnover rate for: (a) executives/senior managers (b) midlevel managers	p. 68
	(c) professionals (d) all others	

SASB code	Metric details	Relevant information
	Percentage of (1) entity's facilities and (2) Tier I suppliers' facilities participating in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program or equivalent third-party audit programs for integrity of supply chain and ingredients	p. 57-65
Topic: Business	s Ethics	
SASB code	Metric details	Relevant information
HC-BP-510a.2	Description of code of ethics governing interactions with health care professionals	p. 77-78, 80
Topic: Activity Me	etrics	
SASB code	Metric details	Relevant information
HC-BP-000.A	Number of patients treated	p. 17-24, 56-57
HC-BP-000.B	Number of drugs (1) in portfolio and (2) in research and development (Phases 1-3)	p. 56

# #MylanMadeAnImpact

# FORWARD LOOKING STATEMENT

This document contains "forward-looking statements". Such forward-looking statements may include, without limitation, statements about the proposed combination of Upjohn Inc. ("Newco") and Mylan N.V. ("Mylan"), which will immediately follow the proposed separation of the Upjohn business (the "Upjohn Business") from Pfizer Inc. ("Pfizer") (the "proposed transaction"), the expected timetable for completing the proposed transaction, the benefits and synergies of the proposed transaction, future opportunities for the combined company and products and any other statements regarding Pfizer's, Mylan's, the Upjohn Business's or the combined company's future operations, financial or operating results, capital allocation, dividend policy, debt ratio, anticipated business levels, future earnings, planned activities, anticipated growth, market opportunities, strategies, competitions, and other expectations and targets for future periods. Forward-looking statements may often be identified by the use of words such as "will", "may", "could", "bolieve", "anticipate", "expect", "plan", "estimate", "forecast", "potential", "pipeline", "intend", "continue", "target", "seek" and variations of these words or comparable words. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: ongoing challenges and uncertainties posed by the Covid-19 pandemic for businesses and governments around the world; the parties' ability to meet expectations regarding the timing, completion and accounting and tax treatments of the proposed transaction; changes in relevant tax and other laws; the parties' ability to consummate the proposed transaction; the conditions to the completion of the proposed transaction, including receipt of approval of Mylan's shareholders, not being satisfied or waived on the anticipated timeframe or at all; the regulatory approvals required for the proposed transaction not being obtained on the terms expected or on the anticipated schedule or at all; inherent uncertainties involved in the estimates and judgments used in the preparation of financial statements and the providing of estimates of financial measures, in accordance with accounting principles generally accepted in the United States of America and related standards or on an adjusted basis; the integration of Mylan and Newco being more difficult, time consuming or costly than expected; Mylan's, the Upjohn Business's and the combined company's failure to achieve expected or targeted future financial and operating performance and results; the possibility that the combined company may be unable to achieve expected benefits, synergies and operating efficiencies in connection with the proposed transaction within the expected time frames or at all or to successfully integrate Mylan and Newco; customer loss and business disruption being greater than expected following the proposed transaction; the retention of key employees being more difficult following the proposed transaction; Mylan's, the Upjohn Business's or the combined company's liquidity, capital resources and ability to obtain financing; any regulatory, legal or other impediments to Mylan's, the Upjohn Business's or the combined company's ability to bring new products to market, including but not limited to where Mylan, the Upjohn Business or the combined company uses its business judgment and decides to manufacture, market and/or sell products, directly or through third parties, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts (i.e., an "at-risk launch"); success of clinical trials and Mylan's, the Upjohn Business's or the combined company's ability to execute on new product opportunities; any changes in or difficulties with Mylan's, the Upjohn Business's or the combined company's manufacturing facilities, including with respect to remediation and restructuring activities, supply chain or inventory or the ability to meet anticipated demand; the scope, timing and outcome of any ongoing legal proceedings, including government investigations, and the impact of any such proceedings on Mylan's, the Upjohn Business's or the combined company's consolidated financial condition, results of operations and/or cash flows; Mylan's, the Upjohn Business's and the combined company's ability to protect their respective intellectual property and preserve their respective intellectual property rights; the effect of any changes in customer and supplier relationships and customer purchasing patterns; the ability to attract and retain key personnel; changes in third-party relationships; actions and decisions of healthcare and pharmaceutical regulators; the impacts of competition; changes in the economic and financial conditions of the Upjohn Business or the business of Mylan or the combined company; the impact of outbreaks, epidemics or pandemics, such as the coronavirus pandemic; uncertainties regarding future demand, pricing and reimbursement for Mylan's, the Upjohn Business's or the combined company's products; and uncertainties and matters beyond the control of management and other factors described under "Risk Factors" in each of Pfizer's and Mylan's Annual Reports on Form 10-K. Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission ("SEC"). These risks, as well as other risks associated with Mylan, the Upjohn Business, the combined company and the proposed transaction are also more fully discussed in the Registration Statement on Form S-4, as amended, which includes a proxy statement/prospectus (as amended, the "Form S-4"), which was filed by Newco with the SEC on October 25, 2019 and declared effective by the SEC on February 13, 2020, [the Registration Statement on Form 10, as amended, which includes an information statement (as amended, the "Form 10"), which has been filed by Newco with the SEC on January 21, 2020 and amended on February 6, 2020 and subsequently withdrawn on March 11, 2020, and is expected to be refiled prior to its effectiveness.] a definitive proxy statement, which was filed by Mylan with the SEC on February 13, 2020 (the "Proxy Statement"), and the prospectus, which was filed by Newco with the SEC on February 13. 2020 (the "Prospectus"). You can access Pfizer's, Mylan's and Newco's filings with the SEC through the SEC website at www.sec.gov or through Pfizer's or Mylan's website, as applicable, and Pfizer and Mylan strongly encourage you to do so. Except as required by applicable law, Pfizer, Mylan and Newco undertake no obligation to update any statements herein for revisions or changes after this the date of this document, which is May 4, 2020.

#### Additional Information and Where to Find It

This document shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended. In connection with the proposed transaction, Newco and Mylan have filed certain materials with the SEC, including, among other materials, the Form S-4, Form 10 and Prospectus filed by Newco and the Proxy Statement filed by Mylan. The Form S-4 was declared effective on February 13, 2020 and the Proxy Statement and the Prospectus were first mailed to shareholders of Mylan on or about February 14, 2020 to seek approval of the proposed transaction. The Form 10 has not yet become effective. After the Form 10 is effective, a definitive information statement will be made available to the Pfizer stockholders relating to the proposed transaction. Newco and Mylan intend to file additional relevant materials with the SEC in connection with the proposed transaction. INVESTORS AND SECURITY HOLDERS ARE URGED TO READ DOCUMENTS FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT MYLAN, NEWCO AND THE PROPOSED TRANSACTION. The documents relating to the proposed transaction (when they are available) can be obtained free of charge from Mylan, upon written request to Mylan or by contacting Mylan at (724) 514-1813 or investor.relations@mylan.com or from Pfizer on Pfizer's internet website at https://investors.Pfizer.com/financials/sec-filings/default.aspx or by contacting Pfizer's Investor Relations Department at (212) 733-2323, as applicable.

#### Participants in the Solicitation

This document is not a solicitation of a proxy from any investor or security holder. However, Pfizer, Mylan, Newco and certain of their respective directors and executive officers may be deemed to be participants in the solicitation of proxies in connection with the proposed transaction under the rules of the SEC. Information about the directors and executive officers of Pfizer may be found in its Annual Report on Form 10-K filed with the SEC on February 27, 2020 and its definitive proxy statement relating to its 2020 Annual Meeting filed with the SEC on March 13, 2020. Information about the directors and executive officers of Mylan may be found in its Annual Report on Form 10-K filed with the SEC on February 28, 2020, and its definitive proxy statement relating to its 2019 Annual Meeting filed with the SEC on May 24, 2019. Additional information regarding the interests of these participants can also be found in the Form S-4, the Proxy Statement and the Prospectus. These documents can be obtained free of charge from the sources indicated above.