We believe everyone deserves the opportunity to live a healthy life. That’s why our business is predicated on providing patients everywhere with access to a sustainable supply of high quality medicines.

Serving Patients Globally

Impressive advances have been made on many health fronts around the globe, but inequalities in access to healthcare within and across countries remain a challenge. People around the world continue to lose their lives to treatable diseases, while the burden imposed by chronic conditions is increasing. This challenge is particularly true in low- and middle-income countries. Our aspiration to help deliver better health for a better world acknowledges our desire and commitment to help patients everywhere. In fact, our ongoing efforts to strive to provide people in all countries with high quality products often sets Mylan apart. Key among these efforts are investing in innovation, expanding patient access and addressing unmet needs.

In 2017 Mylan made more than 500 submissions across 70+ countries, and we received approximately 800 product approvals globally. We expanded our portfolio in all major therapeutic areas.
Investing in Innovation

Innovation has fueled Mylan’s success for nearly 60 years and will continue to do so well into the future. More than 3,000 members of our workforce are dedicated to research and development, clinical, medical and regulatory professions. We have two global R&D centers, in the U.S. and India, and 10 technology-focused R&D sites across the U.S., India, Japan and Europe. From 2013-2017, Mylan invested more than $3 billion in cumulative R&D spend⁵.

Innovation is not just about introducing novel products. It’s also about improving existing ones. We invest in manufacturing and distribution capacity to make more products available to more patients across more countries using the most efficient processes possible.

⁵Cumulative spend refers to adjusted R&D. Adjusted metrics are non-GAAP financial measures. Please see appendix or investor.Mylan.com for the most directly comparable U.S. GAAP financial measures as well as reconciliations of such non-GAAP financial measures to the most directly comparable GAAP financial measure.
Expanding Patient Access

DIFFERENTIATED GLOBAL MANUFACTURING NETWORK

Helping patients have greater access to the medicines they need is a key priority for Mylan. Our diverse manufacturing capabilities and global operating platform – with strategic proximity to local markets – support this goal.

<table>
<thead>
<tr>
<th>Manufacturing Sites</th>
<th>Oral Solid Dose</th>
<th>Injectables</th>
<th>Complex Dosage Forms</th>
<th>API</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facilities</td>
<td>24</td>
<td>7</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>Select Capabilities</td>
<td>Immediate- and modified-release tablets and capsules</td>
<td>Small and large parenteral liquid vials</td>
<td>Transdermal patches</td>
<td>&gt;250 APIs</td>
</tr>
<tr>
<td></td>
<td>Multi-layer tablets</td>
<td>Lyophilized vials</td>
<td>Oral films</td>
<td>Dedicated peptides facility</td>
</tr>
<tr>
<td></td>
<td>Orally dissolving tablets</td>
<td>Liposomal dispersion</td>
<td>Liquid bottles</td>
<td>Capacity dedicated for iron complexes</td>
</tr>
<tr>
<td></td>
<td>Powder-layering technology</td>
<td>Polymeric microsphere</td>
<td>Nasals</td>
<td>Separate facility for high-potent active ingredients</td>
</tr>
<tr>
<td></td>
<td>Wurster coating</td>
<td>Ampoules</td>
<td>Dry powder inhalers</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spheronization</td>
<td>Bags</td>
<td>Devices, e.g., pens and cartridges</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Liquid-filled hard-gelatin capsules</td>
<td>Emulsions</td>
<td>Biologics</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hot-melt extrusion</td>
<td>Dry powder vials</td>
<td>Topicals, e.g., foams, creams, gels and ointments</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OROS technology</td>
<td>Long-acting injectables</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Capacity</td>
<td>&gt;75B Doses</td>
<td>&gt;500M Units</td>
<td>1.3B Units</td>
<td>&gt;4,800 Kiloliters</td>
</tr>
</tbody>
</table>

DIVERSE PRODUCT PORTFOLIO

Expanding Mylan’s footprint into new markets and introducing more products into our pipeline each year is yet another way we support our mission. In 2017 we continued our extension into new geographies such as China, Russia, Turkey, Mexico, Brazil and countries in Southeast Asia and the Middle East. We also enhanced our position as a provider of OTC medicines. Further, we have more than 1,000 projects in our product pipeline across our regions.

North America | Europe | Emerging Markets | Japan, Australia and New Zealand
--- | --- | --- | ---
350 products in pipeline¹ | 174 products in pipeline | 310 products in pipeline | 181 products in pipeline
267 products pending approval¹ | 528 products pending approval | 947 products pending approval | 41 products pending approval

¹Product pipeline is molecule plus form, independent of market. Data as of March 1, 2018.
²Products pending approval is molecule plus form plus country. Data as of March 1, 2018.

Learn more about Mylan’s commitment to global social responsibility. Visit Mylan.com.
Addressing Unmet Needs

Over the past few years, Mylan has organized its products and services into 10 major therapeutic areas, helping us better focus on patients’ needs by providing prescription generic, branded generic and brand-name drugs and OTC remedies where they are needed most. This structure helps us look at healthcare holistically and challenges us to provide access throughout patients’ lives.

We’ve also provided support to patient-advocacy organizations across these areas. In 2017 we helped organizations develop disease-related information that was shared across various platforms, including podcasts, webinars, radio programs, community events, regional summits, roundtables and national forums.

In the pages that follow, we highlight examples of Mylan’s impact in selected therapeutic areas and discuss the company’s commitment to maintaining quality in everything we do.

### MYLAN’S MAJOR THERAPEUTIC AREAS*

<table>
<thead>
<tr>
<th>Products</th>
<th>Cardiovascular</th>
<th>CNS &amp; Anesthesia</th>
<th>Dermatology</th>
<th>Diabetes &amp; Metabolism</th>
<th>Gastroenterology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
<td>1,250</td>
<td>2,000</td>
<td>400</td>
<td>400</td>
<td>700</td>
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<tr>
<td>Pipeline</td>
<td>200</td>
<td>400</td>
<td>50</td>
<td>200</td>
<td>100</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Products</th>
<th>Immunology</th>
<th>Infectious Disease</th>
<th>Oncology</th>
<th>Respiratory &amp; Allergy</th>
<th>Women’s Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current</td>
<td>60</td>
<td>800</td>
<td>350</td>
<td>700</td>
<td>500</td>
</tr>
<tr>
<td>Pipeline</td>
<td>30</td>
<td>700</td>
<td>400</td>
<td>150</td>
<td>150</td>
</tr>
</tbody>
</table>

*Product defined by product/dosage form/country. *All Other Franchise* not shown. Current products taken from internal data and rounded.

>7,500 Products

>2,500 Products in Pipeline

Across many growing franchises, geographies and businesses

Learn more about Mylan’s commitment to global social responsibility. Visit Mylan.com.
Stemming the Tide of HIV/AIDS

Mylan’s commitment to fighting HIV/AIDS is an integral part of our mission and business. In fact, 50% of our API manufacturing capacity is dedicated to ARVs, which we sell in more than 100 countries. More than 40% of the nearly 21 million HIV+ patients being treated today – and 60% of the world’s HIV+ children – depend on one of our products.

Mylan has made tremendous strides over the years in stemming the tide of HIV in low- and middle-income countries. We now are bringing our expertise to help people elsewhere. In Europe, for instance, generic ARVs are among the key drivers of our growth. In the U.S., Mylan recently launched Symfi Lo™, Symfi™ and Cimduo™, novel combinations that are empowering patients to choose the lower-cost ARV treatment option that is right for them.

In 2017 we maintained our position as the world’s largest producer by volume of ARVs. Our launches during 2017 included:

- Tenofovir Disoproxil Fumarate, Lamivudine and Dolutegravir (TLD) and Tenofovir Disoproxil Fumarate, Lamivudine and low-dose Efavirenz (TLE400) in low- and middle-income countries. In 2016 the World Health Organization (WHO) recommended both TLE400 and TLD as alternatives for first-line therapy for adults living with HIV.  
- HIV self-tests in Romania and Italy; and  
- the first generic version of Truvada® in France and Ireland, the only combination prophylactic drug approved for HIV.

We also applied for WHO Prequalification (PQ) status on Lopinavir/Ritonavir (LPV/r) granules, a novel product used for treating HIV in children.

Mylan has invested more than $250 million to expand our ARV production capacity. We produced 4 billion ARV tablets and capsules in 2017 alone.

New Medicine Formulation for Children With HIV

Children sometimes have difficulty swallowing tablets and capsules; that’s why their medicines often take the form of syrups and liquids. However, these forms often present storage and transportation challenges and sometimes require refrigeration. In response, Mylan developed a heat-stable dispersible tablet of an important first-line combination therapy that dissolves into a child’s drink. For another product that also required refrigeration and had a bitter taste, Mylan scientists developed a heat-stable, sweet-tasting formulation that can be mixed into a child’s food, increasing ease of administration and the likelihood of drug adherence.
Our ARV portfolio is a demonstration of the relationship between equitable pricing and access. Mylan uses an equitable-pricing approach with international donors, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria; the Pan American Health Organization; and the President’s Emergency Plan for AIDS Relief, or PEPFAR. 

NEXT-GENERATION TREATMENT NOW AVAILABLE IN LOW- AND MIDDLE-INCOME COUNTRIES

On Sept. 21, 2017, at the U.N., Mylan announced its next step in the fight against the HIV epidemic. Together with partners such as the Clinton Health Access Initiative, UNAIDS, the Bill & Melinda Gates Foundation and the U.K.’s Department for International Development, Mylan entered into a unique public/private partnership to accelerate the availability of a next-generation ARV treatment, TLD, to patients in more than 90 low- and middle-income countries. 

As part of this alliance, Mylan committed to selling this product (a combination tablet, taken once daily, of the three molecules Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate) to public-sector purchasers at about $75 per person per year. This initiative supports SDG No. 3 and marks the first time the best-available one-pill, once-daily regimen is available for a price lower than the most commonly used regimen. The low cost means that governments can address two often-conflicting priorities at once: providing better treatment options for patients while reducing overall treatment cost.

SUPPORTING EARLY DIAGNOSIS AND PREVENTION OF HIV

Additionally, we understand the importance of access and support. Some 2017 highlights:

► We were a founding member of the global consortium OPTIMIZE, which is dedicated to accelerating access and improving treatment outcomes for patients living with HIV in low- and middle-income countries.

► Mylan worked with governments and other key stakeholders to increase access to our Pre-Exposure Prophylaxis (PrEP) regimen and offer it at a lower price. This regimen is a preventive measure for people who do not have HIV, but who are at substantial risk for contracting it. In Poland, we partnered with the Polish AIDS Society and the HIV Association to create PrEP administration guidelines in eight medical centers.

► We provided funding to St. Stephens AIDS Trust to conduct a pharmacokinetic study of 400mg Efavirenz in HIV+ women being treated during pregnancy. The study is critical to filling clinical data gaps and identifying potential opportunities to address HIV/AIDS risk in pregnant women.

It is estimated that only 70% of people living with HIV know their HIV status. Countries are looking for ways to rapidly increase access to and use of HIV testing services. One approach is HIV self-testing, which allows someone to perform a diagnostic test and interpret the results in private.

Mylan offers self-tests in France, Italy, Romania and Spain.

Learn more about Mylan's commitment to global social responsibility. Visit Mylan.com.
Applying Our Success in Fighting HIV/AIDS to Other Infectious Diseases

HEPATITIS C
We are building a robust portfolio of hepatitis C (HCV) drugs based on knowledge and experience derived from our HIV/AIDS work. In 2017 Mylan had active/pending registrations in approximately 50 countries.

Lack of a proper diagnosis remains a hurdle to timely treatment of HCV. Mylan actively supports screening programs in Mongolia and Egypt to identify patients with the disease and place them on life-saving therapy. In Asian and African countries, we assembled an advisory board to help develop and publish guidelines for managing HCV in resource-limited settings. Looking ahead, we will launch Sofosbuvir+Velpatasvir in low- and middle-income countries; this panuniversal regimen can be used for noncirrhotic and cirrhotic patients.

MYLAN LAUNCHES FIRST DRUG IN EIGHT YEARS FOR MANAGEMENT OF CHRONIC HEPATITIS B
Mylan India launched 25mg HepBest™ in December 2017, the first drug approved in eight years for the management of chronic hepatitis B (HBV). Formulated for adults, this 25mg tablet of the drug Tenofovir Alafenamide (TAF) is taken once a day.

In 2014 Mylan signed an agreement with Gilead to enhance access to TAF-based HIV treatments in developing countries. As part of the licensing agreement, on U.S. Food and Drug Administration (FDA) approval, Mylan received a technology transfer from Gilead, enabling it to manufacture low-cost versions of TAF, both as a single agent and in approved combinations containing TAF for developing markets. Monotherapy with TAF has demonstrated non-inferiority to TDF with an enhanced safety profile in chronic HBV.

TUBERCULOSIS
There also are large inequities when it comes to accurately diagnosing and treating tuberculosis (TB). The emergence of drug-resistant TB requires lengthy treatments with toxic drugs that are less effective than the primary treatment. In 2017 Mylan entered into a license agreement with Otsuka Pharmaceuticals to commercialize Delamanid (Deltyba®), a novel drug used to treat pulmonary multi-drug resistant tuberculosis (MDR-TB) in low- and middle-income countries. The agreement is expected to increase access for patients in high-burden countries.

MALARIA
We continue to look for opportunities to expand access and affordability of anti-malarials, especially in low- and middle-income countries. Mylan was the first manufacturer to receive WHO PQ for a higher-strength dose of Artemether Lumefantrine (40mg/240mg). It reduces the number of tablets required by 50% and may improve patient adherence, which may impact health outcomes.

2017 Hepatitis Achievements
► Provided treatment for approximately 200,000 patients living with HCV in low- and middle-income countries;
► became the first generics company to receive WHO prequalification for Sofosbuvir, a direct-acting ARV used to treat the disease; and
► launched Sofosbuvir+Velpatasvir in India through a license with our partner, Gilead Sciences.

Tackling Tuberculosis
In 2017 Mylan entered into a license agreement with Otsuka Pharmaceuticals to sell Delamanid (Deltyba®) in South Africa and India. Both countries are considered to have high rates of multi-drug-resistant tuberculosis and TB/HIV co-infection.

Mylan has 63 products prequalified by the WHO.
Multiple sclerosis, or MS, is a chronic, neurodegenerative autoimmune disease that leads to a variety of debilitating physical symptoms in patients who have it. The average age of onset is about 30 years, a period that often coincides with patients starting families and making important career decisions. As a result, the disease can have devastating effects on personal relationships and professional opportunities.

Glatiramer acetate (GA), discovered in the 1960s, is the active ingredient in Copaxone®, a leading treatment for MS. The company that originated Copaxone began marketing the product in the U.S. and Europe in 1997 and 2001, respectively, first as a 20mg/mL daily injection, and later as a 40mg/mL injection given three times weekly. The originator enjoyed a monopoly on Copaxone for approximately 20 years. As a result, it was able to command premium prices, generating billions of dollars in annual revenues.

Mylan saw an opportunity to help MS patients. So nearly a decade ago, working with our development partner Natco, we set out to bring a generic version of Copaxone to market.

Before any generic drug may be marketed, however, it must be demonstrated to be therapeutically equivalent to its branded counterpart. The processes for doing so are well established and widely accepted for conventional small-molecule drugs, which make up the vast majority of medicines available today.

But GA’s API is complex. To approve Mylan’s version, regulators would require substantial evidence of “sameness” between the originator’s version and ours.

To assemble that proof, Mylan undertook a massive research project in which innovation played no small part. For instance, based on our knowledge of the branded product, our scientists developed an array of highly sensitive testing methods, based on chemistry as well as biology, and applied them hundreds of times just to interrogate and characterize the API itself. Characterization reveals a substance’s size, shape, weight, composition, behavior and other important traits. As the project progressed and data piled up, evidence of sameness mounted.

Meanwhile, we built out the intricate supply chain needed to reach patients. We selected manufacturing sites for the API and finished dosage form, chose a syringe supplier, developed and produced auto-injectors in collaboration with our partners, and lined up logistics for refrigerated transport.

Not surprisingly, as we began filing applications, the originator initiated multifaceted legal attacks to try to preserve Copaxone’s monopoly.

In the U.S., the originator filed four separate patent litigations in federal court. Mylan fought one of them all the way to the Supreme Court. The originator also filed nine citizen petitions against Mylan with the FDA.
In addition, the originator sought to challenge Mylan’s work with Natco by filing a patent lawsuit in India that eventually reached that nation’s Supreme Court. Mylan successfully overcame these barriers. In 2017 we launched our 20mg/mL GA product in the U.S. and became the first generics company anywhere to offer the 40mg/mL strength.

In conjunction with our launch, we introduced resources to help patients. Among them are Mylan MS Advocate, a 24-hour patient-support program; the Mylan Smart Injection Tracker™ app; and WhisperJECT™ Autoinjector, which has features designed by MS patients.

As important, by working with the FDA to define a regulatory pathway (to approval) for GA, Mylan has helped pave the way for launches of other complex generic products – from insulin analogs to respiratory inhalations. In this respect, we hope that knocking down a barrier for the MS community will ultimately prove to be good medicine for countless other deserving patients too.

To serve patients in Europe, Mylan has partnered with a GA developer and supplier, and we’re selling or seeking approval to sell the product in multiple countries. The originator continues to fight us throughout the region. But we keep prevailing. Today our 20mg/mL GA product is available in eight European countries. The 40mg/mL version is available in five.

We also recently announced that Mylan and Mapi, a biopharmaceutical company, will partner on the development and commercialization of GA Depot, a long-acting glatiramer acetate product whose global marketing rights we are acquiring.
Making Biologic Treatments More Affordable

Many conventional drugs, regardless of who develops them, are made up of small chemical compounds. Other well-known medicines, called biologics, such as vaccines and gene therapies, are complex substances derived from living organisms. Many biologics represent the cutting edge of medical science and have become the standard of care for various devastating and debilitating diseases, such as cancer, autoimmune diseases and rare genetic disorders. Both types of medications have been on the market for decades. A biosimilar is a product that is highly similar to and has no clinically meaningful differences from an existing approved biologic product. These products have helped to make biological treatments more affordable.

Mylan has one of the most comprehensive and diverse programs in the industry, with 20 biosimilar and insulin analog products on the market or in our pipeline. These include eight of the world’s top oncology, immunology, endocrinology and ophthalmology biologics. Our program is designed to serve multiple markets, including low- and middle-income countries. In 2017:

► In partnership with Biocon, Mylan received FDA approval for Ogivri™, the first biosimilar for Herceptin® (Trastuzumab) to receive approval in the U.S.

► In India, Mylan launched ABEVMY™, an anti-angiogenic biosimilar to Bevacizumab (Avastin®).

Championing Women’s Health

Gender is a fundamental factor in one’s health and well-being. By promoting access to medicine and healthcare for women and girls, Mylan contributes to their independence, equality, and welfare.

Unfortunately, not all women are able to exercise their right to freely choose when and how to start a family. Being unable to make this decision can significantly challenge prospects for equal opportunity in life and health. Mylan has a goal to provide contraceptives to 25 million women and girls by 2020. Already, we have made progress. In 2017, we provided 11 million women and girls with contraception. Our contraceptives are currently registered in 50 of the 69 countries supported by the FP2020 initiative, some of which are among the poorest in the world. Our average price per couple-years of protection was $3.50 per year in low- and middle-income countries. Mylan has contraceptive products with active/pending registration in 95 countries globally and has submitted Medroxyprogesterone Acetate, an injectable contraceptive, for prequalification by the WHO.

Other important areas of women’s health on which we focus include patient needs related to breast cancer, ovarian cancer, menopause, and healthy pregnancies.

FAMILY PLANNING 2020

Mylan formalized our commitment to the U.N.’s Every Woman Every Child initiative as part of our participation in the 2017 FP2020 summit. Mylan is committed to providing contraceptives to 25 million women and girls by 2020 and we pledge to register our contraceptive portfolio in 80% of the 69 FP2020 countries.
Responding to Challenges

U.S. PHARMACEUTICAL PRICING AND THE EPIPEN® CHALLENGE

Patients are rightfully concerned about drug prices. Mylan has felt the full weight of those concerns in relation to the price of our EpiPen® Auto-Injector brand product in the U.S.

The way consumers in the nation pay for healthcare has changed dramatically over the past few years. In particular, a sharp rise in enrollment in high-deductible health plans (HDHPs) has exposed more consumers to higher out-of-pocket costs for their medications.

In 2016 for example, the estimated 85% percent of consumers not enrolled in such plans paid anywhere from $0 to approximately $100 for EpiPen products, which could vary based on their health insurance and other factors. But the other 15%, many of whom were enrolled in HDHPs for the first time, found themselves in some cases having to pay list prices of $600 or more when filling their prescription.

Outraged patients didn’t understand how they went from paying far less the previous year to paying a full list price.

Initially, we tried to explain the outdated and complex system that determines what someone pays for medicine. We indicated that more than half the list price went back to payers or others in the supply chain. However, parents standing at the pharmacy counter unable to pay for an EpiPen didn’t need an explanation, they needed solutions. We listened and swiftly launched an authorized generic version of EpiPen. Its list price was half of the brand’s. We also significantly enhanced our patient access programs. Both actions helped patients and provided substantial savings to the healthcare system.

As background, Mylan acquired and began selling EpiPen in 2007. In the years that followed, we launched a new EpiPen product, invested more than $1 billion to build awareness of the need for that product and educated people about the risks of anaphylaxis. As a result, 1 million more people now are prepared in the event of a life-threatening allergic reaction. We also worked to change laws to allow access to Epinephrine in schools.
and public entities, so it can be readily available for any child who needs it. In addition, we have given away more than 1 million EpiPen products to schools across America. These free pens have been used thousands of times, potentially saving lives.

We are proud of our positive impact in the allergy community, though we sincerely regret that we did not fully appreciate the impact of the list price of EpiPen products to families that had shifted to HDHPs.

Pharmaceutical companies did not create the current U.S. pricing system, but they must compete within it. That said, Mylan continues to play an active role in helping educate lawmakers and others about opportunities to transform the system to better serve patients. By creating an environment where they know what their medication is going to cost, patients can better leverage their power as consumers.

Indeed, we said in 2016 that we hoped the debate around EpiPen would serve as a catalyst for constructive dialogue around pharmaceutical pricing and the need for more transparency. The conversation has expanded to encompass the entire pharmaceutical supply chain. It also now includes other drugs, like insulin products and cancer treatments, underscoring pricing as a systemic issue.

Since then, Congressional hearings have been held on the topic, other government leaders are calling for decisive action and conversations are happening throughout the supply chain. Everyone agrees that the current system is unsustainable.

Mylan never has shied away from challenging the status quo, and we look forward to doing our part to help treat what ails the system.

THE CHALLENGE OF THE U.S. OPIOID EPIDEMIC

Opioid addiction, abuse and misuse in the U.S. is a national epidemic. Mylan recognizes the scope and seriousness of this health crisis and is deeply concerned for those affected by it.

In the U.S. opioid market, Mylan supplies approximately 1.1% of opioid-containing drug products sold, ranking it fifteenth among pharmaceutical companies. Despite our limited role in the production of opioid products, Mylan is committed to doing its part to help in the fight against opioid addiction, abuse and misuse, and to play a role in the long-term solution. 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 some natural and synthetic opioids, as well as for diagnosis of suspected or known acute opioid over-dosage. In the summer of 2016, Mylan launched a multiple-vial version of its generic Naloxone injectable, thereby increasing supply for customers, physicians and other providers seeking additional inventory of this important therapy. Mylan's injectable Naloxone products are used primarily by hospitals. Today these presentations represent some of the lower-priced options on the overall Naloxone market. Although Mylan has only a small share of the Naloxone market, it stands ready to continue to provide reliable supply and access to this important product, including through a commitment to develop an auto-injector drug-device combination for it.

Mylan also is fighting the opioid epidemic by taking seriously the need to safeguard against diversion and abuse of opioids. We have internal practices designed to detect suspicious orders and prevent the sale of opioid-containing products where there may be a risk of diversion.

In April 2018 the company announced plans to leverage its world-class scientific platform to develop a novel delivery for Meloxicam, a non-opioid pain medication. Promoting the development of non-opioid pain treatments is one of the many tactics the FDA is focused on in its efforts to address this growing public health problem.

Mylan remains committed to working with key stakeholders to continue doing its part to contribute to a long-term solution for this national health issue.
Maintaining Quality in Everything We Do

Because patients’ health and well-being are at stake, ensuring quality is essential for the pharmaceutical industry. That’s why, at Mylan, we view quality as being everyone’s responsibility.

For us, quality begins with product development, as we work to ensure an acceptable safety and efficacy profile for every drug we hope to market, and it extends through every step of the production process, from making or sourcing raw materials to producing finished dosage forms.

Externally we work with health authorities to help develop standards that reflect the requirements needed to develop and manufacture products. We then work hard to ensure that our sites, and those of third parties we rely on, comply with them.

Our manufacturing facilities are routinely inspected by various health authorities around the world. In 2017, 128 inspections were performed across our facilities and affiliates.

Mylan has global systems and processes in place to provide our people with the foundation and tools needed to maintain an effective quality management system.

Our training programs, for instance, are designed to make sure employees are qualified by experience and education to perform their jobs in accordance with GMP. All employees responsible for GMP activities are required to take refresher training periodically.

Our Quality Council program provides management with clear, quantitative data, including that of key performance indicators. It also tracks and analyzes quality trends, reviews inspection results and identifies potential areas for employee training.

Mylan has grown significantly throughout our 55+ year history, but the one thing that remains unchanged is our steadfast commitment to delivering high quality medicines.

<table>
<thead>
<tr>
<th>QUALITY</th>
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</thead>
<tbody>
<tr>
<td>in everything that we do</td>
</tr>
<tr>
<td>the first ingredient in every one of our products</td>
</tr>
<tr>
<td>embedded throughout our company</td>
</tr>
<tr>
<td>the fundamental point of decision-making for every product</td>
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</tbody>
</table>
In addition, we have an extensive, formal internal-audit program to help monitor activity at our facilities, as well as that of our suppliers and other partners. Our program relies primarily on oversight by a specially trained team of global experts, augmented and supported by independent third parties. In addition, we have processes to help ensure that insights gained from our own audits and those conducted on Mylan by third parties, customers and health authorities are reviewed and implemented.

We also proactively work with our supply and manufacturing partners to ensure that they apply stringent quality standards across their operations. We believe being proactive not only helps safeguard patients’ interests, but helps distinguish Mylan among our customers, as a partner of choice.

As health-authority standards continue to evolve around the globe and among various agencies, Mylan is dedicated to continually enhancing our systems and processes to ensure sustainable quality across our network.

In 2017 Mylan conducted GMP audits of over 760 contractors and suppliers.

Diverse Global Health Authority Experience

128 inspections of our facilities and affiliates in 2017. Representative agencies appear below.
Promoting Product Safety and Preventing Risk

We have a global policy on Product Safety and robust global pharmacovigilance (PV) programs throughout products’ complete life cycle in an effort to prevent harm. Through our global PV system, we monitor Mylan’s products and work to detect changes to their benefit/risk profile. A cross-functional team of primarily medical and scientific professionals support the system. We report to health authorities on our risk/benefit assessments through periodic safety and risk management planning reports.

Our Product Safety and Risk Management department oversees Mylan’s activities through regular monitoring, including internal audits, to comply with legal and regulatory requirements. This department also is subject to external audits and health-authority inspections.

We have PV oversight and product-safety committees that manage due diligence and governance with respect to PV, applicable legislation and company procedures. These committees also evaluate new safety information that may arise regarding our products. Information is assessed and communicated to healthcare professionals, patients and health authorities in a timely fashion.

Conducting Responsible Clinical Research

Safety always is a priority in clinical trials, and we are committed to the highest standards and integrity. Mylan abides by the principles of good clinical practice (GCP), as defined in the Declaration of Helsinki and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) framework and implemented in international laws, directives and regulations. We also comply with applicable clinical-trial data-disclosure laws and regulations.

In 2017 we planned, conducted and/or reported on more than 100 clinical trials with two groups of human participants: patients and healthy volunteers. Mylan’s governance councils and quality committees oversee clinical trials using comprehensive quality management systems to ensure participant safety. We partner with external experts and investigational sites to ensure safety and data integrity across Mylan’s development programs, and we hold ourselves and our partners accountable to the same standards. When appropriate, Mylan employs data-safety monitoring boards to ensure patient safety and that study blinding has not been compromised. Independent third parties review Mylan’s protocol design to ensure participant safety and the integrity of the data collected.

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. PV’s aims are to enhance patient care and safety in relation to the use of medicines.

Mylan conducted 60 clinical and more than 35 pharmacovigilance audits at our own sites, external contract research organizations, clinical investigator sites and service providers.