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Mylan Report on U.S. Opioid Crisis

Throughout its history, Mylan N.V. (“Mylan” or the “Company”) 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 is committed to doing its part to help in the nationwide fight against opioid addiction, abuse, and misuse.

Mylan’s Board of Directors is publishing this report 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, including actions taken by the Company to help in the fight against opioid addiction, abuse, and misuse.

I. Mylan’s Opioid Products

Opioid products, which the U.S. Food and Drug Administration (FDA) has recognized provide benefits when used as prescribed, are not a focus area for the Company.

Indeed, while Mylan supplies opioid-based products, Mylan is not promoting or marketing these products and has a very limited role in the United States opioid market. For example, according to IQVIA/IMS data, Mylan supplied approximately 1% of all opioid-containing products sold in the United States in 2016, 2017, and 2018, by total volume (doses). Mylan’s U.S. revenues for opioid-based products generally have been decreasing for several years and they represent only a small share of Mylan’s total revenues.

With one exception described below, Mylan’s opioid products consist of generic products, which typically are automatically substituted for branded products by pharmacies. These products include FDA-approved products across the range of U.S. Drug Enforcement Administration (DEA) schedules, such as acetaminophen/codeine phosphate tablets, tramadol hydrochloride tablets, and diphenoxylate hydrochloride and atropine sulfate tablets. Mylan’s full product catalog can be reviewed on its website at: <https://www.mylan.com/en/products/product-catalog>. Mylan’s opioid pain relievers provide important therapeutic benefits for appropriate patient populations, when prescribed and used responsibly.

While illicit fentanyl is a significant part of the opioid crisis, federal authorities have acknowledged that lawful fentanyl products are not responsible for the national fentanyl problem. In its 2018 National Drug Threat Assessment, the DEA concluded that “[c]landestinely produced fentanyl is trafficked into the United States primarily from China and Mexico, and is responsible for the ongoing fentanyl crisis. In contrast, the diversion of pharmaceutical fentanyl

in the United States occurs on a small scale, with the diverted fentanyl products being intended for personal use and street sales.”

One of Mylan’s opioid products is the Fentanyl Transdermal System, which is a generic version of Johnson & Johnson’s branded fentanyl patch product, Duragesic™. Mylan’s Fentanyl Transdermal System is indicated for the management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative options are inadequate. Its patch design utilizes a matrix technology in which the fentanyl is incorporated into the adhesive layer of the patch. Accordingly, Mylan’s patches have no drug reservoir containing fentanyl gel and are among the products containing the least amount of fentanyl needed to deliver the labeled dose. At the time of its approval, Mylan’s matrix technology design represented an important innovation. In addition, Mylan offers intermediate dosing strengths to allow physicians to fine-tune dosing to provide additional treatment options.

Mylan’s sole branded opioid product, Ultiva®, is not part of the national discussion on opioids, as it is an intravenous anesthesia medication administered exclusively and directly by healthcare providers in surgery-center, in-patient settings.

II. Mylan’s Comprehensive Responses to Help Fight the Opioids Crisis

a. Mylan’s Pursuit of Alternative Products

Given its extensive scientific capabilities, Mylan is taking a leading role in finding pharmaceutical solutions to combat opioid addiction, misuse, and abuse. As the FDA has recognized, steps taken to confront the crisis must be balanced against “the needs of patients in accessing appropriate pain management.” FDA Statement on the FDA’s benefit-risk framework for evaluating opioid analgesics dated June 20, 2019. See <https://www.fda.gov/news-events/press-announcements/statement-fdas-benefit-risk-framework-evaluating-opioid-analgesics>. The Company is actively involved in the research and development of novel non-opioid pain management therapies and products designed to reduce or respond to incidents of opioid abuse. For example:

- Mylan is developing a novel delivery system for meloxicam, a non-opioid pain medication that may serve as an effective alternative therapy for pain patients. The Company is committed to bringing this product to market. Promoting the development of non-opioid pain treatments is one of the many areas the FDA is focused on as part of its efforts to address this public health problem.
- 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, the Company launched a multiple-vial version of naloxone and thereby increased supply for customers, physicians, and other providers seeking additional inventory of this important therapy. Mylan's injectable naloxone products are primarily used by hospitals. Today, Mylan's naloxone presentations have the lowest list price in the overall U.S. naloxone market, which includes auto-injectors and prefilled syringes. Mylan stands ready to continue to provide reliable supply and access to naloxone, including through a commitment to develop an auto-injector drug-device combination for naloxone.

b. Mylan's Commitment to Suspicious Order Monitoring

In addition, Mylan takes seriously the Company's responsibilities to help ensure that its opioid medications are distributed carefully, including by designing and operating a system to identify suspicious orders of controlled substances consistent with its obligations under the federal Controlled Substances Act (CSA) and Drug Enforcement Administration (DEA) regulations.

Specifically, Mylan has established a suspicious order monitoring (SOM) system that consists of internal controls to identify suspicious orders and prevent the sale of opioid-containing products where there may be a risk of diversion. For example:

- Orders for controlled substances, including opioid products, are not sent for distribution center processing until they are approved for release.
- Order information for controlled substances is transmitted to the SOM system, which performs statistical modeling calculations to identify potential suspicious orders. A suspicious order of a controlled substance may include, but is not limited to, an order of unusual size or deviating substantially from a normal pattern, and orders of unusual frequency.
- If the SOM system's statistical modeling "flags" an order as potentially suspicious, the order is placed on hold and will not be shipped unless the suspicion is reasonably dispelled after investigation.
- Flagged orders are investigated by Mylan, including by Mylan's Controlled Substance Monitoring Team (CSMT) within its Regulatory Affairs department.

- Orders not released by the CSMT are elevated to Mylan’s DEA Regulatory Affairs personnel for further investigation.

Mylan’s SOM processes are set forth in clear, comprehensive written policies and Standard Operating Procedures (SOP) that outline the purpose and scope of the SOM program and relevant employee responsibilities. Applicable Mylan personnel are required to complete trainings on the SOM Program and to understand the importance of DEA compliance.

c. Mylan’s Commitment to Compliance

More broadly, Mylan’s operations are governed by the Company’s Code of Business Conduct and Ethics, also known as the Code, which is administered by Mylan’s Office of Global Compliance. It is a condition of employment that Mylan employees comply with the Code and the applicable laws of the countries in which Mylan does business. Mylan employees receive annual training on the Code and must periodically certify that they have read the Code and will, to the best of their knowledge and belief, comply with the Code. Among other obligations, the Code requires adherence to current good manufacturing and good laboratory practices, prompt reporting of concerns regarding product quality and adverse events, and compliance with established internal controls. Interactions with healthcare providers and organizations also must be guided by applicable laws, regulations, and Mylan policies, and promotional activities and materials must be “truthful, accurate, not misleading, consistent with approved product labeling and properly substantiated.”

Moreover, Mylan provides several options for employees and others to report to Mylan’s Compliance Department possible violations of applicable laws, regulations, policies, or the Code, either online or via telephone, mail or email. In particular, Mylan’s Compliance Department administers a Compliance Line that is accessible 24 hours a day, 7 days a week, and reports can be made anonymously. Mylan’s Compliance Department fully investigates any such reports.

d. Mylan’s Participation in REMS

For certain of its products, Mylan also participates in a shared industry Risk Evaluation and Mitigation Strategy (REMS) for extended-release and long-acting opioid analgesics. A REMS is a “drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.” The FDA has determined that a REMS for extended-release and long-acting opioid analgesics is necessary to ensure that the benefits of these drugs continue to outweigh the risks. The REMS is one strategy among multiple national and state efforts to reduce the risk of abuse, misuse, and addiction.

III. Board Engagement and Executive Compensation

a. Mylan's Board-Level Committees

Several of the committees of Mylan's Board of Directors exercise oversight with respect to matters related to certain of Mylan's processes for management of its products, including opioids. In particular, the Compliance Committee of Mylan's Board (the "Compliance Committee"), which consists entirely of independent directors, is charged with overseeing global compliance policies related to Mylan's business methods and operations, including with respect to policies related to the Company's pricing and/or commercialization of products. The Mylan Board added a provision to the Compliance Committee charter to memorialize this responsibility. A copy of the Compliance Committee charter can be found on Mylan's website at: https://www.mylan.com/-/media/mylancom/files/company/corporate-governance/compliancecommitteecharter11_17.pdf

Moreover, the Compliance Committee is responsible for overseeing the Company's policies and procedures for corporate political and lobbying expenditures and making recommendations concerning those policies and procedures to the Board as appropriate. Mylan remains committed to responsible legislative efforts to protect patient access to important generic medicines at affordable prices. Mylan's lobbying activities, including in partnership with other industry associations, primarily have focused on ensuring continued patient access to generic medications.

In the first quarter of 2018, Mylan's Board also formed a Risk Oversight Committee to assist in its oversight of the Company's enterprise risk management framework. The Board subsequently revised that Committee's charter to clarify that it is charged with overseeing management efforts with respect to global social responsibility, which includes the social impact of the company's products. Both the Compliance Committee and the Risk Oversight Committee, each of which consists entirely of independent directors, meet at least quarterly without members of management present. Moreover, the Risk Oversight Committee – at least semi-annually – consults with the Chairs of other Board Committees to discuss risk-related matters delegated to those Committees and the Company's enterprise risk management framework and reports the results of those discussions to the full board. A copy of the Risk Oversight Committee charter can be found on Mylan's website at: <https://www.mylan.com/-/media/mylancom/files/company/corporate-governance/risk-oversight-committee-charter.pdf>

b. Mylan's Engagement with Shareholders Regarding the Opioid Crisis

Mylan's Board and management have also engaged with shareholders regarding the Company's responses to the opioid crisis. As demonstrated by Mylan's statement regarding opioids in the proxy for its 2018 Annual General Meeting of Shareholders (AGM) and statements in its 2017 and 2018 Global Social Responsibility reports, this is an issue on which the Company is focused and endeavors to be transparent. Specifically, from our 2017 AGM through the present, we have held shareholder engagement meetings that have included independent directors, committee chairs, and our Chairman—and, separately, the CEO and other members of management. Over the past year, the Board and management have met with shareholders representing approximately 45% of shares outstanding, which included over 63% of shares held by our 50 largest shareholders. During this engagement, shareholders had the opportunity to meet with independent directors alone. Shareholders may address any topics of interest during these meetings, some of which have included discussions of the opioid crisis.

c. Mylan's Executive Compensation Metrics

Consistent with Mylan's limited role in the opioids market and the breadth of its global business, executive officer compensation metrics are not tied to opioid product sales. Rather, Mylan's Compensation Committee, which is comprised of independent directors, considers both qualitative and quantitative factors in determining executive compensation (or, in the case of the CEO and President, compensation recommendations to be made and approved by independent, non-executive members of the Board). These compensation evaluations are undertaken by the Committee at least annually, taking into account a mix of performance measures and the Committee's analysis of compensation trends and developments. The Committee also considers certain metrics, such as Global Regulatory Submissions, designed to mitigate risks that compensation could become overly dependent on any single product. Mylan's executive compensation metrics are described in the Company's annual proxy statements.

IV. Litigation

We believe this report provides important information and context about Mylan's limited opioids products as well as our commitment to being part of the solution to address this public health crisis. Despite this factual backdrop, Mylan has been named in the U.S., along with numerous other manufacturers, distributors, pharmacies, pharmacy benefit managers, and/or individual healthcare professionals, in civil lawsuits brought by various plaintiffs, including counties, cities, and other local governmental entities, asserting claims related to sales, marketing and/or distribution practices with respect to prescription opioid products. Most of these lawsuits have been consolidated in the multidistrict litigation pending in the United States District Court for the Northern District of Ohio. Mylan believes that the claims against Mylan in these lawsuits

are without merit and intends to defend against them vigorously. Mylan's Board appropriately monitors this and other significant litigation.

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Mylan appreciates the Company's stakeholders' interest in this important issue. As this report reflects, the Company is committed to balancing the patient benefits of opioid pain relievers against the risks associated with such products and remains dedicated to collaborating, both internally and externally, to identify ways in which Mylan can continue to address this public health challenge.