

To: Office of Attorney General
AGO.highcostprescriptiondrugs@vermont.gov

From: Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Road
Morgantown, WV 26505

Date: August 20, 2020

Re: 18 V.S.A § 4637

In compliance with 18 V.S.A. § 4637, on July 24, 2020 Mylan Pharmaceuticals Inc. ("Mylan") provided written notice to the Office of the Attorney General that it introduced a new prescription drug, Doxylamine Succinate and Pyridoxine Hydrochloride Delayed-release Tablets, 10mg/10mg ("the Product"), to the commercial market on July 21, 2020 at a wholesale acquisition cost that is over the threshold set for a specialty drug under the Medicare Part D program.

This letter provides the additional required information by 18 V.S.A. § 4637(c) regarding the Product. Mylan notes that the Office of the Attorney General has not yet prescribed a format for submissions under this section. Further, as authorized by 18 V.S.A. § 4637(d), Mylan has limited the information reported to that which is in the public domain or publicly available.

- (1) A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally;

Doxylamine succinate and pyridoxine hydrochloride delayed-release tablets are indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management. The Wholesale Acquisition Cost (WAC) for the product in the United States is below:

NDC	Product	Package Size	WAC
00378-4615-01	Doxylamine Succinate and Pyridoxine Hydrochloride Delayed-release Tablets, 10mg/10mg	100	\$592.05

Please note that, although not all courses of treatment of the Product trigger the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program (the "threshold"), this notice is being submitted because the Product triggers the threshold only when taking into account the maximum recommended dose as listed in the Product Prescribing Information.

The prices negotiated with customers as well as any marketing plans in the United States or internationally are confidential and not in the public domain or publicly available. In the United States, Mylan sells its products directly to wholesalers, distributors, retail pharmacy chains, long-term care facilities and mail order pharmacies. Mylan also sells its generic products indirectly to several entities, including independent pharmacies, managed care

organizations, hospitals, etc. These customers, called “indirect customers,” purchase our products primarily through our wholesale customers.

- (2) the estimated volume of patients who may be prescribed the drug;

No information specific to the estimated number of patients that may be prescribed Mylan’s Product is in the public domain or publicly available.

- (3) whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval;

The Product was not granted breakthrough therapy designation or priority review by the FDA.

- (4) the date and price of acquisition if the drug was not developed by the manufacturer.

The Product was not the result of an acquisition.