

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

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

Date: January 17, 2019

Re: 18 V.S.A § 4637

In compliance with 18 V.S.A. § 4637, on December 21, 2018 Mylan Pharmaceuticals Inc. (“Mylan”) provided written notice to the Office of the Attorney General that it introduced a new prescription drug, Ketoconazole 2% Topical foam (100) (“the Product”), to the commercial market on December 20, 2018 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;

Ketoconazole foam, 2% is indicated for the topical treatment of seborrheic dermatitis in immunocompetent patients 12 years of age and older. The Wholesale Acquisition Cost (WAC) for the product in the United States is below:

NDC	Product	Package Size	WAC
0378-7007-01	Ketoconazole 2% Topical foam (100)	1	\$690.82

The prices negotiated with customers are confidential and not in the public domain or publicly available. 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. The Product has not yet launched in any international jurisdiction.

- (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.