

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

From: Mylan Institutional Inc.
 3711 Collins Ferry Road
 Morgantown, WV 26505

Date: April 18, 2024

Re: 18 V.S.A § 4637

In compliance with 18 V.S.A. § 4637, on March 25, 2024, Mylan Institutional Inc. (“Mylan”) provided written notice to the Office of the Attorney General that it introduced new a generic prescription drug, Posaconazole Injection 300mg/16.7mL Solution in SDV 1 Pack, (“the Product”), to the commercial market on March 22, 2024 at a wholesale acquisition cost of a 30 day supply 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;

Posaconazole Injection 300mg/16.7mL Solution in SDV 1 Pack is indicated (1) for the treatment of invasive aspergillosis in adults and pediatric patients 13 years of age and older; and (2) for the prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy as follows:

- **Posaconazole injection:** adults and pediatric patients 2 years of age and older

The Wholesale Acquisition Cost (WAC) for the Product in the United States is below:

NDC	Products	Package Size	WAC
67457-0665-20	Posaconazole Injection 300mg/16.7mL Solution in SDV	1	\$503.93

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 a product acquisition.