

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

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

Date: October 29, 2021

Re: 18 V.S.A § 4637

In compliance with 18 V.S.A. § 4637, on October 3, 2021 Mylan Pharmaceuticals Inc. (“Mylan”) provided written notice to the Office of the Attorney General that it introduced new generic prescription drugs, Everolimus Dispersible Tablets, 2mg; Everolimus Dispersible Tablets, 3mg; and, Everolimus Dispersible Tablets, 5mg, (“the Products”), to the commercial market on October 1, 2021 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 Products. 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;

Everolimus tablets for oral suspension are indicated (1) in adult and pediatric patients aged 1 year and older with TSC for the treatment of SEGA that requires therapeutic intervention but cannot be curatively resected; and (2) for the adjunctive treatment of adult and pediatric patients aged 2 years and older with TSC-associated partial-onset seizures. The Wholesale Acquisition Cost (WAC) for the Products in the United States is below:

NDC	Products	Package Size	WAC
00378-0005-85	Everolimus Dispersible Tablets, 2mg	28	\$12,894.98
00378-0006-85	Everolimus Dispersible Tablets, 3mg	28	\$13,024.14
00378-0007-85	Everolimus Dispersible Tablets, 5mg	28	\$13,555.52

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 Products 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 Products were granted priority review by the FDA.

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

The Products were not the result of a product acquisition.