

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

From: Mylan Institutional Inc.
1000 Mylan Boulevard
Canonsburg, Pennsylvania 15317

Date: October 9, 2019

Re: 18 V.S.A § 4637

In compliance with 18 V.S.A. § 4637, on September 12, 2019 Mylan Institutional Inc. (“Mylan”) provided written notice to the Office of the Attorney General that it introduced a new generic prescription drug, Fulvestrant 50mg/mL 5mL Injection 2PK (“the Product”), to the commercial market on September 9, 2019 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;

Fulvestrant 50mg/mL 5mL Injection is indicated for (1) Monotherapy: Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy, or HR-positive advanced breast cancer in postmenopausal women with disease progression following endocrine therapy; and (2) Combination Therapy: HR-positive, HER2-negative advanced or metastatic breast cancer in postmenopausal women in combination with ribociclib as initial endocrine based therapy or following disease progression on endocrine therapy, or HR-positive, HER2-negative advanced or metastatic breast cancer in combination with palbociclib or abemaciclib in women with disease progression after endocrine therapy. The Wholesale Acquisition Cost (WAC) for the product in the United States is below:

NDC	Product	Package Size	WAC
67457-0311-05	Fulvestrant 50mg/mL 5mL PFS 2PK	2	\$1,745.15

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 granted priority review by the FDA.

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

Not applicable.