Mylan
Better Health for a Better World

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

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

**Date:** September 20, 2019

**Re:** 18 V.S.A § 4637

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In compliance with 18 V.S.A. § 4637, on August 26, 2019 Mylan Institutional Inc. ("Mylan") provided written notice to the Office of the Attorney General that it introduced a new generic prescription drug, Hydroxyprogesterone Caproate 250mg/mL 1mL Injection 1PK ("the Product"), to the commercial market on August 23, 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;

*Hydroxyprogesterone Caproate 250mg/mL 1mL Injection is indicated for use in non-pregnant women: for the treatment of advanced adenocarcinoma of the uterine corpus (Stage III or IV); in the management of amenorrhea (primary and secondary) and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer; as a test for endogenous estrogen production and for the production of secretory endometrium and desquamation. The Wholesale Acquisition Cost (WAC) for the product in the United States is below:*

| NDC | Product | Package Size | WAC |
|---|---|---|---|
| 67457-0967-01 | Hydroxyprogesterone Caproate 250mg/mL 1mL Injection | 1 | $682.55 |

*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.

*Please note that Mylan did not develop the drug and also did not acquire the ANDA for this product. Mylan labels and distributes the product in the United States pursuant to a licensing agreement with the drug's ANDA holder. Accordingly, is no "date and price of acquisition" to report for the product, as these information items are not applicable to Mylan.*