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: November 9, 2018

Re: 18 V.S.A § 4637

In compliance with 18 V.S.A. § 4637, on October 12, 2018 Mylan Institutional Inc. ("Mylan") provided written notice to the Office of the Attorney General that it introduced a new prescription drug, Decitabine 50mg POW 1PK ("the Product"), to the commercial market on October 10, 2018 at a wholesale acquisition cost that exceeds 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;

Decitabine for injection is a nucleoside metabolic inhibitor indicated for treatment of patients with myelodysplastic syndromes (MDS) including previously treated and untreated, de novo and secondary MDS of all French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups. The Wholesale Acquisition Cost (WAC) for the product in the United States is below:

NDC	Product	Package Size	WAC
67457-316-25	Decitabine 50mg POW 1PK	1	$950.00

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 priority review by the FDA.

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

The Product was developed by Pharmascience Inc. (formerly known as Uman Pharma Inc.). As such, Mylan and Pharmascience Inc. are subject to a Distribution and Supply Agreement, the terms of which are confidential and proprietary and therefore not available in the public domain or publicly available.