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

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

Date: April 5, 2023

Re: 18 V.S.A § 4637

In compliance with 18 V.S.A. § 4637, on March 9th, 2023, Mylan Pharmaceuticals Inc. ("Mylan") provided written notice to the Office of the Attorney General that it introduced new a generic prescription drug, Lenalidomide Capsules, ("the Products"), to the commercial market on March 7th, 2023 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;

Lenalidomide is indicated for relief of signs and symptoms of:

1.1 Multiple Myeloma
Lenalidomide capsules in combination with dexamethasone are indicated for the treatment of adult patients with multiple myeloma (MM).

Lenalidomide capsules are indicated as maintenance therapy in adult patients with MM following autologous hematopoietic stem cell transplantation (auto-HSCT).

1.2 Myelodysplastic Syndromes
Lenalidomide capsules are indicated for the treatment of adult patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

1.3 Mantle Cell Lymphoma
Lenalidomide capsules are indicated for the treatment of adult patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

1.4 Follicular Lymphoma
Lenalidomide capsules in combination with a rituximab product, are indicated for the treatment of adult patients with previously treated follicular lymphoma (FL).

1.5 Marginal Zone Lymphoma
Lenalidomide capsules in combination with a rituximab product, are indicated for the treatment of adult patients with previously treated marginal zone lymphoma (MZL).

1.6 Limitations of Use
Lenalidomide capsules are not indicated and are not recommended for the treatment of patients with CLL outside of controlled clinical trials [see WARNINGS AND PRECAUTIONS (5.5) of Product's Prescribing Information].

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

NDC	Products	Package Size	WAC
00378-1935-01	Lenalidomide 2.5mg Oral capsule	100	$71,990.62
00378-1935-28	Lenalidomide 2.5mg Oral capsule	28	$20,157.36
00378-1942-01	Lenalidomide 20mg Oral capsule	100	$71,990.62
00378-1942-21	Lenalidomide 20mg Oral capsule	21	$15,118.04

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 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 Products were not the result of a product acquisition.