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

**From:** Mylan Specialty, L.P.
3711 Collins Ferry Road
Morgantown, West Virginia 26505

**Date:** December 15, 2021

**Re:** 18 V.S.A § 4637

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In compliance with 18 V.S.A. § 4637, on November 18, 2021, Mylan Specialty L.P. ("Mylan") provided written notice to the Office of the Attorney General that it introduced a new interchangeable biosimilar prescription drug, Semglee™ (Insulin Glargine-YFGN) ("the Product"), to the commercial market on November 15, 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 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;

*SEMGLEE is indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus. The Wholesale Acquisition Cost (WAC) for the product in the United States is below:*

| NDC | Product | Package Size | WAC |
|---|---|---|---|
| 49502-0250-80 | Semglee™ (Insulin Glargine-YFGN) 1000IU/10mL vial | 1 | $269.38 |
| 49502-0251-75 | Semglee™ (Insulin Glargine-YFGN) 300IU/3ML pen | 5 | $404.04 |

*Please note that, although not all courses of treatment of the Products trigger the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program (the "threshold"), this notice is being submitted because the Products may trigger the threshold depending on the units a patient may use in a 30-day period.*

*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 or other hospital facilities and mail order pharmacies. Mylan also sells its 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 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 Product was co-developed by Viatris and Biocon Biologics and was not a result of an acquisition.*