

GRIFOLS

December 12, 2019

AGO.highcostprescriptiondrugs@vermont.gov

Report Concerning a New Prescription Drug Pursuant to 18 V.S.A. § 4637(c)

Dear Office of the Vermont Attorney General,

Grifols USA, LLC. (“Grifols”) is issuing this notice pursuant to 18 V.S.A. § 4637(c), which asks prescription drug manufacturers to report certain information to the Office of the Attorney General (the “Office”) within thirty calendar days of providing initial notice to the Office that the manufacturer has released a drug in the commercial market whose wholesale acquisition cost (“WAC”) exceeds the threshold set for a specialty drug under the Medicare Part D Program.

On November 12, 2019, Grifols informed the Office that it introduced Xembify[®], 20% solution into the commercial market at a WAC that exceeds the threshold set for a specialty drug under the Medicare Part D Program.

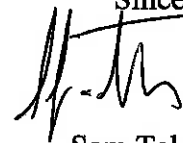
Below is the information related to Xembify[®], 20% solution, issued pursuant to 18 V.S.A. § 4637(c). Consistent with 18 V.S.A. § 4637(d), Grifols has limited the below information to what Grifols believes is otherwise in the public domain or publicly available.

18 V.S.A. § 4637(c) Reporting Requirement	Response for Xembify[®], 20% solution
Description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally	Grifols does not believe this information is otherwise in the public domain or publicly available. Accordingly, Grifols is limiting its response to this item pursuant to 18 V.S.A. § 4637(d).

18 V.S.A. § 4637(c) Reporting Requirement	Response for Xembify®, 20% solution
Estimated volume of patients who may be prescribed the drug	2019: 1 Patient 2020: 5 Patients
Whether the drug was granted breakthrough therapy designation by the federal Food and Drug Administration prior to final approval	NO
Whether the drug was granted priority review by the federal Food and Drug Administration prior to final approval	NO
The date and price of acquisition if the drug was not developed by the manufacturer	N/A

In the event 18 V.S.A. § 4637 is found invalid, Grifols reserves all of its legal rights. In issuing this notice in an attempt to comply with 18 V.S.A. § 4637, Grifols does not waive any legal claims or legal rights related to potential constitutional defects with 18 V.S.A. § 4637.

Sincerely,



Sam Talarico
Assistant General Counsel