Pfizer Inc.
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May 3, 2024

BY ELECTRONIC DELIVERY

State of Vermont
Office of the Vermont Attorney General
AGO.highcostprescriptiondrugs@vermont.gov

Notice of a New Prescription Drug Pursuant to 18 V.S.A. § 4637(b)

Pfizer Inc. ("Pfizer") is issuing this notice pursuant to 18 V.S.A. § 4637(b), which requires prescription drug manufacturers to provide the Office of the Attorney General (the "Office") written notice within three calendar days of releasing 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.

Pfizer released BEQVEZ™ (fidanacogene elaparvovec) gene therapy (10^{13} vg/ml 4X1ml; 10^{13} vg/ml 5X1ml; 10^{13} vg/ml 6X1ml; 10^{13} vg/ml 7X1ml) into the commercial market on May 2, 2024. BEQVEZ™'s WAC exceeds the threshold set for a specialty drug under the Medicare Part D Program.

18 V.S.A. § 4637 does not currently define "release of the drug in the commercial market." Further, Pfizer is not aware of any guidance issued by the Office or any Vermont regulation that defines "release of the drug in the commercial market" for the purpose of 18 V.S.A. § 4637.

As a result, Pfizer considers a drug to be "release[d] . . . in the commercial market" when Pfizer publishes a trade letter to wholesale customers announcing the introduction of the new drug and begins accepting orders for the drug.

Please note that the WAC-related information provided in this notice may be subject to change.

In the event Vermont S. 92 and the laws it implements, including 18 V.S.A. § 4637, are found invalid, Pfizer reserves all of its legal rights. In issuing this notice in an attempt to comply with 18 V.S.A. § 4637, Pfizer does not waive any legal claims or legal rights related to potential constitutional defects with Vermont S. 92.