



January 24, 2023

To: The Office of Attorney General of Vermont

Via: Electronic Mail at AGO.highcostprescriptiondrugs@vermont.gov

Re: Notice & Report of New Drug Introduction Pursuant to 18 V.S.A. §§ 4637(b) & 4637(c)

Pursuant to 18 V.S.A. § 4637, TruPharma, LLC (“TruPharma”) provides the Office of Attorney General with notice and a report relating to the introduction of a new prescription drug at a wholesale acquisition (WAC) price above the threshold set for a specialty drug under the Medicare Part D program.

Pursuant to § 4637(b), TruPharma provides written notice of the release of the drug in the commercial market on or shortly after January 27, 2023. The published WAC price is as follows:

NDC	Name of Prescription Drug	Strength & Size	Qty.	WAC
52817-615-16	Tramadol Hydrochloride Oral Solution	5mg/mL	1	\$471.05

Furthermore, pursuant to § 4637(c) as limited § 4637(d), TruPharma hereby provides the following information to the extent in the public domain or otherwise publicly available.

§ 4637(c)(1): A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally:

- This drug product is an authorized generic Tramadol Hydrochloride Oral Solution 5mg/mL and therapeutically equivalent to the reference listed drug (RLD), QDOLO branded product. No other marketing and pricing plans are available. The generic product is approved for sale in the United States only.

§ 4637(c)(2): The estimated volume of patients who may be prescribed the drug:

- TruPharma does not know the estimated volume of patients who may be prescribed the drug.

§ 4637(c)(3): Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval:

- The drug was not granted breakthrough therapy designation.

§ 4637(c)(4) The date and price of acquisition if the drug was not developed by the manufacturer:

- Not applicable.

Sincerely,

John E. Mooney
For TruPharma, LLC