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VIA ELECTRONIC MAIL (AGO.highcostprescriptiondrugs@vermont.gov)

May 25, 2021

Office of The Attorney General
State of Vermont
Attn: TJ Donovan, Attorney General
109 State Street
Montpelier, VT 05609

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

Dear Mr. Donovan:

On April 26, 2021, GlaxoSmithKline (“GSK”) issued a notice pursuant to 18 V.S.A §4637(b) to inform you that on April 23, 2021 GSK introduced a new prescription drug to market (in the U.S. and Vermont) at a wholesale acquisition price above the threshold set for a specialty drug under the Medicare Part D program.

The new drug, listed below with its respective NDC, is:

- (1) JEMPERLI, JEMPERLI INJ 500MG/10ML (NDC: 00173089803)

This letter is to provide reporting requirements under 18 V.S.A §4637 (c).

Reporting Requirement Under 18 V.S.A §4637(c)	Reporting Requirement Response for JEMPERLI (NDC:00173089803)
(1) a description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally	GSK has not made marketing and pricing plans available in the public domain and is limiting its response to information that which is otherwise in the public domain or publicly available under 18 V.S.A §4637(d)
(2) the estimated volume of patients who may be prescribed the drug	Endometrial cancer is a main type of uterine cancer that forms in the inner lining of the uterus, known as the endometrium. Endometrial cancer can be classified as mismatch repair-deficient/microsatellite instability-high (dMMR/MSI-H) or mismatch repair-proficient/microsatellite stable. There are limited treatment options for women whose disease progresses

	<p>on or after first-line therapy. Nearly 60,000 new cases of endometrial cancer are expected in the US in 2021, making endometrial cancer the most common gynaecologic malignancy in the US. Approximately 25% of women with endometrial cancer will be diagnosed with advanced disease or will experience a recurrence. Of these, approximately 25% will be mismatch repair deficient with 71% or approximately 2,663 patients having progressed on prior platinum-based chemotherapy and therefore eligible for JEMPERLI. Diagnosed patients may or may not be prescribed JEMPERLI (NDC: 00173089803) depending on their known resistance to the medicines and other patient specific factors such as allergic reactions or other medical conditions that may preclude a patient's ability to be effectively treated with JEMPERLI (NDC: 00173089803).</p>
<p>(3) whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval</p>	<p>JEMPERLI (NDC:00173089803) was granted breakthrough therapy designation and priority review by the FDA prior to final approval</p>
<p>(4) the date and price of acquisition if the drug was not developed by the manufacturer</p>	<p>JEMPERLI (NDC:00173089803) was developed by GSK</p>

Regards,

Jennifer Smith
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 US

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