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VIA E-MAIL

May 8, 2020

Office of the Vermont Attorney General
Attn: Jill Abrams, Assistant Attorney General
109 State Street
Montpelier, VT 05609
Jill.Abrams@vermont.gov

Re: Reasonable Assumption Related to 18 V.S.A. § 4637

Dear Assistant Attorney General Abrams,

I am writing to inform the Office of the Vermont Attorney General (the "Office") of a reasonable assumption Gilead Sciences, Inc. ("Gilead") is taking with respect to new drug notifications and reports ("New Drug Reports") pursuant to 18 V.S.A. § 4637 ("Statute").

Specifically, the term "new prescription drug" is undefined under the Statute and the Office has not issued any guidance to define such term. Pursuant to a phone call Gilead's outside counsel placed to the Office on March 30, 2020, the Office acknowledges that the Statute does not define "new prescription drug" and stated that the Office is not in the process of drafting any clarifying guidance on the matter. As a result, Gilead would like to inform the Office of the assumption it is taking with respect to the definition of "new prescription drug" as it relates to New Drug Reports.

I. Issue

The Statute asks that prescription drug manufacturers provide notification and additional information for "new prescription drugs." Specifically, the Statute provides the following:

> "A prescription drug manufacturer shall notify the Office of the Attorney General in writing if it is introducing a new prescription drug to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D program. The manufacturer shall provide the written notice within three calendar days following the release of the drug in the commercial market."
>
> 18 V.S.A. § 4637(b).
>
> "Not later than 30 calendar days following notification pursuant to subsection (b) of this section, the manufacturer shall provide all of the following information to the Office of the Attorney General in the format that the Office prescribes:
>
> (1) a description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally;

(2) the estimated volume of patients who may be prescribed the drug;

(3) whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval; and

(4) the date and price of acquisition if the drug was not developed by the manufacturer."

18 V.S.A. § 4637(c).

However, the Statute does not define "new prescription drug" and the Office has not issued any guidance providing an interpretation of "new prescription drug" as it applies to New Drug Reports.

II. Gilead's Reasonable Assumption

Section 4637(a)(2) of the Statute defines "[p]rescription drug" as "a drug as defined in 21 U.S.C. § 321" but does not define what constitutes a "*new* prescription drug" under the Statute (emphasis added). Other states with similar provisions to Vermont's New Drug Report requirements have issued regulatory and/or subregulatory guidance to clearly define "new prescription drug" as a drug receiving approval under an original New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), or a Biologics License Application (BLA) and some have clarified that each product listed on the application is considered a new prescription drug.[1]

Absent guidance from the Office, we reasonably assume that "new prescription drug" under Vermont's Statute refers to prescription drugs (1) receiving approval pursuant to an original NDA, ANDA, or BLA and (2) for those having already received FDA approval, that involve the introduction of a new dosage form as reflected in the new, FDA-approved labeling.

If you disagree with our interpretation above, please contact us in writing immediately.

[1]*See* California (Cal. Health & Safety Code § 127681(a), (b) and 22 C.C.R. § 96060(f), which defines "[n]ew prescription drug" as "a drug receiving initial approval under an original new drug application under Section 355(b) of Title 21 of the United States Code, under an abbreviated new drug application under Section 355(j) of Title 21 of the United States Code, or under a biologics license application under Section 262 of Title 42 of the United States Code. Each product listed on the application shall be considered a new prescription drug."); Oregon (ORS 750.055(2)(6) and OAR 836-200-0505(6), which defines "[n]ew prescription drug" as "a prescription drug that has received initial approval under an original new drug application under 21 U.S.C. 355(b), under an abbreviated new drug application under 21 U.S.C. 355(j), or under a biologics license application under 42 U.S.C. 262. In cases where multiple products are included on an application, each product will be considered a new prescription drug."); Maine (22 MRSA § 8732(1)(C) and Maine Health Data Organization Final Regulations, 90-590 Chapter 570, Section 1(I), which define "[n]ew prescription drug" as "a drug receiving initial approval under an original new drug application under Section 355(b) of Title21 [sic] of the *United States Code*, under an abbreviated new drug application under Section 355G) [sic] of Title 21 of the *United States Code*, or under a biologics license application under Section 262 of Title 42 of the *United States Code*. Each product listed on the application shall be considered a new prescription drug."); and New Hampshire (RSA 318:68(I), (II) and The State of New Hampshire Insurance Department Bulletin, Docket No: INS 20-017-AB, which defines "[n]ew prescription drug" as a "prescription drug that has received initial approval under an original new drug application under 21 U.S.C. 355(b), under an abbreviated new drug application under 21 U.S.C. 355(j), or under a biologics license application under 42 U.S.C. 262.").

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Please note that this letter and its contents are exempted from disclosure under the Vermont Public Records Law and Freedom of Information Act ("FOIA") as the material contains and constitutes Gilead's proprietary commercial information and otherwise would not be in the public interest to disclose. We ask that you please contact Gilead's General Counsel, available at generalcounsel@gilead.com, if you receive any Vermont Public Records Law or FOIA request so that we may take appropriate steps to work with you to protect such information.

Sincerely,

Kristie Banks

Kristie Banks
Vice President, Managed Markets Strategy & Operations
Gilead Sciences, Inc.