Otsuka

Otsuka-people creating new products for better health worldwide

Vermont Attorney General's Office
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March 29, 2019

Re: New Drug Information for ABILIFY MYCITE®

To Whom It May Concern:

In accordance with 18 V.S.A. § 4637, Notice of Introduction of New High-Cost Prescription Drugs (Act 193, 2018), below please find the additional information required within 30 days of notification of a new prescription drug being introduced to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D Program.

1. **A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally.**

   ABILIFY MYCITE® (aripiprazole tablets with sensor) is the first FDA-approved drug with a digital ingestion tracking system and is being marketed through a limited rollout of the product in the United States in close collaboration with select health plans and providers. ABILIFY MYCITE® has an ingestible sensor embedded in the pill that records that the medication was taken. The limited rollout will help prescribers, payers, and Otsuka learn from patients' experiences with the ABILIFY MYCITE® System and answer questions such as how the system fits best within the daily lives of those with serious mental illness and their loved ones; how doctors integrate this system into their daily practice; and how we can improve the system to better serve patients, healthcare providers and health plans.

   ABILIFY MYCITE®'s pricing plans are proprietary and Otsuka does not believe this information is in the public domain or otherwise publicly available. As a result, Otsuka is limiting its response pursuant to 18 V.S.A. § 4637(d).

2. **The estimated volume of patients that may be prescribed the drug.**

   Otsuka has not made any publicly available statements, or statements that are otherwise in the public domain, about the estimated volume of patients that may be prescribed ABILIFY MYCITE®. As a result, Otsuka is limiting its response pursuant to 18 V.S.A. § 4637(d).

3. **Whether the drug was granted breakthrough therapy designation or priority review by the federal Food and Drug Administration prior to final approval.**

   No.

4. **The date and price of acquisition if the drug was not developed by the manufacturer.**

   Not applicable.

If additional information is required please contact OAPIDrugPricing@otsuka-us.com.