

Souligny, Andre

From: Wozniak, Jon <jwozniak@dsi.com>
Sent: Thursday, January 16, 2020 2:32 PM
To: AGO - High Cost Prescription Drugs
Cc: Papandrikos, Gus; McCormick, Albert
Subject: RE: Notice of Introduction of New High-Cost Prescription Drugs

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Good Morning,

Following up on our notification of a new high-cost prescription drug from December 23, 2019, Daiichi Sankyo Inc. is providing below the responses to § 4637 Part C for Enhertu.

§ 4637 Part C

1. "A description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally"
The Company is committed to pricing its products fairly and appropriately, and acts independently when setting prices, by factoring in costs (including variation in dosing costs by patient), patient affordability under various coverage scenarios, market conditions, Payer and Physician responses, the state of competition, the medicine's expected impact on patients, a company's investment in research, development of the drug, fees associated with distribution, as well as producing and maintaining safety and quality. The Company evaluated the cost of biologics products to determine a price range for Enhertu; with additional consideration for total patient is dosed based on the weight of the patient with the average person needs 4 vials/3 week cycle to get to the 5.4mg/kg dose. For additional dosing information refer to product's Package Insert for the safety profile of the product in order to establish an average patient monthly cost.
2. "The estimated volume of patients who may be prescribed the drug."
Forecast Assumptions are not made public
3. "Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval"
Enhertu was granted both breakthrough therapy designation and priority review by the FDA prior to final approval.
4. "The date and price of acquisition if the drug was not developed by the manufacturer"
Enhertu was developed by Daiichi Sankyo, Inc.

Please let me know if there are any questions or issues.

Thank you,
Jon

Many Thanks!
Jon

From: Wozniak, Jon
Sent: Monday, December 23, 2019 10:19 AM
To: AGO.highcostprescriptiondrugs@vermont.gov

Cc: Papandrikos, Gus <kpapandriko1@dsi.com>; McCormick, Albert <amccormick@dsi.com>

Subject: Notice of Introduction of New High-Cost Prescription Drugs

Good Afternoon,

Pursuant to 18 V.S.A. § 4637 (Notice of Introduction of New High-Cost Prescription Drugs), Daiichi Sankyo, Inc. is writing to notify the Office of the Attorney General in writing of the introduction of 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.

Brand Name: ENHERTU

Chemical Name: fam-trastuzumab deruxtecan-nxki

Not later than 30 days from today, Daiichi Sankyo, Inc. will provide the AGO with the additionally required information from § 4637 subsection C which is in the public domain or otherwise publicly available.

Please let me know if there are any questions or issues.

Thank you,
Jon

Jonathan Wozniak

Associate Director – Compliance Monitoring & Transparency Reporting

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