

Notice of Introduction of a New Prescription Drug Pursuant to 18 V.S.A. § 4637

Dear Office of the Attorney General:

By email dated June 8, 2023, Otsuka America Pharmaceutical, Inc. (“Otsuka”) provided the required notice under 18 V.S.A. § 4637(b) that it had released ABILIFY ASIMTUFII® (aripiprazole) into the market at a Wholesale Acquisition Cost that exceeds the threshold set for a specialty drug under the Medicare Part D program.

Pursuant to 18 V.S.A. § 4637(c), Otsuka hereby provides the following information:

- (1) the description of the marketing and pricing plans used in the launch of ABILIFY ASIMTUFII in the United States and internationally is not in the public domain or publicly available;
- (2) the estimated volume of patients who may be prescribed ABILIFY ASIMTUFII is not in the public domain or publicly available;
- (3) ABILIFY ASIMTUFII was not granted breakthrough therapy designation or priority review by the FDA prior to final approval;
- (4) ABILIFY ASIMTUFII was developed by the manufacturer, therefore, the date and price of acquisition is not applicable.