May 10, 2024

SUBMITTED VIA EMAIL TO: comments.pdab@maryland.gov

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: Maryland Prescription Drug Subset List

Dear Members of the Maryland Prescription Drug Affordability Board,

On behalf of Takeda Pharmaceuticals America, Inc. ("Takeda"), I am writing regarding the inclusion of Vyvanse® (lisdexamfetamine dimesylate) on the list of drugs that the Maryland Prescription Drug Affordability Board ("PDAB") is considering for inclusion in the cost review process. We appreciate the opportunity to provide written feedback and respectfully ask that the PDAB remove Vyvanse from consideration for this review process in part because numerous generic versions of Vyvanse, covering all dosage forms and strengths of the product, have been approved and launched beginning in August 2023.[1] Of the eight products on the PDAB-approved list, Vyvanse is the only product with generic alternatives currently marketed in the United States.

Vyvanse is approved for the treatment of attention deficit hyperactivity disorder (ADHD) in adults and pediatric patients 6 years and older and for adults with moderate to severe binge eating disorder (BED). Although Vyvanse was selected for consideration based on 2022 data, patent protection covering Vyvanse and the associated FDA-granted regulatory exclusivity period expired in the U.S. in August 2023. Since that time, multiple manufacturers have launched AB-rated generic versions of lisdexamfetamine dimesylate. In fact, seven AB-rated generics launched immediately after Vyvanse loss of exclusivity occurred. To date, ten manufacturers have launched generic versions of lisdexamfetamine dimesylate, covering in total all dosage forms and strengths of Vyvanse. While the pricing by generic manufacturers varies, the weighted average Wholesale Acquisition Cost (WAC) for generic manufacturers across the six months from September 2023 to February 2024, was 47% lower than the Vyvanse WAC for the same period.[2]

Generic entry following the expiration of patent exclusivity organically creates market dynamics for increased patient choice and affordability, which can also achieve the PDAB goals of greater access and equity.[3] In fact, the FDA has shown that when six or more generic manufacturers are on the market, drug prices decreased more than 95%.[4] Generics often enter the market immediately upon patent expiration and some capture as much as 90% of the market within three months of becoming available.[5]

[1] Vyvanse formulations includes seven (7) capsule strengths (10mg-70mg) and six (6) chewable tablet strengths (10mg-60mg) all of which are also now approved by the FDA in generic version.
[2] Weighted average WAC Pricing information across generics based on WAC Pricing via Price Rx Feb 2024.
[3] "Bylaws of the Maryland Prescription Drug Affordability Board," https://pdab.maryland.gov/documents/pdab_Bylaws.pdf
[4] US Food and Drug Administration, "Generic competition and drug prices," https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm
[5] PhRMA Fact Sheet, "What is Hatch-Waxman," https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/Fact-Sheet_What-is-Hatch-Waxman_June-2018.pdf

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Vyvanse brand share erosion in the U.S. has been slightly milder than initially anticipated due to constraints of generic supply.[6] However, per statements made by generic manufacturers to FDA, these supply constraints are expected to begin to ease gradually over the coming months. As such, Takeda anticipates further Vyvanse brand share erosion over this timeframe, pending any additional constraints in the generics market. In the meantime, as noted in FDA's drug shortages record, Takeda is not experiencing manufacturing or supply delays for Vyvanse.[7] We remain confident in our capability to continue maintaining an adequate supply of Vyvanse to meet its U.S. forecasted demand.

Given the approval of ten AB-rated generic versions of lisdexamfetamine dimesylate and erosion of Vyvanse branded share, alternative cost containment strategies under consideration by the PDAB, such as an upper payment limit (UPL), may prove to be redundant and/or unnecessary to achieve the PDAB's affordability goals. **Therefore, we respectfully request that the PDAB remove Vyvanse from consideration for the cost review process**.

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Takeda is focused on creating better health for people and a brighter future for the world. We aim to discover and deliver life-transforming treatments. Together with our partners, we aim to improve the patient experience and advance a new frontier of treatment options through our dynamic and diverse pipeline.

Thank you for considering our comments. Should you have any questions, please contact me at william.gazda@takeda.com.

Sincerely,

William M. Gazda

William Gazda
Head – US Established Brands Portfolio
Takeda Pharmaceuticals America, Inc.

[6] Takeda Quarterly Earnings Report for the Quarter Ended March 31, 2024, https://assets-dam.takeda.com/image/upload/v1715219664/Global/Investor/Financial-Results/FY2023/Q4/qr2023_q4_qfr_en.pdf
[7] FDA, "Current and Resolved Drug Shortages and Discontinuations Reported to FDA," https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Lisdexamfetamine%20Dimesylate%20Capsule&st=c