May 3, 2023

Van T. Mitchell, Chair
Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: COMAR 14.01.02.02 – Prescription Drug Affordability Fund (Fee Assessment, Exemption, Waiver, and Collection) Amendments

Dear Chairman Mitchell:

Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer Ingelheim" or "The Company") is pleased to submit these comments in response to the Maryland Prescription Drug Affordability Board's ("PDAB" or "The Board") Draft Proposed Regulations for Comment, "Prescription Drug Affordability Fund (Fee Assessment, Exemption, Waiver, and Collection) Amendments". Boehringer Ingelheim's comments focus on the clause in the Proposed Regulation regarding the fees incurred by a manufacturer that qualifies for exemption under Section B(c) of the Prescription Drug Affordability Fund (Fee Assessment, Exemption, Waiver, and Collection) Amendments (COMAR 14.01.02.02).

Boehringer Ingelheim is a leading global research-driven biopharmaceutical company with extensive expertise developing therapies to treat a variety of chronic and life-threatening diseases. The Company is committed to ensuring that patients have access to life-saving treatments through lower costs and better alignment of health care systems.

I. Annual Fee Exemptions

According to Maryland statute (Health-General Article, Section §21–2C–11), the PDAB will assess and collect an annual fee on manufacturers that sell or offer prescription drug products to person in the State[1]. Currently, Boehringer Ingelheim contracts with UPS Supply Chain Solutions to provide general 3PL receiving, storage, and distribution services. UPS leases a facility at 700 Manor Park Dr in Columbus, Ohio, and uses it to perform these services. As a 3PL, UPS is not required to maintain a license with MD BOP.

According to the written statute, the aforementioned facility should receive exemption from the annual fees. Each year, the Company receives an invoice for this fee, for which the Company applies for an exemption. Thus, Boehringer Ingelheim recommends an addition be made to the amendments regarding this issue. **Specifically, Boehringer Ingelheim recommends that in**

[1] Health-General Article, Section §21–2C–11*:*
(b)(1) The Board shall assess and collect an annual fee on:
(i) Manufacturers that sell or offer for sale prescription drug products to persons in the State;
(ii) Pharmacy benefits managers, as defined in § 15-1601 of the Insurance Article;
(iii) Carriers, as defined in § 19-132 of this article; and
(iv) Wholesale distributors, as defined in § 12-6C-01 of the Health Occupations Article, that sell or offer for sale prescription drug products to persons in the State.

cases where an exemption has been granted, the Board should provide certification and acknowledgement that where no changes have occurred, manufacturers should not be required to undergo the process of exemption application each year.

According to Maryland statute (Health-General Article, Section § 21-2C-01), the definition of "Prescription drug product" refers to a brand name drug, a generic drug, a biologic, or a biosimilar[2]. Boehringer Ingelheim manufactures Animal Health (AH) products that provide advanced, preventive animal healthcare. These AH products are not included in the fee schedule statutory definition[2]; therefore, there should be no need to file an exemption and the Company should not receive an invoice. **Boehringer Ingelheim recommends that the Board specify and provide further clarification that these AH products do not require the filing of exemptions, as they do not fall within the definition of "prescription drug product".**

II. Conclusion

Boehringer Ingelheim appreciates the opportunity to provide feedback to the Committee and would welcome additional discussions of the recommendations and suggestions included in these comments.

Sincerely,

Bridget Walsh
Vice President
Government Affairs & Public Policy
Boehringer Ingelheim Pharmaceuticals, Inc.

SENT ELECTRONICALLY

[2] Health-General Article, Section § 21-2C-01:
(h) "Prescription drug product" means a brand name drug, a generic drug, a biologic, or a biosimilar.