Biosimilars FORUM

March 19, 2024

Administrator Chiquita Brooks-LaSure
CMS, Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-10858
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically via: www.regulations.gov

Re: Rebate Reduction Requests under Sections 11101 and 11102 of the Inflation Reduction Act (CMS-10858)

Dear Administrator Brooks-LaSure:

The Biosimilars Forum ("The Forum") appreciates the opportunity to comment on the Centers' for Medicare & Medicaid Services (CMS) *Information Collection Request: Rebate Reduction Requests under Sections 11101 and 11103 of the Inflation Reduction Act* (IRA), which was released by CMS on January 29, 2024. The Forum is a non-profit organization whose mission is to educate stakeholders on the value of biosimilar biological products (biosimilars) and advance biosimilars in the United States with the intent of expanding access to biological medicines (biologics) and improving health care. Our members represent the majority of companies with the most significant U.S. biosimilars development portfolios, including Amneal Pharmaceuticals, Biocon Biologics, Coherus BioSciences, Meitheal Pharmaceuticals, Organon, Pfizer, Samsung Bioepis, Sandoz, and Teva Pharmaceuticals.

The Forum is a voluntary group working on a consensus basis to develop policy positions to ensure the United States has a competitive, safe, and sustainable biosimilars market, providing more options to patients and physicians. Further, the Biosimilars Forum provides evidence-based information to support the development of public policies that encourage access to and awareness and adoption of biosimilars.

While the Forum supports the IRA's provision for inflation rebates owed for a Part B or Part D biosimilar to be waived or reduced in the event of a severe supply chain disruption or a probable risk of shortage, as determined by the agency, we contest the agency's claim that it lacks the necessary information to assess whether one of these scenarios is taking place. Moreover, the Forum contends that CMS's proposal to require manufacturers to submit requests for rebate reductions with supporting documentation would be duplicative of existing processes, unnecessarily increasing administrative burden on drug manufacturers.

In accordance with Sections 506C and 506E of the Food and Drug Administration's (FDA) Food, Drug, and Cosmetic (FD&C) Act, all manufacturers of covered and approved prescription drugs or biological products are required to inform the FDA of any manufacturing interruption for a product that could potentially lead to a significant disruption in supply. This mandatory notification process is designed to aid the FDA in complying with Section 506E of the FD&C Act, which requires the FDA to maintain a publicly available list of drugs in shortage. This list is required to provide: (1) the names and nationally determined contributions (NDCs) of the drug or biological product in subject; (2) the name of the manufacturer; (3) the reason(s) for the shortage; and (4) the estimated duration of the shortage.

We contend that this information, found in the FDA's Drug Shortage Database, is sufficient for CMS to determine whether severe supply chain shortages exist for the purposes of waiving the IRA inflationary rebate provisions. While CMS asserts that the agency consulted with the FDA, it is not clear why, once receiving a request from a manufacturer, that CMS could not then request the requisite information from the FDA. If not covered by an existing Memorandum of Understanding (MOU), CMS could enter an MOU with the FDA to obtain the needed information. There is precedent for this as early as June 23, 2010. CMS and the FDA can and should share information to reduce burden on manufacturers.

The Forum urges CMS to leverage this existing tool for such determinations instead of establishing an additional process for manufacturers to accomplish the same objective.

The Forum appreciates your consideration of its comments and looks forward to continuing to serve as a resource for CMS. If you have any questions regarding this response, please contact Juliana Reed at juliana@biosimilarsforum.org.

Sincerely,

Juliana Reed
Executive Director
Biosimilars Forum