



Ohio Public Employees Retirement System

May 3, 2017

Lauren D. Tesh, PharmD, BCPS
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
WO31-2417
Silver Spring, MD 20993-0002

Delivered electronically through <https://www.regulations.gov>

Reference: Docket No. FDA 2017-N-1063

To the Food and Drug Administration Oncologic Drugs Advisory Committee:

The Ohio Public Employees Retirement System (OPERS) appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee regarding the approval of Hospira Inc.'s, a Pfizer company, Biologics License Application (BLA) 125545, an epoetin alfa biosimilar to Amgen Inc's Epogen/Procrit. .

Upon learning that the FDA had accepted Hospira Inc.'s BLA for a biosimilar epoetin alfa, we felt that it was appropriate to offer our support. OPERS is the largest public retirement system in Ohio, and the twelfth-largest public retirement system in the United States. With more than 218,000 non-Medicare and Medicare Retiree Health Care participants, it is extremely important to us that costs within the health care system remain affordable and sustainable. The availability and accessibility of safe, effective, and affordable biosimilar and interchangeable products are an integral part of OPERS' strategy to manage its future prescription drug costs for its retiree health care plan and plan participants.

Hospira has submitted evidence, including analytical, animal and clinical studies, demonstrating that its epoetin alfa is biosimilar to the US-licensed reference product (Amgen's Epogen/Procrit) for the following indications:

- 1) For the treatment of anemia due to chronic kidney disease, including patients on dialysis and not on dialysis, to decrease the need for red blood cell (RBC) transfusion;
- 2) for the treatment of anemia due to zidovudine administered at $\leq 4,200$ mg/week in HIV-infected patients with endogenous serum erythropoietin levels of ≤ 500 m units/mL;
- 3) for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy; and
- 4) to reduce the need for allogeneic RBC transfusions among patients with perioperative hemoglobin > 10 to <13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, and nonvascular surgery.

OPERS believes that the FDA's approval of Hospira's epoetin alfa filing will increase patient access to high quality biological medications, while also reducing the financial burden on primary payers such as the federal government and health plan sponsors. OPERS believes that access and affordability go hand-in-hand. Biological products may revolutionize medical care, but only if patients and payers can afford them. The availability of safe, effective, and affordable biosimilar products will ensure that more patients have access to these life-changing medications. Access means earlier and more consistent treatments, the opportunity to slow the progression of diseases and reduce episodes, and may address some of the social and psychological costs associated with disease management. Improving access is the long-term goal, and will require changes in the ways we manufacture, prescribe, consume, and pay for prescription drugs. But, the FDA can take steps to improve access today by approving Hospira's epoetin alfa filing.

As this application is for the first epoetin alpha to be considered under the biosimilar pathway established by the Biologics Price Competition and Innovation Act, OPERS requests favorable consideration for Hospira's epoetin alfa submission.

Comment

In 2016, OPERS' total non-Medicare prescription drug cost was \$187.5 million, \$66.5 million of which was spent on specialty/biological drugs. Although only 3% of current OPERS Retiree Health Care participants utilize specialty drugs, these medications account for 35% of our overall drug spend and represent the fastest growing segment of our annual drug cost. In the absence of biosimilar and interchangeable products, specialty drug costs are projected to grow 14-17% per year through 2021.ⁱ

Biosimilar and interchangeable product competition is a necessary part of OPERS' long-term strategy to manage the growth of its health care expenditures and increase patient access to affordable, high quality biological drugs. These innovative biological medicines do and will continue to have the potential to revolutionize medical care in the future, but only if plan sponsors and consumers can afford to cover and purchase them. Marketplace competition is one of the most effective tools we have for managing prescription drug cost inflation moving forward. We believe the Agency is uniquely positioned to protect and promote the public health while also developing policies that facilitate biosimilar and interchangeable products becoming a quick and viable alternative in the marketplace. Therefore, OPERS urges the FDA to improve patient access and enhance marketplace competition by accepting Hospira's BLA for epoetin alpha.

We thank you again for the opportunity to provide comments on this process. If you have questions or would like additional information regarding OPERS' comments, please contact Brian Pack, OPERS' Health Care Finance and Policy Officer, at 614-225-1858.

Sincerely,

A handwritten signature in blue ink, appearing to read "Tonya Brown".

Tonya Brown
Interim Director of Member Operations

ⁱ QuintilesIMS Institute. Outlook for Global Medicines through 2021, December 2016.