



June 28, 2016

Moon Hee Choi
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue, Bldg. 31, Room 2417
Silver Spring, MD 20993-0002

To the Food and Drug Administration Arthritis Advisory Committee:

The Ohio Public Employees Retirement System (OPERS) appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) Arthritis Advisory Committee supporting the approval of Sandoz's Biologics License Application (BLA) 761042 for GP2015, an etanercept biosimilar to Amgen's ENBREL (etanercept).

OPERS has 222,000 non-Medicare and Medicare Retiree Health Care Program participants, and ensuring that costs within the health care system remain affordable and sustainable is of paramount concern to us. The availability and accessibility of safe, effective, and affordable biosimilar medications is an integral part of OPERS' long-term strategy to manage its future prescription drug costs for our retiree health care plan and plan participants.

Sandoz has submitted significant evidence demonstrating that its etanercept is biosimilar to the US-licensed reference product (Amgen's ENBREL); for the proposed indications:

- 1) Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (in combination with methotrexate (MTX) or used alone);
- 2) Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages two and older;
- 3) Reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis (in combination with MTX in patients who do not respond adequately to MTX alone);
- 4) Reducing signs and symptoms in patients with active ankylosing spondylitis; and treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

The BLA consists of a comprehensive data package that includes data from analytical, functional, pre-clinical and clinical studies; a pharmacokinetic study in health volunteers and a confirmatory safety and efficacy study in patients with chronic plaque psoriasis that provides confirmation of similarity to the reference product established in prior analytical comparability investigations.¹

OPERS supports the FDA's stringent 351(k) approval process for biosimilars and interchangeable biologicals, where sponsors must use a stepwise approach to develop the evidence needed to demonstrate biosimilarity and the FDA considers the totality of the evidence provided by a sponsor to evaluate the sponsor's demonstration of biosimilarity.

¹ Biosimilar News, "The FDA Accepts SFDA Accepts Sandoz Regulatory Submission for a Proposed Biosimilar Etanercept," October 5, 2015 <http://www.biosimilarnews.com/fda-accepts-sandoz-regulatory-submission-for-a-proposed-biosimilar-etanercept>.

OPERS also supports the FDA's current practice of science-based extrapolation, where safety, potency, and purity are confirmed, after which extrapolation occurs for the other indications of the reference product (that are not protected by exclusivity). Extrapolation to all indications of the reference product is not an extrapolation from a single study of the biosimilar to those other indications. Extrapolation relies on demonstrating biosimilarity and any clinical study provides the final data component confirming similarity.²

As this application is among the first to be considered under the biosimilar pathway established by the Biologics Price Competition and Innovation Act (BPCIA), OPERS requests favorable consideration for Sandoz's etanercept submission. Also, OPERS respectfully requests that the FDA:

1) Finalize All Biosimilar Guidance Pertaining to the Biologics Price Competition and Innovation Act

OPERS has supported the FDA's efforts to implement the biosimilar pathway described in the BPCIA. With two biosimilar products approved for sale and others being offered for consideration and approval, it is important that the FDA provide a clearly defined pathway for manufacturers who may be considering their own biosimilar medications by finalizing its existing guidance regarding biosimilar products. In so doing, the FDA will help to ensure that the new biosimilar pathway encourages development and market adoption of biosimilar products, as intended by the authors of the BPCIA. Many stakeholders, including OPERS, are depending on the success of the biosimilar pathway and its impact on the prescription drug market. We remain concerned that, seven years after the passage of the BPCIA, the US has approved only two biosimilars, while the European Union has approved more than 20 biosimilar medications.

2) Reconsider Guidance on Nonproprietary Naming of Biological Products

OPERS urges the FDA to reconsider its current proposal regarding the naming of biological products and adopt the standard United States Adopted Name (USAN) naming system, for all biosimilar and interchangeable biosimilar products. As noted in OPERS' previous comments on the issue, the use of an additional four-letter suffix to distinguish various biosimilar and interchangeable biological products would increase patient and provider confusion and discourage market adoption of biosimilar medications, thereby undermining efforts to improve patient access.

3) Reconsider Guidance on Labeling for Biosimilar Products

OPERS urges the FDA to reconsider its current proposal regarding the labeling for biosimilar products. OPERS believes that biosimilar products should be labeled like generic drugs, which are not required to have distinct labeling from reference brand drugs. Requiring distinct labeling for biosimilar products will lead to unwarranted safety concerns among physicians and patients, which will decrease market adoption of biosimilar medications, thereby negatively impacting affordability and access.

4) Release Guidance that Increases Competition by Supporting the Development of Interchangeable Biological Products

OPERS respectfully requests that the FDA release guidance that (1) provides clear rules for the designation of a biosimilar product as "interchangeable" or "substitutable" with a reference brand biologic,³ and (2) allows manufacturers to apply for interchangeability in an original 351(k) application.⁴ The opportunity to have a medicine declared "interchangeable" or "substitutable" has played a large role in the success of the existing generic drug market and will contribute significantly to the success of the biosimilar market.

² McCamish et al, "Toward Interchangeable Biologics," *Clinical Pharmacology & Therapeutics*, Clinical Pharmacology & Therapeutics, Volume 97, No. 3, March 2015.

³ "Reference brand product" refers to the single biological product licensed by the FDA under section 351(a) of the PHS Act against which a proposed biosimilar biological product is evaluated in its biosimilar application.

⁴ "351(k)" refers to the abbreviated licensure pathway that permits a biosimilar biological product to be licensed under 351(k) of the Public Health Service Act.

Additionally, OPERS respectfully requests that the FDA and/or US Department of Health and Human Services adopt a clear preemption policy to preclude conflicts with state laws regarding substitution and promote consistency with the definition of interchangeability under the BPCIA.

Comment

In 2015, OPERS' total prescription drug cost was \$706 million, \$174 million of which was spent on specialty drugs. Although only 3.1% of current OPERS Retiree Health Care Program participants utilize specialty drugs, these medications account for 25% of our overall drug spend and represent the fastest growing segment of our annual drug cost. According to Express Scripts' 2015 Drug Trend Report, specialty drug costs are projected to increase an average of 17.1% per year for the next three years.⁵

Biosimilar competition is a necessary part of OPERS' long-term strategy to manage the growth of its health care expenditures and improve patient access to safe, effective, and affordable biological products. We believe the FDA's current 351(k) approval process and use of extrapolation of clinical data across indications support the development and proliferation of biosimilar products within the marketplace. Biological products have the potential to revolutionize medical care in the future, but only if plan sponsors and patients can afford them.

We urge the FDA to accept Sandoz's etanercept BLA based on the totality of the evidence they have provided. Additionally, we respectfully request that the FDA: (1) finalize all biosimilar guidance pertaining to the BPCIA, (2) reconsider its guidance regarding the nonproprietary naming of biological products, (3) reconsider its guidance on labeling for biosimilar products, and (4) release guidance that increases competition by supporting the development of interchangeable biologic products.

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,



Marianne Steger, MS, CEBS
Director, Health Care

⁵ Express Scripts, Inc., The 2015 Drug Trend Report, <http://lab.express-scripts.com/lab/drug-trend-report>, March 2016.