

February 9, 2016

BPC Statement on FDA Arthritis Advisory Committee Meeting

On Tuesday, February 9th, the U.S. Food and Drug Administration (FDA) met with its Arthritis Advisory Committee to discuss Celltrion's Remsima, a proposed biosimilar of Johnson & Johnson's Remicade and most likely the second biosimilar to be approved in the U.S. The Biologics Prescribers Collaborative (BPC) along with five other physician groups - Alliance for Patient Access, American Association of Clinical Endocrinologists, Coalition of State Rheumatology Organizations, American College of Rheumatology, and Endocrine Society - submitted a comment to FDA's Arthritis Advisory Committee acknowledging the agency's continuing commitment and careful deliberation on biosimilar-related issues. While this new type of treatment option could change the face of medicine, their availability will increase the complexity of the treatment landscape and this meeting represented an important step towards expanding patient access to these lifesaving therapies.

Twenty-one members of the Arthritis Advisory Committee recommended the FDA approve this biosimilar candidate, while three members voted "no" that the FDA should not approve the application. Committee discussion included many of the safety and efficacy issues that need to be addressed as biosimilars market continues to grow. It is imperative that sound policies are in place to promote the fully informed and safe use of biosimilars. Therefore, BPC asks the FDA to consider the following factors as biosimilar-related policies are implemented:

- Each biological product needs a distinguishable non-proprietary name
- Biosimilar product labeling must contain all needed data for physicians to make appropriate prescribing decisions for their patients
- Proceed with extreme caution when considering biosimilar application requests for indication extrapolation

With nearly 60 biosimilar products awaiting FDA's approval, BPC looks forward to additional advisory committee hearings and will continue providing the critical perspective of biologics prescribers to ensure patient safety.

The full statement to FDA's Arthritis Advisory Committee can be found below or on the BPC website:
<http://biologicsprescribers.org/resources/comment-to-the-arthritis-advisory-committee-regarding-bla-125544>

For additional information, please contact BPC's lead physician co-convener Dr. Dennis R. Cryer, M.D.

February 3, 2016

Comment to the Arthritis Advisory Committee

RE: February 9, 2016 meeting to discuss biologics license application (BLA) 125544

Stephanie L. Begansky, PharmD
Center for Drug Evaluation and Research, Food and Drug Administration
10903 New Hampshire Avenue (WO31-2417)
Silver Spring, MD 20993-0002
AAC@fda.hhs.gov

As physicians who routinely prescribe biologic medicines and on behalf of professional organizations with numerous biologics prescribers as members, the Biologics Prescribers Collaborative (BPC) supports sound policies that promote the fully informed and safe use of biologics, including biosimilars, for all patients. We appreciate this opportunity to share our perspective on issues critical for the safe use of biosimilars, as well as other biologics, before the Arthritis Advisory Committee. Our comments will therefore be general, addressing these issues rather than a specific biosimilar.

First, each biological product needs a distinguishable non-proprietary name.

FDA's draft guidance calls for all biological products to bear a nonproprietary name that includes a four-letter suffix. We agree with FDA, which explained, "there is a need to clearly identify biological products to improve pharmacovigilance, and, for the purposes of safe use, to clearly differentiate among biological products that have not been determined to be interchangeable." However, our experience as biologics prescribers tells us that in addition to being unique, the suffix must also be memorable.

The randomized four-letter code proposed by the agency may complicate pharmacovigilance and permit inadvertent substitution. A memorable suffix that reflects the license-holding manufacturer equips patients, physicians and pharmacists to accurately recall or ascertain specifics about the biosimilar that may differ from those of the originator, such as approved indications, administration routes or delivery systems. It will also facilitate prompt, accurate adverse event reporting by patients and physicians to the correct manufacturer, and mandated manufacturer reporting to FDA.

Second, biosimilar product labeling must contain all needed data for physicians to make appropriate prescribing decisions for their patients.

The label is a critical tool for physicians to make prescribing decisions and manage potential adverse events, including side effects and drug-drug interactions. As such, it is of the utmost importance that any drug label be complete and accurate. A biosimilar label identical to that of its reference product omits readily available, product-specific data and may imply that a biosimilar is interchangeable with the reference product and approved for all of the same indications when it may not be.

Further, given that a biosimilar – unlike a generic small molecule – has its own clinical data, there will likely be specific information from this data package that will help physicians, including the provision of information on immunogenicity, which can vary from the reference biologic. Greater transparency and inclusion of data will protect patients while increasing physician confidence in the use of biosimilars and encouraging greater and informed utilization.

Third, FDA should proceed with extreme caution when considering biosimilar application requests for indication extrapolation.

Biologic medicines are often used to treat multiple and unrelated disease states and indications. Historically, when a new biologic medicine has been approved for a disease state, complete clinical trials have been conducted. FDA reviews that data in making its determination. Under the new abbreviated approval process, data is presented for certain indications but not for others. As FDA considers which disease states and indications a particular application receives approval for, we urge caution in approving medicines for diseases for which no clinical data is being produced. Simply because one biologic medicine has proven effective in multiple disease states does not ensure that a biosimilar product will have the same effect or efficacy. FDA should continue to act to ensure the utmost safety and confidence in new medicines.



We thank FDA for allowing us to submit these comments to the Arthritis Advisory Committee. This comment is submitted by specific members of the **Biologics Prescribers Collaborative** including:

Alliance for Patient Access

American Association of Clinical Endocrinologists

Coalition of State Rheumatology Organizations

American College of Rheumatology

Endocrine Society