FDA and CTTI Patient Engagement Collaborative Meeting

April 25, 2024 | 1:00 – 2:00 pm ET | Zoom Virtual Meeting

Disclaimer: *The purpose of this meeting was to facilitate a discussion of ideas, and as such, not all of the content below will be within the scope of the FDA or PEC. The views and opinions expressed in this meeting are those of the individual speakers and participants and do not necessarily reflect the official views of their organizations, the FDA, or CTTI.*

Meeting Overview

The purpose of this virtual meeting was to discuss the FDA Office of Therapeutic Biologics and Biosimilars' efforts to educate patients and health care providers around biosimilars – medications that are highly similar versions of existing FDA-approved biologic medications. This meeting included a review of biosimilars and interchangeable biosimilars and background on the educational resources and dissemination practices the FDA has used to educate and inform patients and health care providers.

Education Efforts to Help Increase Biosimilar Understanding and Acceptance

- Most biologics are made from living sources, such as animal cells and microorganisms like bacteria or yeast. Because biologics generally come from living sources and have natural differences, they can be more complicated to produce than drugs made from chemicals.
- A biosimilar is very similar, but not identical, to an original biologic medication (reference product) that the FDA has already approved.
- For biosimilars to be approved by the FDA, studies must show that there are no clinically meaningful differences from the original biologic, including no differences in safety and effectiveness.
- Interchangeable biosimilars are biosimilars that could be substituted at the pharmacy for the reference product without the intervention of the prescribing health care provider – much like how generic drugs are routinely substituted for brand name drugs.
- The FDA did research with health care providers and patients to evaluate baseline knowledge and perceptions around biosimilars, assess communication needs, and test communication materials.

- The FDA has created several webpages, fact sheets, infographics, videos, educational courses, and other resources to inform and educate patients and health care providers about biosimilars and interchangeable biosimilars. They have also engaged in a variety of dissemination strategies to spread this information. You can find all the materials at www.fda/gov/biosimilars

Conclusion and Next Steps

The FDA and CTTI will review the discussion points and ideas generated during this virtual meeting. The FDA will share comments from this meeting with agency departments to facilitate engagement with patient communities and PEC members. The fourth annual joint meeting between the PEC and the European Medicines Agency's (EMA) Patients' and Consumers' Working Party will be held on June 18, 2024.

The PEC is a public-private partnership between the FDA and the Clinical Trials Transformation Initiative (CTTI) that is not intended to advise or direct the activities of either organization. The PEC is primarily a forum to facilitate the exchange of information between patient community representatives and the FDA on areas of common interest, including regulatory discussions and strategies to increase patient engagement. Public summaries of all PEC meetings are available on the PEC website.