BIOSIMILAR USER FEE ACT (III) PERFORMANCE GOALS LETTER WILL HELP INCREASE OPTIONS FOR PATIENTS AND PROMOTE COMPETITION

The Biosimilar User Fee Act (BsUFA) was first authorized in 2012 as part of the Food and Drug Administration Safety and Innovation Act (FDASIA) to supplement the Agency's resources to implement a biosimilar approval pathway and promote greater consistency, efficiency and predictability in the review of biosimilar medicines. Congress created the abbreviated approval pathway for biosimilars while maintaining 12 years of data protection for innovative biologics, balancing the goals of reducing health care costs with preserving innovation by creating additional competition in the marketplace.

Recently, the U.S. Food and Drug Administration (FDA) released the Performance Goals Letter for BsUFA III[1]. Each BsUFA reauthorization period provides an opportunity for stakeholders to enhance their commitment to advancing initiatives that support the efficient development and review of biosimilar and interchangeable biosimilar products.

Biosimilars are playing an increasingly critical role in bringing new options to patients and increasing competition in the marketplace.

Currently, there are 31 FDA-approved biosimilar products[2], including one interchangeable biosimilar. In addition, the FDA reported as of June 2021, there are nearly 100 biosimilars in development for which sponsors are paying BsUFA fees and benefiting from BsUFA-supported meetings with the FDA. And while the U.S. has not had a biosimilar market in place as long as the European Union (EU), the U.S. market has significantly evolved over the last decade and is rapidly gaining ground. In fact, the U.S. has approved more biosimilar products than the EU had in a comparable period of time. This is largely due to the regulatory predictability and efficiencies that have been provided by the FDA's successful implementation of the abbreviated approval pathway for biosimilars and the resources provided through BsUFA.

As a result of growing competition, annualized savings due to biosimilars reached $6.5 billion[3] in 2020 and potential savings are estimated to exceed $100 billion over the next four years. Many innovator medicines are now competing with multiple biosimilar versions, with two originator biologics each currently facing competition from 4-5 biosimilars. In 2020, the biosimilar average sales prices were as much as 45% less[4] than originator products.

BsUFA III initiatives will build on the success of the program and help increase timely access to safe and effective biosimilar products. In helping provide FDA with the resources needed to enhance the development and review of biosimilars, BsUFA III will, in turn, help increase competition in the marketplace to the benefit of patients.

Key provisions outlined in the BsUFA III Performance Goals Letter include:

- Advancing development of interchangeable biosimilar products, including additional guidance to sponsors, and piloting a regulatory science program with demonstration projects focused on advancing the development of interchangeable biosimilar products and improving the efficiency of biosimilar product development.
- Commiting to timelines for review of certain application supplements, including those seeking to update safety labeling to reflect changes to the reference product labeling, to provide enhanced consistency and predictability of review timelines.
- Enhancing manufacturing inspection-related communications and modernizing facility assessment approaches.
- Modernizing FDA's information technology infrastructure and supporting adoption of cloud-based technologies.
- Enabling timely interactions between sponsors and the FDA during biosimilar development and review, including establishment of a new meeting type for rapid, targeted feedback.
- Enhancing FDA hiring, retention and financial management.

PhRMA looks forward to working with Congress, the administration, patient and medical provider groups, the FDA and other stakeholders to ensure timely reauthorization of the BsUFA program as we continue working together to help patients live longer, healthier lives.

Learn more about biosimilars and PhRMA's BsUFA III priorities at PhRMA.org/Biosimilars.

Endnotes:

1 https://www.fda.gov/media/152279/download

2 https://www.fda.gov/drugs/biosimilars/biosimilar-product-information

3 https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/iqvia-institute-biosimilars-in-the-united-states.pdf?_=1606843358393

4 https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/iqvia-institute-biosimilars-in-the-united-states.pdf?_=1606843358393