



July 12, 2016

Arthritis Advisory Committee Biosimilars Council Comments on the Biosimilar Approval for Adalimumab

Introduction:

Thank you. My name is Christine Simmon, and I am Executive Director of the Biosimilars Council (Council) and Senior Vice President of the Generic Pharmaceutical Association (GPhA), providing some brief comments on behalf of our members. I have no disclosures to make.

On behalf of our members, I would like to commend the Agency on its continued progress in its implementation of the Biologics Price Competition and Innovation Act (BPCIA). We greatly appreciate the work the agency has done towards the creation of a regulatory framework that maximizes patient access to these medicines. The Council was pleased recently to ratify the BSUFA II Goals Letter to facilitate product reviews.

The Biosimilars Council is a division of GPhA, which works to ensure a positive environment for biosimilar products, and works to educate policymakers, providers and patients about biosimilars. Areas of focus include education, access, the nascent regulatory environment, reimbursement, and legal affairs. Member organizations include companies and stakeholder organizations working to develop biosimilar products with the intent to compete in the U.S. market.

Biologic medicines are often the only lifesaving treatments for some of the most severe diseases suffered by patients. However, the high cost of these treatments frequently keeps them out of reach for many patients. Our manufacturers and others look forward to bringing life-saving biosimilar medicines to the U.S and strive to promote patient access through savings.

Science supporting biosimilar approvals and FDA expertise:

The Council recognizes that development, production and approval of biosimilar products must be grounded in sound science. As part of the BPCIA, FDA was granted important discretion to determine scientific requirements on a case by case basis to ensure safety and efficacy. Therefore, FDA can require any information that is necessary to support a determination that the biosimilar product is ‘highly similar’ and has ‘no clinically meaningful differences.’

In making these determinations, the Agency relies upon the same scientists that assess applications for new biological products, and who are experienced with the product or product class. Thus, the scientific underpinnings for biosimilar approvals will represent all necessary robust and rigorous scientific approaches as determined by FDA. The foundation of biosimilar development is based on extensive analytical characterization of the application, as well as any



necessary additional clinical trials. As such, the Council is confident in the FDA and the process, and we will continue to work to educate providers and patients so they can be too.

That is why the Council has opposed regulatory guidance requiring a statement of biosimilarity on the product label. In most cases, the scientific information necessary to approve a biosimilar will primarily focus on establishing biosimilarity between the two products. This means that safety and efficacy information will come from studies of the reference product rather than the biosimilar. Including a biosimilar product's biosimilarity data in addition to that of the reference product would only provide unnecessary information and create confusion for prescribers and patients.

This differentiation between biosimilars and their reference products risks undermining the important provider education that is being done by the FDA today. Informing providers that “biosimilars have no clinically meaningful differences in terms of safety, purity and potency (safety and effectiveness) from the reference product”, while requiring a differentiator in the labeling sends mixed signals to providers responsible for driving patient familiarity and comfort with these products.

Additionally, extrapolation of data is already an established scientific and regulatory principle that has been utilized for many years by the innovator industry. For example, in the case of major changes in the manufacturing process of innovator biologicals, FDA has used comparability, or extrapolation of information, for nearly 20 years. In such cases, clinical data are typically provided to confirm safety and efficacy of one indication and, taking into account the totality of information gained from the comparability exercise. Based on the acceptable outcome of the comparability and clinical evaluations, the data may then be extrapolated to the other indications.

Summary:

In conclusion, the Council applauds the Agency for its effort to support the biosimilar pathway in the United States and for the opportunity for public comment at today's meeting. Approval of biosimilars appropriately represents a high scientific standard for sponsors to assure that the biosimilar provides the same safety and efficacy for the same indications as the innovator product. FDA's extensive experience with the scientific methods used to confirm similarity can safely be used to approve the same indications as the innovator product. Ultimately, patients will benefit from the efforts of sponsors and the FDA in bringing biosimilar products to the U.S. market.