PUBLIC MEETING ON BSUFA REAUTHORIZATION

The Biosimilars Council
A Division of GPhA

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About the Biosimilars Council

The Biosimilars Council, a division of the Generic Pharmaceutical Association (GPhA), works to ensure a positive environment for patient access to biosimilar medicines. The Biosimilars Council is a leading source for information about the safety and efficacy of these more affordable alternatives to costly brand biologic medicines. Areas of focus include public and health expert education, strategic partnerships, government affairs, legal affairs and regulatory policy. More information is available at www.biosimilarscouncil.org.

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Council Membership

13 Member Companies

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Impact of Biosimilars on Patients

- Biosimilars and interchangeable biological products hold great promise, not just for consumers and the pharmaceutical industry, but for sustaining a healthcare system with finite resources.
- By 2016 it is predicted that eight of the top ten most dispensed pharmaceuticals in the U.S. will be biologics.
- Express Scripts estimates potential savings of $250 billion in the next decade with the approval of just 11 biosimilar products.

Where things stand in implementing BsUFA I

FY2013 Final and FY 2014 Preliminary BsUFA Performance Metrics

- FDA has expended a considerable effort in drafting guidances, some of which are now final. FDA has met with multiple sponsors and to date, there are estimated to be around 50 products under development in the U.S. in the BsUFA pathway.
- Although it may be too soon to judge the Agency's performance on applications given the number of submissions, the BsUFA program can be evaluated for the biosimilar-related work that consumed the greatest amount of FDA resources - development phase support (categorized as meeting management in FDA performance goals) and policy.
- To date, 8 BLAs have been announced as submitted to FDA and the action date for 5 of these submissions has passed. We only know the review outcome and timing for 2 of these 5. And for the 2, FDA has completed their review within the 10 month goal – Sandoz' filgrastim with an approval and Pfizer's epoetin alfa with a complete response letter. Of the remaining 3 we do not have public information concerning their status. Overall, there are fewer biosimilars approved at this point in time than FDA had predicted.

Where things stand in implementing BsUFA I

- Development phase support or meeting management is the predominant activity where improvement is needed.
  - FY 2013 BsUFA Performance Report found that all 3 goals not met related to meeting management
  - FY 2014 Report (Preliminary) found that of 7 goals where there is a potential to miss, 6 relate to meeting management
- According to the Eastern Research Group (ERG) BsUFA workload study meetings and policy development consumed a majority of CDER staff activities:
  - 45% meeting activities
  - 19% policy activities
  - 7% BLA review (2 BLAs submitted by FY14, 3 in first quarter of FY15, first licensure March 2015)

Assessment of current BsUFA process

- We have found interactions with FDA under BsUFA constructive.
- We believe a 10-month review clock for biosimilars, which is two months less than that of standard PDUFA drug review is justified because FDA is granting multiple development meetings prior to the BLA submission, allowing for extensive feedback and alignment prior to submission in order to improve the completeness and quality of BLAs.
- These multiple meetings permitted under BsUFA enable industry to obtain extensive feedback which in turn led to improved dossiers.
- At present, FDA is expending a very significant portion of biosimilar resources on regulatory policy issues. We are hopeful that these issues will be resolved in the near future, which will free up significant resources to provide timely and detailed feedback to sponsors and for product reviews.

Biosimilar Policy Activities

- To date FDA has issued 4 final and 8 draft biosimilar guidances, plus a proposed rule on nonproprietary naming.
- It is critical that FDA continue to provide guidance to industry and proceed with the outstanding guidances the agency said would be introduced this year (including interchangability, labeling, statistical considerations for demonstrating analytical similarity).
- Additionally, FDA should prepare a guidance to address life-cycle management or post-approval requirements covering topics such as requirements for biosimilar and interchangeable biologics as well as supporting manufacturing changes such as the need to establish similarity to originator or comparability to approved biosimilar.

Future State

- Increase and strengthen FDA resources and capabilities to improve the review and approval of these critical products .
  - Staffing goals should be met at FDA commitment levels.
  - Advisory Committees should increase the number of scientific experts from outside the agency. More analytical and functional experts with a strong understanding of the science of comparison and the assessment of biosimilarity should be added. They are imperative since the risk/benefit considerations for biosimilars are highly driven by analytical and functional data.

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Future State

- Maximize the efficacy of FDA meetings and improve the outcomes of meetings.
  - A clear process with timelines should be established for follow-up clarifications to a BsUFA meeting.
  - Application Orientation meetings, permitted under PDUFA and very beneficial to FDA reviewers, should be encouraged in BsUFA.
- Additional touch points during the review of a 351(k) BLA.
- Type 2 meetings should be specifically authorized to provide written advice on whether the achievement of certain pre-defined product quality attributes would enable the use of a targeted clinical program and allow for a determination of interchangeability.

Provider, Prescriber & Patient Education

FDA and industry need to work collaboratively to create a public education campaign around biosimilars. These collaborative educational efforts will provide a key and independent source of information regarding biosimilar products, their safety and scientific development. Additionally, other key stakeholders (e.g., payors, patients, clinicians) would contribute to an extensive educational campaign.

Thank You

- Given the strong public health need for more affordable biologics, it is critical for FDA and industry to focus negotiations on efforts to ensure more timely patient access to these more affordable, high quality biosimiliars.

- The Biosimilars Council thanks FDA for their accomplishments under BsUFA I and looks forward to working with FDA on BsUFA II reauthorization.