Biosimilars Action Plan Report Card

In July of 2018, the U.S. Food and Drug Administration (FDA) released the Biosimilars Action Plan (BAP). The plan detailed key actions to promote innovation and competition among biologics and enhance the development of biosimilars, potentially lowering costs for patients and payors. At the one year mark, the agency has made significant progress with the BAP, but more can be done to ensure biosimilars are approved as efficiently as possible.

BAP INITIATIVE	STATUS	DETAILS
Improve the efficiency of the biosimilar and interchangeable product development and approval process.		
Application review templates for 351k Biologics License Applications (BLAs)	🔴	No new application review templates.
Develop an index of critical quality attributes for use in comparing biosimilars to reference products	🔴	No updated index of critical quality attributes for use in comparing proposed biosimilars to certain reference products since 2016.
Develop effective communications to improve understanding of biosimilars among patients, clinicians and payors.		
Outreach Campaign	🟢	An outreach campaign launched in September 2018 outlining steps to educate and inform physicians, pharmacists, and patients about biosimilars and interchangeability.
Develop shareable one-pager and video communications for patient audiences	🟢	Videos and graphics have been created and shared on social media beginning in Fall 2018.
Webinar on labeling and prescribing biosimilar and interchangeable products	🟢	A webinar titled "Biosimilar and Interchangeable Products in the U.S.: Scientific Concepts, Clinical Use, and Practical Considerations" was hosted in December 2018.
Maximize scientific and regulatory clarity for the biosimilar product development community.		
Guidance on Implementation of the "Deemed to be a License" Provision of the Biologics Price Competition and Innovation Act of 2009	🟡	Final guidance was released December 2018. However, the policy announced in the Final Guidance (and the delay in issuing it) led to a "regulatory dead zone", slowing development of products affected by the guidance.
Guidance on Considerations in Demonstrating Interchangeability with a Reference Product	🟢	Final guidance was released in May 2019 which allows the use of non-U.S. reference product in development.
Guidance on Statistical Approaches to Evaluate Analytical Similarity	🟢	FDA issued revised draft guidance that reflects significant improvements over the previous withdrawn draft.
Guidance on Reference Product Exclusivity for Biological Products	🟡	Draft guidance issued in 2014 and FDA continues to update the Purple Book with exclusivity information, although gaps remain.
Guidance on processes and considerations related to post-approval manufacturing changes for biosimilar biological products	🟡	FDA provided limited guidance in a single Q&A in a 2018 draft guidance document, which references a final 2005 ICH guidance on comparability testing.
Develop an enhanced Purple Book to include a modernized, interactive user experience	🔴	No action has been taken to enhance the Purple Book.

🔴 No Formal Action Taken 🟡 Action In Progress 🟢 Action Completed

Biosimilars Council
A Division of AAM

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