AMCP PARTNERSHIP FORUM
No. 3 — 2020

EXECUTIVE **SUMMARY**

Biosimilars: Policy, Practice, and Post-Marketing Surveillance to Support Treatment and Coverage Decisions

With the dual goals to identify key actions that can support the further development and use of biosimilars in the U.S. health care system and to provide consistent and accurate messages about the value of biosimilars, AMCP held a multidisciplinary stakeholder virtual Partnership Forum from Dec. 15–16, 2020. A variety of participants, including payers, pharmacists, integrated delivery system leaders, health economists and analysts, academicians, patient advocates, pharmaceutical manufacturers, and other key decision makers, spent the two days working to:

- Identify challenges with biosimilar adoption within the U.S. health care system;
- Identify clear and unbiased scientific messaging to support broader acceptance of biologics as valid therapeutic options and to facilitate faster time to biosimilar adoption; and
- Discuss real-world evidence (RWE) needs and opportunities to help with biosimilar adoption.

Participants identified a number of challenges associated with biosimilar adoption in the United States:

- **High degree of complexity:** A variety of factors cause the biosimilar landscape to be highly complex and diversified. These include different approval pathways due to the complexity of molecules, differing benefit types and sites of care, complex electronic medical record (EMR) systems and order sets, differences in administration routes and approved indications, confusion around terminology, physician clinical specialties, and the differing needs of patients depending on the disease state as well as whether they are treatment-naïve. All of these complexities present an overall challenge from which many other challenges flow.

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WATCH FOR FOLLOW-UP

The Partnership Forum was just the beginning of AMCP's efforts to support the further development and continued use of biosimilars in the U.S. health care system, and to provide consistent and accurate messages about the value of biosimilars. Our next steps will be to:

- **Publish a proceedings document** on all findings and recommendations from the Partnership Forum in an upcoming issue of AMCP's *Journal of Managed Care + Specialty Pharmacy* and disseminate it widely to decision makers around the country.
- **Host a forthcoming webinar** to report these findings and recommendations.
- **Provide more educational opportunities** around the value of biosimilars, associated terminology, and other key topics of interest.
- **Support efforts to create incentives** for providers to help promote the use of biosimilars, particularly for treatment-naïve patients.
- **Continue to seek strategic partners,** including payers, patient advocates, physician groups, regulatory groups, and more, to help encourage creation of guiding principles around biosimilars.

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- **Health plan variations:** Some of the complexities from the health plan side, including contracting arrangements may reduce or remove the anticipated cost savings of a biosimilar versus the reference biologic.
- **Clinical and administrative barriers:** With complexities around setting up the EMR and order sets in each provider system, particularly given that each patient might be associated with different payers and formularies, it can be difficult for providers to determine the right biosimilar that will provide the right treatment at the right cost for a given patient, especially when the biosimilar is one drug in a multi-drug regimen.
- **Patient support:** Some reference biologics may offer more robust patient support programs, making them a more attractive option from the patient perspective than a new-to-market biosimilar that does not offer any patient support.
- **General scientific landscape:** In the United States, recent events have caused some members of the public to harbor mistrust of science in general, and the drug approval process in particular. This may need to be overcome to help patients understand the positive benefits of biosimilars.

Participants discussed and highlighted opportunities in several areas to address these challenges:

- **Education:** Build positive, evidence-based communication and educational materials around biosimilar adoption, differentiated to meet various audiences, including patients, prescribers/providers, and payers. Amplify existing resources, such as IQVIA data and FDA education resources, that help clarify some of the complexities around biosimilars.
- **Language:** Draw from best practices to clarify and simplify language around biosimilars, particularly around the concepts of interchangeability and substitutability, as well as implement common language to increase confidence in switching.
- **RWE:** Identify gaps in data that may require development of new resources and surveillance mechanisms for biosimilar use. Collect RWE and post-marketing surveillance data related to adverse events and side effects, as well as switching data (reference products to biosimilars; biosimilars to biosimilars) to help evaluate relative effectiveness and safety.
- **Benefit design:** Review benefit design to address complexities to identify improvements that enhance access to biologic drugs, especially as more come to market that will be covered under the pharmacy benefit. In addition, investigate how to change provider reimbursement incentives to support prescribing of the most cost-effective product.
- **Legislation and regulations:** As the biosimilar marketplace grows, it is expected that more experience will help to spur more evidence around and comfortability with biosimilars. It is important to continue to combat attempts to unfairly delay competition and to reduce barriers that are keeping biosimilars from gaining traction in the market.
- **Confidence:** Work to rebuild the public's confidence in science and the FDA approval process through education and positive messaging, particularly as it pertains to biosimilars.
- **Thought sharing:** Share learnings from across disease states, stakeholder groups, and the globe with the goal to pull together and disseminate best practices from areas where biosimilar uptake efforts have succeeded.

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