MedicalXpress

Rheumatology providers, FDA leaders discuss biosimilars at national policy briefing

June 21 2016

Experts from the American College of Rheumatology (ACR), Food and Drug Administration (FDA), and other leading national healthcare groups spoke about the emerging biosimilars market, including key policy and regulatory questions for patients, providers and the healthcare system, during a national policy briefing held by the nonpartisan Alliance for Health Reform.

Dr. Angus Worthing, MD, FACR, FACP, who spoke on behalf of the American College of Rheumatology, stressed the importance of current FDA regulatory efforts to ensure the safety and efficacy of biosimilars for patients.

"Full transparency is key for physicians to be able to prescribe safe and effective biosimilars. Patients need to know what they're taking, and physicians need to know what they're prescribing. This can be accomplished by using distinct names for biosimilars, having clear information on FDA drug labels, and implementing consumer-oriented pharmacy dispensing practices," said Worthing. "The American College of Rheumatology has had a number of conversations with the FDA and other stakeholders at both the federal and state level about how to achieve that transparency, and we are fully supportive of the FDA's efforts to implement distinct naming and transparent labeling for biosimilars."

Worthing also voiced concern about potential biosimilar substitution practices by pharmacists without prior notification. Biosimilars, which

are administered as shots under the skin or by IV infusion, are different from small molecule drugs, or pills, due to their complex nature and the way they interact with a person's immune system.

"We currently do not know what may happen when switching a patient back and forth between a biosimilar drug and its original reference biologic. It's possible that switching may be safe and effective, the way a person can go back and forth between brand and generic versions of small molecule drugs. However, it's also possible that a person who is switched from an original biologic to its biosimilar may become immune to the new biosimilar, and then in a worse-case scenario, may also become immune to the original biologic drug as well," said Worthing. "This may cause the drugs not to work or even cause allergic reactions, which is why it is incredibly important that we protect patients against forced switching between biologics and biosimilars by insurance companies and pharmacy benefit management companies."

Dr. Leah Christl, Associate Director for Therapeutic Biologics at the FDA, said that biosimilar drug development was "very different from standalone drug development" and that demonstrating biosimilarity requires different types of data. When asked about the FDA's draft guidance calling for distinct names for biosimilars, Christl said that having distinct names for biosimilar therapies will help to ensure pharmacovigilance - which includes the ability to monitor for, report, and track adverse reactions - and also help to prevent inadvertent substitutions.

When asked how physician prescribing behavior might change with a robust biosimilars market, Worthing said he believes prescribing physicians are "cautiously optimistic" about biosimilars and will welcome the opportunity to prescribe new treatment options as long as they are safely adopted into the market with full transparency and proper naming and labeling. He noted that physicians will likely be most

comfortable using biosimilars in patients who are just starting their first biologic treatment, as opposed to switching patients who are currently taking a biologic, due to the lack of clinical information about switching and adverse reactions.

"Ultimately, the decision about whether to prescribe a biosimilar to a new patient - or to switch an existing patient from his or her current biologic therapy - will depend on a number of factors, including the clinical data surrounding the biosimilar, the patient's condition and medical history, and whether the patient is having success with his or her current therapy. The cost of the therapy and the patient's ability to afford it may also come into play. If the biosimilar represents a lower cost yet clinically effective option, that is a consideration we will probably discuss with the patient, but that decision should be made by prescribers and patients - not third party payers," said Worthing.

In closing remarks, Worthing said, "It's easy to get lost in the weeds of regulatory issues, but biosimilars naming, labeling and interchangeability issues have real and profound safety and health consequences for patients. We certainly appreciate the work of Ms. Christl and her colleagues at the FDA to ensure these therapies are safe and effective."

More information: To access additional materials from the briefing, including a transcript, click here.

Provided by American College of Rheumatology