THE IMPORTANCE OF PHYSICIAN DECISION MAKING

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SUMMARY

Biosimilars are similar but not identical to originator biologics. We conducted a series of surveys among physicians prescribing biologics to find out their opinions on biologic substitution. Data gathered from 1832 physicians from across the US, EU, Latin America, Australia, and Canada indicated that they would prefer to retain decision making authority regarding choice of biologic medication for their patients. In an environment where multiple biologic treatment options within the same product class are available, distinguishable names and collaboration between physicians, pharmacists, and patients is important for tracking which product a patient received, to allow for monitoring a patient's response to the medicine, and to track any side effects.

Key words: *biosimilars, collaborative practice, substitution*

1 INTRODUCTION

Biosimilars are similar but not identical to originator biologics. In an increasingly resource-constrained environment, pharmacy or hospital-level substitution of biologics with biosimilars is becoming a commonly adopted approach to realize cost savings. As a result, physicians may be excluded from decisions regarding the treatment of their patients. There is also an increased need for communication among prescribers and pharmacists to assure the effectiveness and safety of treatment in addition to cost considerations.

2 METHODOLOGY

The Alliance for Safe Biologic Medicine (ASBM) is an organization whose mission is to be an authoritative resource on biologic medication issues. Between 2015 and 2017 ASBM conducted a series of web-based surveys among 1832 physicians around the world with specialties in dermatology, endocrinology, oncology, nephrology, neurology, rheumatology, to find out their opinions on biologic substitution. Prescribers were asked to rate: (1) the importance of authority to decide the most suitable biologic for their patients, (2) the importance of notification of biologic substitution, and (3) the importance of distinguishable names for biologics.

3 RESULTS AND CONCLUSIONS

A total of 1832 responses were received: 470 (25%) Europe, 403 (22%) Canada, 400 (22%) US, 399 (22%) Latin America, and 160 (8.7%). Most prescribers were from the hospital setting, and most had ≥ 11 years in practice. Across regions, most feel that it is critically/very important to have sole decision-making authority regarding the suitability of a biologic, or to have dispense as written authority. Most also feel that it is critically/very important that pharmacists communicate with the prescriber when a substitution is made. Data are summarized in the table below.

Table. Responses by Region

Survey Question*	US n = 400	EU n = 470	Latin America n = 399	Canada n = 403	Australia n = 160
Very/critically important that physicians are able to decide which therapeutic biologic medicine are dispensed to their patients (% of responders)	66%	72%	85%	83%	91%
Very/critically important that they are notified in the event of a pharmacy substitution (% of responders)	68%	77%	87%	78%	89%
Believe that biologics should have distinguishable names to facilitate product identification (% of responders)	66%	Not collected	Not collected	68%	76%

*Surveys were not identical across regions

Our survey indicates that most physicians believe it is important for them to be able to decide which biologic—original product vs biosimilar—is provided for their patients. Further, most think it's critical that they are informed in the event of a pharmacy substitution. In an environment where multiple biologic treatment options within the same product class are available, it is important that health care practitioners have a method to facilitate accurate identification, as a way to monitor a patient's response to a medicine as well as track any side effects. One way to achieve this is via distinguishable names for each biologic or biosimilar. Our survey indicated that distinguishable non-proprietary names are important to physicians prescribing biologic medicines. Collaboration and communication among physicians, pharmacists, and patients is critical to be able to accurately know and document the medication a patient has received. In the US, this has been facilitated by the State legislation that specifies this communication. This is case study that could be considered for other regions.

One potential solution for harmonized, distinguishable naming across regions is the Biological Qualifier (the BQ) suffix—an alphabetic suffix assigned at random to a biological active substance manufactured at a specified site—to the names of similar biologic products. This naming paradigm, proposed by the World Health Organization has the potential to become a harmonized global system for pharmacovigilance for all biologic medicines improve patient safety and if implemented will avoid proliferation of other non-consistent national naming schemes.

Disclosure: The Alliance for Safe Biologic Medicines (ASBM) is an organization composed of diverse healthcare groups and individuals – from patients to physicians, innovative medical biotechnology companies and others – who are working together to ensure patient safety is at the forefront of the biosimilars policy discussion. The activities of ASBM are funded by its member partners who contribute to ASBM's activities. Visit www.SafeBiologics.org for more information.
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