BIOSIMILARS

DISTINCT NAMING AND PHARMACOVIGILANCE

BIOSIMILARS: A PROMISING NEW ADDITION TO THE GLOBAL HEALTHCARE ARENA

Biologic Medicines are used to treat millions of patients with serious illnesses like cancer, arthritis, and psoriasis. As patents for many of these therapies expire, attempted copies called **BIOSIMILARS** are entering the global marketplace, bringing patients and their physicians new therapeutic options at reduced cost.

But with these new choices also come new challenges.

Unlike generics, biosimilars are not exact copies of their reference products; they are only, as their name suggests, *similar* to the originator. While safe and effecacious, the inherent differences between these similar medicines can produce unexpected effects in patients, including unwanted immune responses.

TRACEABILITY IS KEY

The ability to track and trace any problem to the correct biologic medicine is essential for patients to enjoy the many benefits of biosimilars. This also builds confidence in their safe use among prescribers of biologics medicines.

An inability to accurately attribute adverse events to the correct product, or to quickly trace problems when dealing with multiple similar products could jeopardize the viability of biosimilars in the long term, if steps are not taken by policymakers to ensure traceability.

For these reasons, regulatory authorities around the world are putting policies in place to ensure that a biosimilar can be clearly distinguished both from the originator product upon which it is based, and from other approved biosimilars to that product.

PHYSICIANS SUPPORT DISTINCT BIOLOGIC NAMING

Since 2012, ASBM has gathered the perspectives of biologic prescribers in twelve countries, most recently in Australia. These surveys have consistently shown broad support for distinct biologic naming among these physicians. 66% of U.S. physicians support distinct naming for all biologics, including biosimilars, as do 79% of Canadian physicans. 94% of Latin American physicians say the BQ proposal would be “helpful in ensuring [their] patients recieve the correct medicine”.

All ASBM surveys may be viewed at www.safebiologics.com/surveys.

AUSTRALIA: A LEADER ON DISTINCT BIOLOGIC NAMING

Australia’s Therapeutic Goods Administration (TGA) has historically shown visionary leadership on biosimilar naming. Australia was one of the first countries to recognize the need for biologics and biosimilars to have identifying suffixes, and created its own system. The TGA’s expertise and experience with biologic naming has also been instrumental to the World Health Organization (WHO’s) development of its own Biological Qualifier (BQ) proposal.

BUILDING A GLOBAL PHARMACOVIGILANCE SYSTEM FOR BIOLOGICS

The BQ is a proposed modification to the WHO’s longstanding International Nonproprietary Name (INN) system that recognizes the global need for clear product identification between similar biologic medicines.

A voluntary standard, the BQ will ensure that all biologics, including biosimilars, are named so as to show their therapuetic similarity yet remain distinguishable from one another. It consists of a four-letter identifying suffix appended to a root name shared by the originator biologic and any biosimilars which are based upon it.

When implemented, this BQ system will establish a global standard that will ensure traceability for all biologics and biosimilars, so that a patient will have the benefits of good pharmacovigilance in whichever country he or she seeks treatment.

PATIENT SAFETY: OUR FIRST PRIORITY

ASBM welcomes the opportunity to work with Australian policymakers, prescribers, and patients to advance the success of biosimilars- in Australia and worldwide.

Ensuring that patient safety is kept at the forefront of biosimilar policy discussions is an important first step toward this goal.

The Alliance for Safe Biologic Medicines (ASBM) is an organization of physicians, patient advocates, pharmacists, rmanufacturers of originator biologics and biosimilars, researchers, and others working together to promote their safe use. As of October 2016, ASBM has 66 members spread across five continents; the overwhelming majority of these are patient groups. ***Learn more at www.SafeBiologics.org.***

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ALLIANCE *for* SAFE BIOLOGIC MEDICINES