On August 24-26 in Rio de Janeiro, Brazil, GAfPA hosted the Latin American Biologics and Biosimilars Policy Advocacy Summit, an interactive, professionally moderated set of short presentations by experts and roundtable discussions on the issue of biologics and biosimilars. The summit brought together the most prominent cross-disease patient advocacy leaders from Argentina, Brazil, Colombia, Central America, Chile, Uruguay, and Peru. The focus was progress in Latin America on the regulation of these important medicines from the patient and health professional’s perspectives aimed at establishing a dialog about the best opportunities to strengthen the patient advocacy community in the region, while also building a joint action plan for sustainable collaboration. Participants discussed the current state of affairs, mapped the desired future for biologics and biosimilars regulations, identified barriers and prioritized solutions to yield the maximum impact.

### Summit Goals

- Demonstrate GAfPA commitment to supporting strong policies related to biologics and biosimilars in Latin America with “knowledge transfer” to narrow the gap between what is known and what is applied in access to innovative therapies.
- Review the current state of policies, regulations and the advocacy movement in Latin America.
- Identify challenges, opportunities and solutions for improved access to innovative therapies in Latin America.
- Build out a framework for continued, sustainable collaboration among patient advocates and medical professionals in Latin America.

### Summit Outcomes

- GAfPA has strengthened the capacity of advocacy leaders by providing them with the necessary tools and materials to collaborate with the media and the public on policy issues related to biologic and biosimilar medicines.
- GAfPA has strengthened inter-functional and trans-national relationships among stakeholders to foster an active and committed pharmacovigilance network in Latin America.
- GAfPA has further developed advocacy tools that can be locally adapted or expanded regionally to improve pharmacovigilance programs.
- Opportunities have been identified to advance pharmacovigilance policy in Latin America.
- GAfPA should continue to share best practices with local and regional networks such as BIORED BRASIL, BIORED SUR, and BIAC CAC to continue to strengthen the patient and medical advocacy community.
The regulatory procedure for a biosimilar product should demonstrate an understanding of the long-term consequences. Multiple exchanges are not appropriate, since traceability is required. The policy and guidelines on substitution and interchangeability imply broader issues (specific studies, results, comparisons with reference products), and require informed consent of patients.

The main uses and applications of these are for the treatment of diabetes, hepatitis B and C, rheumatoid arthritis, psoriatic arthritis, multiple sclerosis, Cohn’s disease, anemia, hemostasis alterations, neurological and hematological diseases, cancer, macular degeneration, and transplants. Recent research shows potential uses in gene therapy, as well.

**What are Biotechnology Medications?**

Biotechnology drugs are obtained through complex and very sophisticated production methods. Their manufacture is made from the manipulation of living organisms. Unlike traditional chemical synthesis drugs, molecules obtained by biotechnological processes are often high molecular weight proteins, with a size that can exceed 1,000 times that of chemical synthesis molecules. These molecules are less stable, which decreases their useful life compared to chemical synthesis products. Molecules developed from living organisms or biotechnological drugs include:

- Hormones
- Recombinant proteins
- Coagulation factors
- Antivenoms and immunoglobulins
- Enzymes
- Nucleic acids
- Cytokines
- Monoclonal antibodies
- Protein fragments
- Prionics
- Vaccines
- Medications containing live, attenuated, or dead microorganisms.

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**What are Biosimilar Medications?**

Biosimilar drugs are also products of biotechnological origin and are similar in structure, function, and clinical use as their “reference” biological medicines. Biosimilars are a new step in biological drugs, they are very similar to the reference biological products and are obtained using new cellular sequences, so that they are similar but not exactly identical to the reference products.

**The Importance of Pharmacovigilance**

“There may be very small differences with the active ingredient, but these differences may have a different clinical effect for the patient,” Dr. Charles said. It is for this reason that implementing pharmacovigilance policies that allow for tracking of possible adverse events, from a biological or biosimilar, are of paramount importance.

The complexity of modern medicines, such as biological drugs, has intensified the need for pharmacovigilance. Biological drugs develop from living cells or tissues, and may vary from batch to batch. Biosimilars, which may offer a similar benefit at a lower price, also vary. Biosimilars extend patient treatment options, but also present the need for pharmacovigilance tools that differentiate different drugs.

**Immunogenicity**

The fundamental difference between the molecules of chemical synthesis and those obtained by biotechnological processes is the risk of immunogenicity. The use of immunogenicity is necessary for physicians and patients. The importance of pharmacovigilance increases significantly since 2009, thus increasing the responsibility for regulatory authorities in each country to register and monitor these drugs. He added that regulatory and surveillance systems can be improved through increased efficiencies, autonomy and authority.

**Policy Issues**

New therapeutic alternatives are being discovered present opportunities to treat or cure diseases that were once considered incapacitating or even terminal. Policy makers at the international, regional and national levels are struggling to balance access to new therapies with cost considerations and patient safety in part because of the speed with which new therapies are entering the market. Ensuring government leaders are informed about the physician and patient perspectives with regard to new therapies enables them to make more informed decisions.

Dr. Charles concluded by reinforcing that policies in this area must stress that the decision to switch should not be determined by accountants or bureaucrats, but by physicians who are acting in the best interest of, and in consultation with, their patients.
Desired Future of Biological and Biosimilar Regulations in LatAm: CHALLENGES IN BIOSIMILARS IN LATIN AMERICA

CONCLUSIONS

- The decision to switch a medication should rest with the patient, and patient organizations and medical experts should be involved in advocating for this policy.
- It is necessary to work together to inform policy makers about the importance of the physician-patient relationship with regard to switching medications; neither price nor policy should drive the decision to switch.
- Patient organizations are not against biosimilar drugs. In fact, biosimilars present a great opportunity for patients, but the low quality of some intended copies is concerning. Robust health surveillance systems for capturing and analyzing data are necessary to ensure quality and efficacy of biosimilar products.
- Patient organizations, scientific associations, and medical societies need to be more active in discussing and negotiating these important topics with policy makers.
- Biotechnology has contributed to the advancement of treatments for the betterment of patient health and quality of life. Thanks to these advances, patients can be optimistic about treatment when discussing their illness with their physician.
- In Latin America, investment is lacking in the development and modernization of infrastructure to enable the use of innovative treatments. Many hospitals and health facilities do not have modern devices and tools.
- The fragmentation between health systems in Latin America hinders transparent decision making, adversely affects the effectiveness of regulatory agencies, and creates unnecessary risks with regard to patient safety.

Ongoing work is needed to improve processes related to record keeping and traceability of medicines, which is why product identification as advised by WHO in its INN program is important.
The Global Alliance for Patient Access (GAfPA) is a network of physicians and patient advocates with the shared mission of promoting health policy that ensures patient access to appropriate clinical care and approved therapies. GAfPA accomplishes this mission through educating physicians and patients on health policy issues and developing education material and advocacy initiatives to promote informed policymaking.

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