BIOLOGICS & BIOSIMILARS

Policy Advocacy

SUMMIT

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RIO DE JANEIRO
BRAZIL

GAfPA
Global Alliance for Patient Access

INTRODUCTION

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.

DAY 1

EXPLORING BIOLOGICAL AND BIOSIMILAR MEDICATIONS: IMPORTANT POLICY ISSUES

David Charles, MD, Chairman, GAfPA

Dr. Charles explained the origin of biological medicines, the complex structure of these products, and consequently how difficult it can be to adjust treatments for patients. Dr. Charles discussed the worldwide policy challenges facing these new technologies.

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

The main uses and applications of these are for the treatment of diabetes, hepatitis B and C, rheumatoid arthritis, psoriatic arthritis, multiple sclerosis, Crohn'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 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.

Immunogenicity

The fundamental difference between the molecules of chemical synthesis and those obtained by biotechnological processes is the risk of immunogenicity, hence the reason doctors monitor their patients for an immune response following any drug treatment.

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.

Policy Issues

New therapeutic alternatives 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.

Non-medical Switching

Non-medical switching is a concern for patients who have stabilized their condition, often with the use of biologics. Any decisions to switch to a lower cost biosimilar drug with similar, but not identical, properties should be made based on clinical justification and only after the physician and patient have discussed potential consequences the change could have with regard to disease management.

Non-medical switching policies should:

- Reflect relevant and current data
- Demonstrate an understanding of the long-term consequences
- Preserve the role of physicians in making health care decisions
- Require informed consent of patients.

Dr. Charles concluded by reinforcing that polices 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.

session 1

DEFINING THE STATUS OF REGULATIONS ON BIOLOGICS AND BIOSIMILARS AND THE ADVOCACY MOVEMENT IN LATIN AMERICA

Daniela Cerqueira, PhD

Dr. Cerqueira, from ANVISA, indicated that Brazilian regulations for biological and biosimilar products are aligned with WHO's recommendations. She said it is necessary for the global market to create an international framework for transparency and to work on the harmonization of requirements with other regulatory authorities. For these reasons, it is very important to participate in international forums, network with experts, and work with WHO.

Dr. Cerqueira also talked about the interchangeability policy in Brazil. Interchangeability is more directly related to clinical practice than to regulatory status in the following ways:

- The regulatory procedure for a biosimilar product should be limited to demonstrating comparability in terms of quality, efficacy and safety, including an assessment of immunogenicity;
- Interchangeability implies broader issues (specific studies, bibliographic data, medical evaluation, drug traceability and safety);
- Multiple exchanges are not appropriate, since traceability and monitoring of use are extremely difficult in these cases;
- The policy and guidelines on substitution and interchangeability should be determined by prescribing physicians and the Ministry of Health;
- It is essential that the doctor in charge assesses and monitors the situation, so that they can determine the ideal product to use in each situation and according to the individual response of each patient; and
- The data will be included on the label and the prescription, so that the prescribers and the Ministry of Health can decide on the interchangeability in each situation.

Ricardo García, PhD

Dr. García, Director of CLAPBio, summarized the regulation of biologics and biosimilars in the region, and explained the difference between a biosimilar, an intended copy and a chemical synthesis drug.

"[The] science is dynamic and we need this same dynamism in the development and implementation of new policies, and regulatory frameworks in the region," Dr. García said. Global regulatory activity around biosimilars has increased 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.

Dr. García concluded by stating that biosimilar drugs can be used to treat some diseases, potentially at a reduced cost, but challenges remain including those related to quality, traceability, and the implementation of efficient models of pharmacovigilance that give safety and security to doctors and patients.

Desired Future of Biological and Biosimilar Regulations in LatAm:

CHALLENGES IN BIOSIMILARS IN LATIN AMERICA

Gilberto Castañeda-Hernández, PhD

Latin American countries have or are implementing appropriate regulations for biosimilar commercialization and use. However, despite these regulations, intended copies that have not been demonstrated to be therapeutically equivalent are being marketed in some countries. He indicated that there are challenges with regard to:

- Proper regulation,
- Regulatory implementation,
- Quality evidence,
- Safety evidence,
- Evidence of effectiveness, and
- Transparency.

Dr. Castañeda-Hernández pointed out that regulations must be strengthened to address problems with surveillance, and it is necessary for proper registration and marketing controls to be enforced.

He stated the main problem in Latin America is non-compliance with the biosimilar regulation, which allows the entry of intended copies that are not biosimilar. Causing further distrust is the representation of intended copies as being on the same level as biosimilars. A large number of true biosimilars are available, and are already being marketed in the European Union and other countries, at reasonable prices. Therefore, there is no reason that some countries in Latin America should be accepting intended copies, putting the safety of their patients at risk.

CONCLUSIONS

- The decision to switch a medication should rest with the physician in consultation with the patient. 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 and strict controls for the entry of true biosimilars are important and can help 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.

BIOSIMILARS: WHAT WE SHOULD CONSIDER

Alejandra M. Babini, MD

Dr. Babini shared that biosimilars are a therapeutic reality, thus doctors should have a clear understanding of the concepts so they can explain them to their patients, who, in turn, also have a responsibility to understand their therapeutic options. She explained that the regulations for the use of these products are vary from country to country, which poses risk to patients.

Substitution refers to the practice of dispensing a drug instead of another equivalent drug at the pharmacy level without consulting the physician. It is important to have policies that require physician and patient notification when substitution occurs within a certain time frame.

She also mentioned the importance of pharmacovigilance stating, "Latin American countries should intensify their efforts to improve pharmacovigilance, including training more regulatory personnel dedicated to this effort, more public and professional awareness about the importance of reporting adverse events, and better systems for capturing and analyzing data. Regulatory authorities should also establish a process by which the traceability of an adverse event to a biosimilar or to its RBP can be determined."

PLANNING AHEAD FOR THE FUTURE

Group 1: Biological and Biosimilar Medicines

The conversation around biologics and biosimilars should be balanced and advocates should forward proposals that help foster meaningful debate on topics including International Nonproprietary Names (INN), pharmacovigilance, interchangeability, automatic substitution and switch, quality, and access.

Group 2: Patient Empowerment

The role of patients has evolved from passive to active; many patient fears are being assuaged as patients have more information available and are becoming more sophisticated in their knowledge of topics including regulation and health technology.

Group 3: Pharmacovigilance

There are current pharmacovigilance challenges related to security, surveillance, and bureaucracy, but solutions to these challenges are attainable through multidisciplinary collaboration. The goal is an active, modern pharmacovigilance system that harnesses technology.

Group 4: Networks-BioRED

A lot of work remains for this area, starting with improved communication. To this end, using modern, creative tools like apps and other information and communication technology can be helpful. In addition, establishing new networks via medical societies and scientific societies should be explored.

GAfPA
Global Alliance for Patient Access

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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