

**BIOLOGICS & BIOSIMILARS**

# Health Journalist Educational Workshop

2018



**BUENOS AIRES  
ARGENTINA**





# INTRODUCTION

GAfPA hosted a Health Journalist Educational Workshop on Biologics and Biosimilars on April 9, 2018 in Buenos Aires, Argentina during the Pan American League of Rheumatology Associations meeting. The workshop brought together more than 25 journalists from seven countries to discuss key issues and progress related to the regulation of biologics and biosimilars. The journalists represented outlets in Brazil, Mexico, Colombia, Chile, Paraguay, Uruguay and Argentina.

The workshop served as a platform for participants to increase their knowledge of the biosimilar regulatory landscape in Latin America, share experiences and discuss possible solutions to overcome access barriers that keep patients from optimal care and treatment of their rheumatoid arthritis.

# WORKSHOP GOALS



Increase awareness among health journalists in the region about the importance of biotechnological medicines in the management of diseases.



Encourage journalists to engage more frequently on the relevant issues related to these medicines.



Empower patient-based organizations to build relationships with journalists and rheumatology experts across borders and with like-minded groups to articulate a coordinated voice regarding rules and policy proposals related to the regulation of biotechnological medicines in the region.



Generate momentum for cross-border regional collaborations, including formation of an advocacy coalition that can serve as a platform for further education and communication about biologics and biosimilars.

## KEY TAKEAWAYS



Guidelines for biologics and biosimilars are being implemented inconsistently across Latin America with limited alignment to European Medicines Agency or U.S. Food and Drug Administration standards, resulting in significant policy challenges around regulatory pathways, interchangeability, pharmacovigilance and naming.



Patient experts across the region are working actively with BIO NETWORKS to inform biologics and biosimilars policies. Significant progress has been made in the region, but improvements are needed in most countries.



Journalists need more information on biotechnological medicines to competently write about the issues and challenges in this area.

### Pharmacovigilance

The complexity of modern medicines like biological drugs has intensified the need for pharmacovigilance. Biological drugs are developed 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 between drugs.

### Regulations

Latin American countries have or are implementing 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. There are challenges with regard to proper regulation, 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 that 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 regulations. Non-compliance allows the entry of intended copies that are not biosimilar, even though a large number of true biosimilars are available and are already being marketed in the European Union and in other regions at reasonable prices. Latin American countries should not accept intended copies, which put the safety of their patients at risk.

### Dr. Gilberto Castañeda-Hernández, Clinical Pharmacologist



Biologic medicines are complex proteins manufactured in or isolated from living organisms. They cannot be copied exactly. Biosimilars are structurally highly similar versions of already authorized biologic medicines that have demonstrated similarity in physicochemical characteristics, efficacy and safety in comprehensive comparison studies. The structure of a biologic affects its activity. In development, the structure of a biosimilar must be examined extensively in early stage lab investigations (phase I trials) before it can be tested in the human body (in phase III trials). Once a biosimilar protein has been developed, scaling up the manufacturing process and maintaining a consistent product can be very challenging.



### **Dr. Alejandra Babini, Rheumatologist**

Dr. Babini shared that biosimilars are a therapeutic reality. As such, doctors should have a thorough understanding of biosimilars, ensuring they can explain biosimilars to their patients, who, in turn, also have a responsibility to understand their own therapeutic options. Dr. Babini explained that the regulations for the use of these products vary from country to country in Latin America, which poses a risk to patients.

### **Non-Medical Switching and Automatic Substitution**

Automatic substitution refers to a pharmacy-level practice of dispensing an equivalent drug instead of the prescribed drug without consulting

the treating physician. It is important to have policies that require physician and patient notification when substitution occurs within a certain period. Dr. Babini also touched on the importance of pharmacovigilance. “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,” she stated.



## SESSION 3:

## Patient Perspective

**Priscilla Torres** from *ENCONTRAR* and *BIONETWORK BRAZIL* and **Emma Pinzon** from *FUNARP* and *BIONETWORK CAC* shared their testimony about how it is to live with rheumatoid arthritis in Latin America. They spoke to the challenges that exist related to achieving a diagnosis and timely treatment. They also shared the difference they now experience in quality of life thanks to new treatments and advanced drugs, such as biologics and biosimilars.

Priscilla addressed the importance of adherence to treatment and the work she is doing in Brazil to protect patients' rights relative to access to ongoing treatments and informed consent of medication switches.

Emma added there is value in patients actively participating in their treatment decisions. She also shared her life experiences as someone who has lived with rheumatoid arthritis for more than 30 years.

### RECOMMENDATIONS & NEXT STEPS

- The PANLAR meeting served to establish important journalistic relationships. GAfPA should invest in strengthening these new collaborative ties so the journalists can continue to inform their respective audiences about the use of and access to biologic/biosimilar medicines.
- In an effort to maintain ongoing communication and the journalists' interest, GAfPA should share new information regularly.
- GAfPA should offer an educational workshop for 10 journalists at the upcoming regional meeting so the journalists can continue to learn more about biologics/biosimilars. Periodic training can also promote ongoing interest.



# POST WORKSHOP EARNED MEDIA

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Medicamentos biológicos  
*(Argentina)*

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Panlar 2018 lidera consenso  
para el uso de biosimilares  
*(Colombia)*

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Destacan el valor de los  
medicamentos biosimilares  
cuando la eficacia y seguridad  
es equivalente al producto  
de referencia  
*(Argentina)*

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Medicamentos biológicos: una  
revolución para el tratamiento  
de muchas enfermedades  
*(Argentina)*

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Destacan el valor de los  
medicamentos biosimilares  
cuando la eficacia y seguridad  
es equivalente al producto  
de referencia  
*(Argentina)*

Biotecnologia é opção para  
quem tem artrite reumatoide  
*(Brazil)*

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Medicamentos biológicos: una  
revolución para el tratamiento  
de muchas enfermedades

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La artritis reumatoidea causa  
infarto si no se detecta y  
trata a tiempo  
*(Paraguay)*

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Llegan copias de remedios caros  
*(Uruguay)*

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Fármacos biológicos: sabe lo  
que son y cómo funcionan

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Los biológicos fueron un paso  
muy grande en el camino que  
tenemos los médicos para  
conseguir nuestro objetivo  
*(Argentina)*





**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.

The background of the entire page is a photograph of a modern cable-stayed bridge with a white, curved deck, spanning a river. The sun is setting behind a city skyline, creating a warm, golden glow. The bridge has several tall, white pylons and numerous stay cables. People are visible walking on the bridge deck. The city skyline includes various buildings, some with red brick facades and others that are modern glass skyscrapers. The sky is filled with soft, white clouds.

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