

BIOLOGICS & BIOSIMILARS

GAfPA's 3rd Annual Latin American Conference

| 2018 |



OPENING AND WELCOME

Congresswoman Ursula Letona opened GAfPA's 3rd Annual Latin American Conference on Biologics and Biosimilars. She shared the initiatives and progress that is being made by Congress to support better health outcomes for patients. She specifically noted the value of hearing from patients during the law drafting process.

Congressman Letona discussed the potential for corruption that exists in Peru because of the cumbersome procedures for acquiring drugs at the Social Security Service and the Ministry of Health. She also talked about the black-market counterfeit drugs in Peru, and the responsibility the government has in eradicating them. Finally, she discussed drug pricing and the interest of government in setting drug prices. However, she said, that it is critical that in a free market system, the market must regulate the costs of these drugs and there must be policies and regulations to support this.

Eva Maria Ruiz de Castilla, Latin American Director of GAfPA, thanked Congresswoman Letona and pointed out to the group the importance of engaging with members of the legislative branch and the value of having face-to-face meetings to give legislators an opportunity to interact with patient groups. "In our home countries, more needs to be done by groups like GAfPA to raise awareness and support policymakers who have the strength to introduce powerful legislation, all the while working hand in hand with medical associations to build better societies and create better health outcomes," said Eva Maria.

Brian Kennedy presented Congresswoman Letona with a Patient Access Champion Award for her unrelenting efforts to increase access to medicines for patients in Peru.



GAfPA IN LATIN AMERICA

Brian Kennedy, Executive Director of GAfPA, addressed the group, reminding everyone that GAfPA's meetings in Latin America began in December of 2015 in Buenos Aires, Argentina. "Year after year, more advocates come together from throughout Latin America, representing many different disease states, patient representatives and providers, all to work on access issues related to important medicines," said Brian.

Brian discussed the value of medical innovation, which offers new treatments and the promise of continued life to patients whose diagnosis may have been considered a death sentence. "There are barriers that lie between the patient and their treatment that keep vital medicines just out of reach," Brian said. "GAfPA's work starts there, by providing a network for patients and other stakeholders to come together. It is critical that health systems are developed with policies that support access to treatment for patients." Brian provided examples of policies that directly impact patient access, such as non-medical switching, biosimilar substitution and compulsory licensing. GAfPA's latest educational handout, "**Fast Facts: Compulsory Licensing**" in English and "**Fast Facts: Licencia Obligatoria**" in Spanish was distributed to attendees.

FASTfacts August 2018

COMPULSORY LICENSING

Latin Americans are living longer than ever before. But like people in other regions, Latin Americans also suffer from numerous chronic conditions, such as diabetes and heart disease.¹ This is why it is vital that policymakers encourage investments in medical innovation and ensure access to life-saving medication that has been proven safe and effective.

Compulsory licensing doesn't do either of these. Nevertheless, governments in Colombia,² Chile³ and Peru⁴ are considering adopting this scheme. Here's what patients, health care providers and policymakers need to understand about compulsory licensing.

Q: What is compulsory licensing?

For a limited period, patents provide an exclusive right to the manufacturer of a new medicine to sell that medicine. Compulsory licensing occurs when regulators ignore that right and allow other companies to sell copies of the medication before the exclusivity period has ended.⁵

Q: Is compulsory licensing good for patients?

While some patients may benefit from increased access to cheaper copies of medications, they do so at the expense of the larger population for years to come. Compulsory licensing has long-term consequences that can hinder broader access to future medical innovations.



SESSION 1: SITUATION ANALYSIS

Gilberto Castaneda-Hernandez, PhD, CINVESTAV, spoke about the importance of regulating biologics and biosimilars due to their complexity. “There are dramatic consequences when mistakes occur after a drug is made available to patients,” said Dr. Castaneda. He provided an overview of the differences between biologics and biosimilars. “Biologics and biosimilars are not identical but they are very close. It is incorrect to consider a biosimilar a generic, which is what happens in some countries in Latin America and across the world,” he pointed out.

Dr. Castaneda detailed the importance of the Guidelines on Biosimilars that were released in Geneva in October of 2009¹. Specifically, he focused on the guidelines pertaining to Quality, Non-Clinical Evaluation, Clinical Evaluation, and Pharmacovigilance. Dr. Castaneda said, “Regulations are not always a barrier to access, they are an extremely important part of having safe medicines for patients.” The vast majority of countries in Latin America are now or in the process of regulating biosimilars, separately from generic medicines.

He also discussed the value of respecting laws and noted that regulations and laws are considered mere suggestions sometimes. But as they relate to drugs, there are serious consequences if these regulations and laws are not properly respected.



¹Geneva, 19-23 October 2009¹, Guidelines on Evaluation of Similar Biotherapeutic Products (SBPs)

Jose Josan, M.D., MBA stressed that patients must adopt the phrase, “nothing for me, without me.” It is critical that patients are managers of their own circumstances. Dr. Josan also discussed the complexity of biologics and biosimilars.

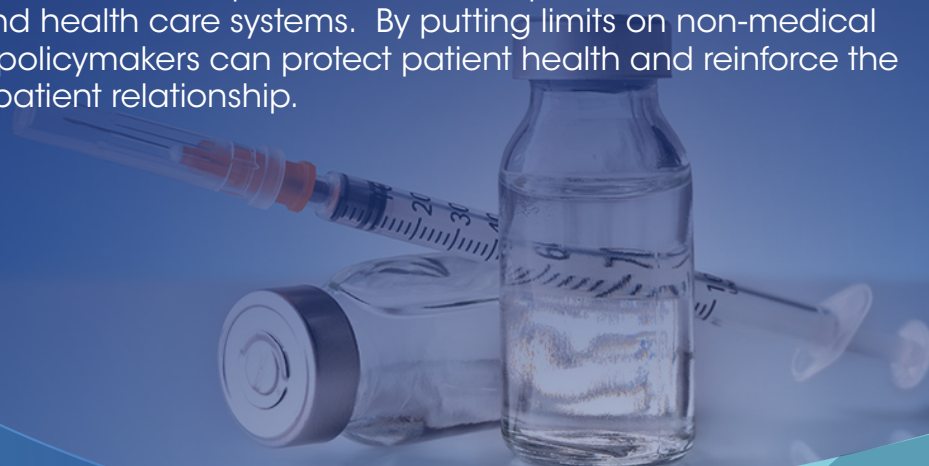
Dr. Josan stressed that automatic substitution should not be allowed and pointed to examples of academics and medical societies throughout the U.S., LATAM, and the EU have stated positions that biologics should not be automatically switched by a pharmacist. Dr. Josan concluded by telling patients they need to “become informed, educate yourself, your physicians, and replicate these actions.” “Otherwise, the knowledge you gain at events like this is wasted,” he added.

NON-MEDICAL SWITCHING

Another policy that Dr. Josan discussed is non-medical switching, a practice that compels patients to abandon an effective medicine for a lower-cost alternative—without regard to the patients’ well-being. To achieve this switching, governments may simply eliminate coverage for certain medications.

Non-medical switching ignores the effort that physicians and patients put toward finding an effective treatment. It also disregards the impact of switching medications arbitrarily. As a result of losing access to the therapy that stabilizes their condition, patients may lose control of their health. Old symptoms may re-emerge alongside new side effects.

Patients’ struggle may require emergency room care, as well as additional appointments with their physician, lab tests and hospitalizations. These complications mean that non-medical switching is often more expensive, not less expensive, for both patients and health care systems. By putting limits on non-medical switching, policymakers can protect patient health and reinforce the physician-patient relationship.



Gustavo Arroyo, M.D. discussed the process that pharmaceutical companies and regulators go through for indication extrapolation. Indication extrapolation is when a biosimilar medication is used to treat a condition that it hasn't directly been studied for based on its similarity to an approved biologic.

Dr. Arroyo said for patients, "substitution is the worst case scenario." Substitution occurs when the pharmacy swaps in a different drug than the one that was prescribed by the physician. "Medicines can and should be switched under certain circumstances, but it must be done with the patient's participation and informed consent," he said. He also talked about the lack of international consensus on interchangeability, and the importance of going through that process before policymakers allow automatic substitution to occur.

SESSION 2: SWITCHING AND AUTOMATIC SUBSTITUTION

Attendees were transported to the Congress of the Republic of Peru for a session on health care sponsored by Rosa Maria Bartra, the First Vice President of Congress and member of the Commission on Public Health. The session, titled "Challenges of Pharmacovigilance in Latin America," was co-hosted by a local Peruvian patient advocacy group, Esperantra.



Speakers were **Cecilia Beltran Noblega**, Representante De Digemid; **Eva Maria Ruiz de Castila**, LATAM Director of GAfPA; **Dr. Gilberto Castaneda Hernandez**, Pharmacovigilance Expert; **Brian Kennedy**, Executive Director of GAfPA; **Rosa Maria Bartra**, First Vice President of Congress; **Edwin Gotzch**, President of the Commission on Public Health and former General of the Peruvian Army; and **Miguel Angel Elias**, Member of Congress.



Speakers focused on patient access to medicines and the role of policymakers in making sure that the voice of patients is not lost when writing new laws. The audience erupted in thunderous applause following **Cecilia Noblega** discussion about the impact that patient voices are having on developing regulatory policies in Peru.

Brian Kennedy presented Congresswoman **Rosa Maria Bartra** with a Patient Access Champion Award for work in health care and for championing patient access to medicines. Congresswoman Bartra ended the session by encouraging the patient groups in attendance to participate more in the legislative process and reminded patients and patient advocates that policymakers need to hear from them.



SESSION 3: PATIENT EXPERT “BEST PRACTICES”



After returning from the Congress, attendees engaged with the morning's speakers for a Q&A. **Gustavo Campillo**, from Fundación Rasa in Colombia, asked who should be responsible for proving that a biosimilar is interchangeable.

Karla Ruiz de Castilla, ESPERANTRA, spoke about the importance of the link and relationship with other stakeholders. The interaction and relationships between governments, industry and academia should be transparent, especially in the field of advocacy. A code of ethics was created in Latin America, together with APEC (Asian Pacific Economic Cooperation), as a unique example of how these relationships should have the highest ethical standards and transparency so that there is no doubt about the role of advocacy groups and their role as defenders of patients' interests.

Priscila Torres, Biored Brazil, showed how the patient advocacy movement has developed and how fundamental it is to have relationships with the high-level decision makers, and how the bio-network has positioned itself in the debates on medicines in Brazil. The motto is “nothing without us,” meaning the patients. Now patients are represented on the committee that is working on interchangeability issues. They also participate in public consultations for ANVISA, CONITEC and the Brazilian Senate.

CLOSING

At the end of the meeting, GAfPA was invited to speak at the meeting with Peruvian Patient Advocates - BIORED Peru, Esperantra and COPEPOFRE (Coalicion Peruana de Enfermedades Poco Frecuentes).

Brian Kennedy spoke about compulsory licensing, referencing the **Fast Facts** document that GAfPA produced last month. Brian explained that normally, for a limited period, patents provide an exclusive right to the manufacturer of a new medicine to sell that medicine. Compulsory licensing occurs when regulators ignore that right and allow other companies to sell copies of the medication before the exclusivity period has ended. While there are temporary financial benefits for cheaper copies of medicines, the savings come at the cost to the larger population for years to come.

Voluntary licensing arrangements are an alternative to compulsory licensing that don't negatively affect patients. Brian explained that voluntary arrangements allow patent holders to partner with other companies to make, use, sell or import a patented medicine. Partners in voluntary arrangements collaborate to ensure necessary knowhow, capacity and product quality. In Sub Saharan Africa, for example, the majority of antiretroviral medicines to treat HIV are produced under voluntary licenses to local generic drug companies.





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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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