2017

YEAR IN REVIEW

GAfPA
Global Alliance for Patient Access

Building on the successes of 2016, GAfPA's reach expanded across Europe and Latin American in 2017. GAfPA worked to educate, empower and mobilise patient representative and clinicians, equipping them with a range of educational materials such as videos, infographics and policy papers.

Examples of 2017 educational materials produced by GAfPA include:

A white paper entitled, "The Role of Drug Donations in Expanding Access to Medicines"

A Spanish-language explainer video on non-medical switching

A "Fast Facts" policy paper on pharmacovigilance

A "Fast Facts" policy paper on non-medical switching

An infographic on chronic pain in Europe.

With the help of these materials, GAfPA drove consensus and raised key issues with policymakers at the local, regional, national and international level.

Across Europe and Latin America, GAfPA remained consistent with core values: informed consent, patient choice, shared decision-making and – above all – patient access.

FAST*facts*

October 2017

PHARMACOVIGILANCE

As many as one out of three drugs on the U.S. market may have safety issues, according to a recent study published in the Journal of the American Medical Association.[1] In the EU, the European Medicines Agency (EMA) reported in 2017 that as many as 200,000 deaths have resulted from preventable safety issues with drugs.[2]

These statistics highlight a key challenge of modern medicine: the need to track adverse events long after regulatory agencies have approved new drugs.

Q: What is "pharmacovigilance"?

Pharmacovigilance is the process of detecting, tracking, analyzing, and preventing negative side effects of drugs.[3] It allows manufacturers and regulators to continue studying drugs and their effects after the drugs are released.

Physicians and patients play a vital role in identifying and reporting patient responses. Data on patients are collected separately from drug companies, doctors, and governing bodies. Pharmacovigilance data can have many effects, from the simple communication of new data to the public or, in severe cases, a drug's removal from the marketplace.

The complexity of modern drugs such as biologics has intensified the need for pharmacovigilance. Biologic medicines are developed from living cells or tissue, and they may vary from batch to batch. They also vary from biosimilars, follow-on drugs that can offer similar benefit at a lower price. Biosimilars broaden patient options but also present the need for pharmacovigilance tools that differentiate similar but distinct drugs.

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IN **EUROPE** IN 2017, GAFPA HAS:

- Delivered four regional advocacy workshops with support of partners, including EFCCA and AGORA
- Coordinated a successful advocacy workshop at the Societal Impact of Pain annual conference in Malta
- Attended and presented informative posters at large medical congresses such as EADV and UEG Week
- Met EU Commission officials and MEPs
- Published blog posts, meeting reports and policy papers
- Secured media coverage in respected outlets such as the PinkSheet and PMLive
- Built the network of physicians and patient advocates.

BUILDING CONNECTIONS

Through advocacy workshops and attendance at major medical congresses in Europe, GAfPA successfully developed new connections with patient advocates and physicians from a range of therapy areas across the continent. For example, GAfPA presented at the biannual meeting of the European Pain Federation, EFIC, in Copenhagen in September.

Strong relationships are invaluable to helping GAfPA members understand the unique policy situation of each European country. Attending high-level meetings in the European Parliament is also important in this regard, with GAfPA attending the European Patients' Rights Day and events on Access to Healthcare hosted by the European Patients Forum. This year, GAfPA successfully communicated key issues and workshop highlights with policymakers and officials. For example, GAfPA representatives met with the Chief Medical Officer of Malta at the Ministry of Health, and MEPs and Commission officials in Brussels.

EARNED MEDIA

GAfPA, with support from our network of physicians and patient advocates, continued its effort toward ensuring the patient voice around biologic and biosimilar medicines is heard in the media coverage of the issue. This year, GAfPA's work and views received fantastic exposure, which helped increase awareness of patients' views and raised GAfPA's profile as an organisation.

Coverage included:

- 'Facing the new wave of biosimilars: don't drown out the patient voice' (PMLive)
- 'Non-Medical Switching' (PinkSheet)
- 'New biosimilar switching paper prioritizes physician-patient relationship and robust pharmacovigilance'
- 'Clinical judgement first, value proposition second: drugmakers issue joint global position paper on biosimilar switching'.

RESOURCES

Over the course of the year, the policy landscape for biologics and biosimilars rapidly changed. As of May 2017, there were 28 biosimilars approved for use in Europe with 17 biologics with biosimilars in the pipeline. Alongside the reports and best practice case studies gathered at regional meetings, GAfPA continued its work in informing patient advocates of the most important policy developments in an accessible way.

MEDICAL CONGRESSES

GAfPA attended several medical congresses this year, including the European Crohn's and Colitis Organisation's annual conference in Barcelona in February, the European Society for Medical Oncology's annual congress in Madrid in September and the European League Against Rheumatism's annual congress in Madrid in June, where GAfPA held a successful meeting with patient advocates.

Societal Impact of Pain Conference, July

Under the auspices of the 2017 Maltese Presidency of the Council of the EU, Malta hosted this year's Societal Impact of Pain conference. GAfPA presented an advocacy workshop for more than 30 delegates that featured presentations from the heads of the European Pain Federation, Active Citizenship Network and Pain Alliance Europe.

European Pain Federation

GAfPA had the opportunity to outline important policy developments for pain management for patients in Europe at EFIC 2017 in Copenhagen, Denmark

European Society of Medical Oncology, September

GAfPA participated in patient advocacy events at ESMO 2017 in Madrid, Spain. Each year, ESMO creates an environment where cancer researchers, clinicians and patient advocates can come together to collaborate and exchange ideas.

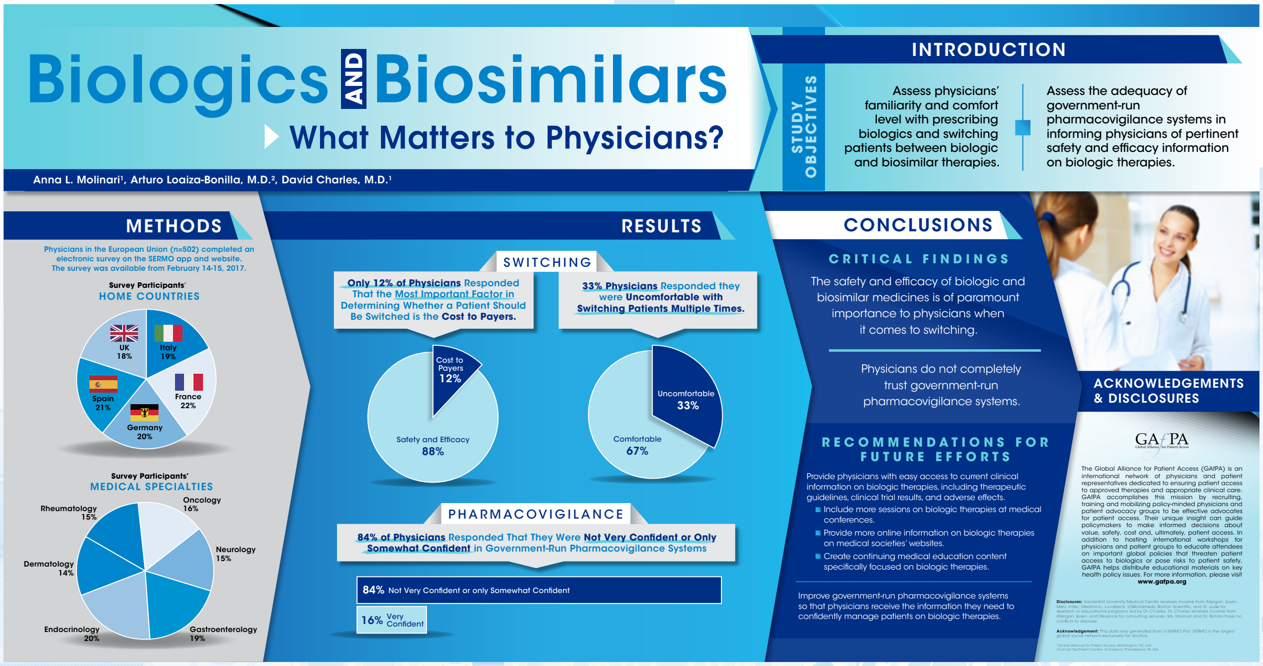
MADRID 2017 ESMO congress

EADV, September

In September, GAfPA travelled to Geneva, Switzerland for the European Academy of Dermatology and Venerology's annual congress. GAfPA had a place in the Patient Society Village and was pleased to attend a patient group event on the future of dermatology.

UEG week, October

GAfPA presented 'Biologics and Biosimilars – What Matters for Physicians?' at UEG Week. This research found that physicians prioritise the safety of the patient above cost considerations in making a decision over whether or not to switch a patient from their medication. Delegates at UEG week asked insightful questions about the poster, and outlets across Europe received a press release detailing the findings.



Biologics AND Biosimilars

What Matters to Physicians?

Anna L. Molinari[1], Arturo Loaiza-Bonilla, M.D.[2], David Charles, M.D.[1]

INTRODUCTION

STUDY OBJECTIVES

Assess physicians' familiarity and comfort level with prescribing biologics and switching patients between biologic and biosimilar therapies.

Assess the adequacy of government-run pharmacovigilance systems in informing physicians of pertinent safety and efficacy information on biologic therapies.

METHODS

Physicians in the European Union (n=502) completed an electronic survey on the SERMO app and website. The survey was available from February 14-15, 2017.

RESULTS

SWITCHING

Only 12% of Physicians Responded That the Most Important Factor in Determining Whether a Patient Should Be Switched is the **Cost to Payers.**

33% Physicians Responded they were **Uncomfortable with Switching Patients Multiple Times.**

PHARMACOVIGILANCE

84% of Physicians Responded That They Were **Not Very Confident or Only Somewhat Confident** in Government-Run Pharmacovigilance Systems

CONCLUSIONS

CRITICAL FINDINGS

The safety and efficacy of biologic and biosimilar medicines is of paramount importance to physicians when it comes to switching.

Physicians do not completely trust government-run pharmacovigilance systems.

RECOMMENDATIONS FOR FUTURE EFFORTS

Provide physicians with easy access to current clinical information on biologic therapies, including therapeutic guidelines, clinical trial results, and adverse effects.

- Include more sessions on biologic therapies at medical conferences.
- Provide more online information on biologic therapies on medical societies' websites.
- Create continuing medical education content specifically focused on biologic therapies.

Improve government-run pharmacovigilance systems so that physicians receive the information they need to confidently manage patients on biologic therapies.

ACKNOWLEDGEMENTS & DISCLOSURES

GAfPA Global Alliance for Patient Access

The Global Alliance for Patient Access (GAfPA) is an international network of physicians and patient representatives dedicated to ensuring patient access to approved therapies and appropriate clinical care. GAfPA accomplishes this mission by recruiting, training and mobilizing policy-minded physicians and patient advocacy groups to be effective advocates for patient access. Their unique insight can guide policymakers to make informed decisions about value, safety, cost and, ultimately, patient access. In addition to hosting international workshops for physicians and patient groups to educate attendees on important global policies that threaten patient access to biologics or pose risks to patient safety, GAfPA helps distribute educational materials on key health policy issues. For more information, please visit **www.gafpa.org**

Disclosures: Vanderbilt University Medical Center receives income from Allergan, Ipsen, Merz, Intec, Medtronic, Lundbeck, USWorldmeds, Boston Scientific, and St. Jude for research or educational programs led by Dr. Charles. Dr. Charles receives income from Allergan, Ipsen, and Revance for consulting services. Ms. Molinari and Dr. Bonilla have no conflicts to disclose.

Acknowledgement: This data was generated from a SERMO Poll. SERMO is the largest global social network exclusively for doctors.

1Global Alliance for Patient Access, Washington, DC USA
2Cancer Treatment Centers of America, Philadelphia, PA USA

EUROPE Regional Events

GAFPA-AGORA CONFERENCE
BUDAPEST

GAfPA and the Platform of Organisations of People with Rheumatic Diseases in Southern Europe, AGORA, began the year in Budapest by delivering a workshop for patient advocates representing groups that primarily focus on rheumatic diseases. Attendees at this workshop signed on to five consensus principles on biologic and biosimilar medicines, as noted in the full report.

GAFPA-EFCCA WORKSHOP
MUNICH

In May, 17 attendees from 13 different countries representing specialities from across rheumatology, gastroenterology and neurology, convened to discuss their experiences advocating on biologics and biosimilars. The workshop encouraged best-practice sharing amongst attendees, the results of which were written up for use by other groups. GAfPA produced a blog post on the event, as well as a full report for distribution among advocates.

GAFPA-EFCCA WORKSHOP
WARSAW

GAfPA and EFCCA held a patient advocacy workshop in Warsaw in September that focused on organisations from across Eastern Europe sharing their experiences of advocating on biologics and biosimilars. Representatives from 15 patient advocacy organisations and two physicians attended and shared advocacy examples such as joint group positon papers on biosimilars. *An overview and findings were compiled in a report.*

GAFPA- EFCCA WORKSHOP
ROME

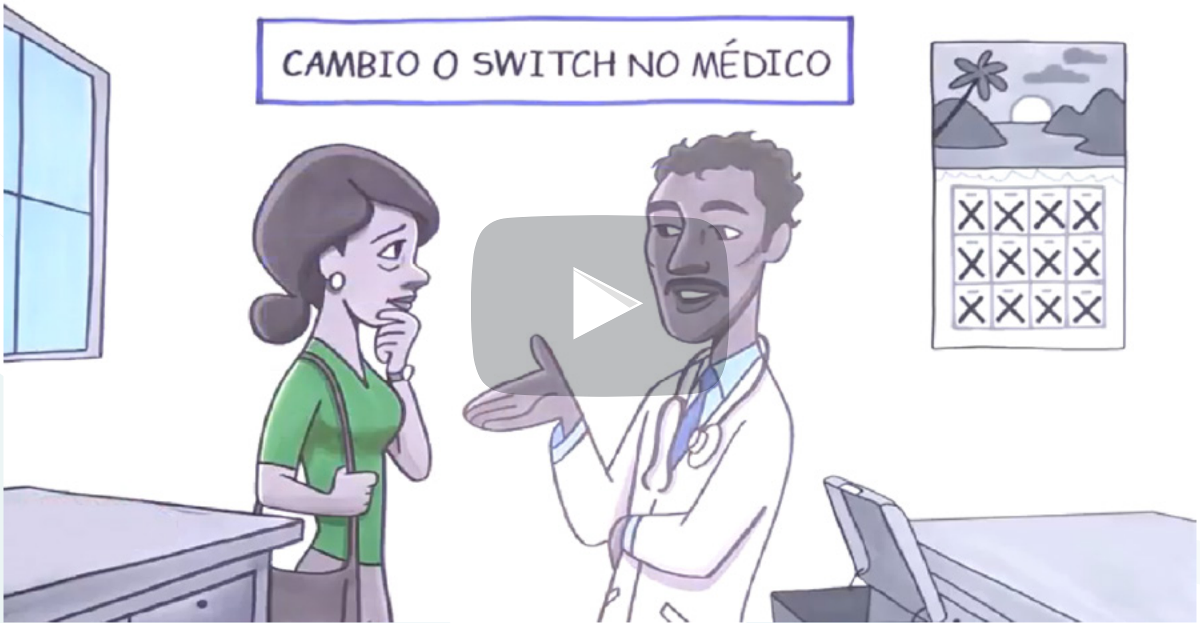
The final GAfPA and EFCCA advocacy best practice workshop was held in Rome, with 17 patient delegates from nine different countries representing specialties from across rheumatology and gastroenterology. The workshop discussion encouraged attendees to share their experiences with biologics and biosimilars in their own countries as well as the advocacy techniques they have already undertaken around this policy area. *GAfPA produced a full report of the event.*

IN **LATIN AMERICA** IN 2017:

Fragmented health systems and a high level of inequality and have resulted in access challenges for people across much of Latin America. GAfPA worked to support decision makers and interest groups in improving the design and execution of public policies and regulations that guarantee greater equity, security and opportunity in access.

Following the success realized with the 2015 Biologics and Biosimilar Regulations meeting in Buenos Aires, GAfPA continued to strengthen its presence through working with leaders in the region, participating in important meetings and forums, and contributing with the formulation of proposals on how to work better at the multisectoral level.

Since GAfPA began working in the Latin America, it has established solid bases of collaboration with medical societies and patient organizations. That collaboration has allowed for the implementation of capacity building programs with leaders from different therapeutic areas, including oncology, rheumatology, psoriasis, rare diseases, prematurity, and NCDs and autoimmune diseases.



GAfPA's Spanish-language explainer video on non-medical switching

This year GAfPA established several workstreams with different networks of patient organizations and medical societies:

Costa Rica

GAfPA presented a workshop at the BIORED CAC meeting in San Jose, Costa Rica. Patient advocates from across Central America received trainings on developing effective advocacy campaigns to ensure informed policymaking.

Argentina and Uruguay

In Argentina and Uruguay, GAfPA worked closely with the BIORED Del Sur, FUNSALUD and the Uruguayan Patients Forum.

Peru

BioRed of Peru was established and educational materials were distributed to attendees to support their advocacy activities.

Colombia

Following the biosimilar workshop in 2016 where representatives signed the GAfPA declaration of principles for access to biotechnological medicines, GAfPA worked in Colombia to support the formation of a BIO Network. GAfPA continues to adapt educational materials that will serve to strengthen groups in pharmacovigilance and regulations.

Brazil

In Brazil, GAfPA worked with leaders and authorities to support the improvement of the capacities of patient groups, networks and with BIORED BRAZIL together with the Senate and the National Health Council on regulatory issues and non-medical change.

GAfPA's *First Annual* Latin American Biologics and Biosimilars Policy Advocacy Summit in Rio de Janeiro Brazil

GAfPA brought together prominent experts, leaders and advocates from the region in 2017. GAfPA plans to continue developing educational materials, training and empowerment programs for physicians and patients in 2018.

Conclusion

In 2018, GAfPA will build upon the work of 2017 by:

- Holding more regional advocacy workshops to share best practices
- Building GAfPA's network of patient advocates, physicians and partners
- Developing relevant briefings and materials
- Expanding GAfPA's presence at key medical congresses and in Brussels.

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.

www.gafpa.org