



BIOLOGICS & BIOSIMILARS Patient Access

W O R K S H O P



United We Stand

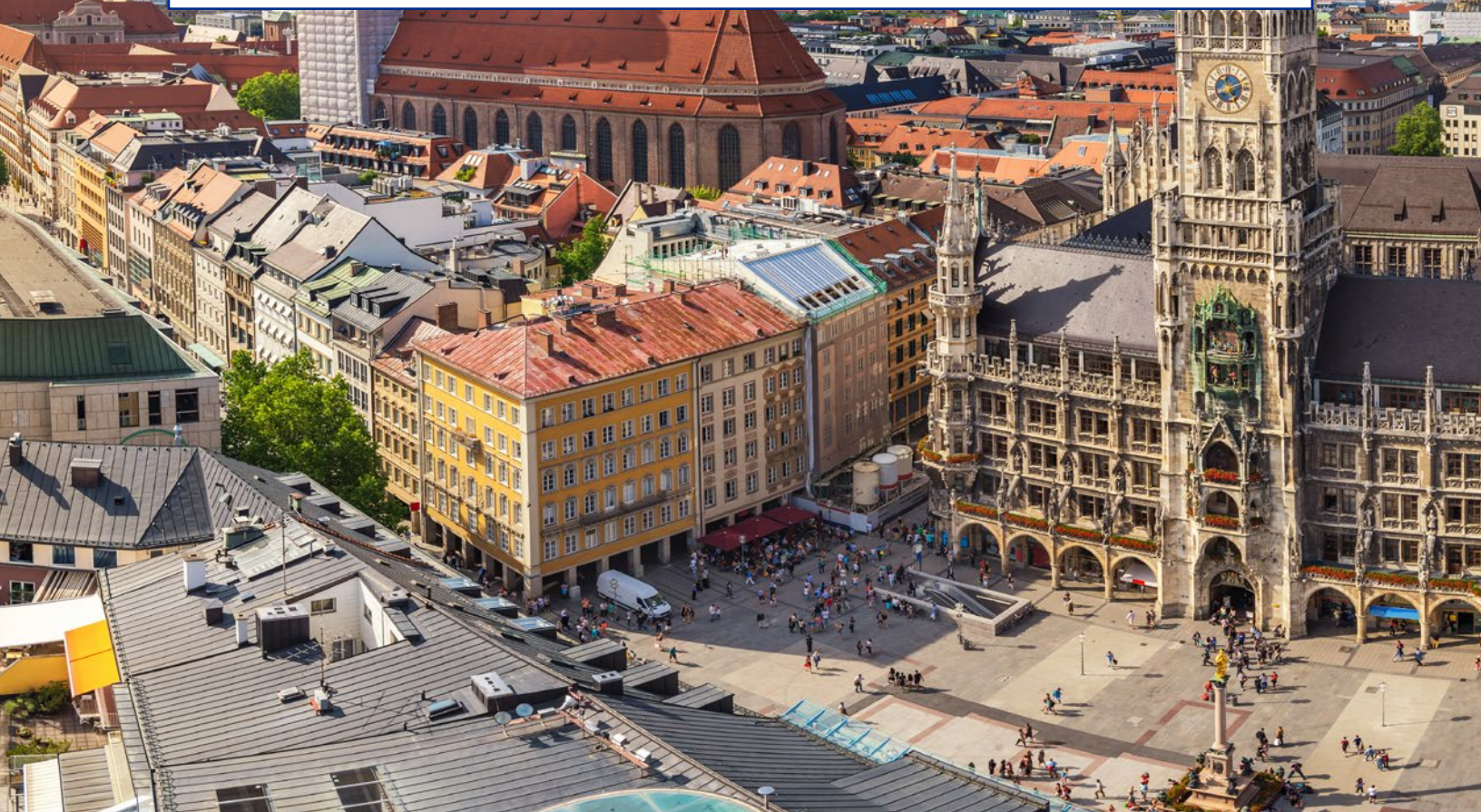




OVERVIEW

The Global Alliance for Patient Access (GAfPA) and the European Federation of Crohn's and Colitis Associations (EFCCA) came together to hold a Biologics and Biosimilars Patient Access and Advocacy Workshop in Munich, Germany on May 4-5, 2017. The 17 attendees from 13 different countries represented specialities from across rheumatology, gastroenterology and neurology, including several members of EFCCA's European network.

The workshop built upon the successful events held by GAfPA and EFCCA in 2016 in Barcelona and Brussels, bringing together patient representatives, physicians and healthcare professionals from across Europe to consider policy questions around the use of biologic and biosimilar medicines. Discussion touched on patient access, use of biological medicines, and how to most effectively ensure that the patient voice informs policy decisions.



Global Alliance for Patient Access

BRIAN KENNEDY

GAfPA's Executive Director **Brian Kennedy** opened the workshop by describing the current position facing European policy-makers around biosimilar medicines. As Brian explained, these innovative medicines will ultimately increase patient access by lowering the price of treatments. To take advantage of these innovations however, patients and physicians must be confident in biosimilar products.

Brian identified key policy issues, including the importance of robust pharmacovigilance (PV) requirements and the highest standards of testing and evidence on medicine safety. Alongside this, patient choice must be respected. GAfPA continues working toward this goal by helping bring together and raise the patient and physician voice in policymaking throughout Europe.



Biosimilars Policy Issues in the European Union

NEIL BETTERIDGE

In the first session, leading UK patient advocate and GAfPA representative **Neil Betteridge** provided background on biologic and biosimilar medicine use in Europe. Neil explained the different aspects of biosimilars policy, which are set separately by the European Medicines Agency and individual EU member states' governments. This country-by-country variation in policy is significant as it is leading to differing levels of patient access to biological medicines across Europe and European patients having very different experiences.

Neil spoke authoritatively from the patient perspective, highlighting the emotional investment made by patients in their treatment and the delicate nature of the relationship between patients and physicians. That relationship can be undermined by any perception that a physician is encouraging the patient to switch medication for non-medical reasons. The EU Commission appreciates the importance of confidence in any switch, Neil explained, and has published new guidance for physicians around switching.





Regional Best Practice for Advocacy

In the second session of the workshop, participants shared their experiences in different countries, describing the state of play and best practices.



AUSTRIA

Evelyn Gross, Austrian Crohn's and Colitis Association, presented on the current situation in Austria. The health care system is divided between the nine Austrian provinces, and is supplemented by additional insurance. Access to any biological treatment is tentative; at present, patients need a statement from a doctor to confirm that the treatment would be effective.

The decision of whether biosimilars can be used lies with whether the health insurance companies will cover the prescription of biosimilars. However, Evelyn explained that it is far from clear what guidance from the insurance companies is provided to physicians. Her anecdotal evidence suggests that naïve patients are currently being started on biosimilars, with other patients not currently being switched. The Austrian Crohn's and Colitis Association has therefore written to the health insurance companies asking for clarification on their prescribing policies. Evelyn shared that her group is also working on developing a position paper on biosimilars, along with five other autoimmune patient representative groups in Austria, which will ask for the right for patients to be informed about prescribing choice and not to be switched for non-medical reasons.



SERBIA

Marko Perovic from the Serbian Crohn's and Colitis organisation described experiences in Serbia, which has a universal health system with a health insurance fund that covers treatment costs. Biosimilars were introduced for Serbian patients toward the end of 2016 and, within six months, most naïve patients are now being started on biosimilars. Switching does not yet seem to be taking place.

Like Austrian patients, Serbian advocates are concerned that there is no clear criteria for which therapy is prescribed. The ultimate decision lies with the physician committee, which advises the insurance providers. Patient representatives have expressed concern about the lack of patient voice on this committee and inability to feedback to the committee on the efficacy of their decisions, as patient groups are currently only able to attend as observers. The Serbian Crohn's and Colitis group is calling for a greater role for patients in the decisions of the committee and for a more accountable system of evidence collecting, which can then inform the committee's work.





CYPRUS AND GREECE

Souzi Makri, chair of AGORA, the platform of organizations of people with Rheumatic and Musculoskeletal Diseases in Southern Europe, shared the success that the Cyprus League Against Rheumatism has achieved in Cyprus. There, the group's work has led to the Cypriot Government consulting them on policy development. Working with other patient advocates, the group also successfully managed to secure a specific law in Cyprus requiring that patients must be consulted on decisions about their care.

Eva Kritza shared the similar success of the Arthritis Foundation of Crete, which has held a series of roundtable discussions on decision making. The discussions brought together patients, physicians and policymakers to consider the question of biological treatments.



SWITZERLAND

Bruno Raffa, Swiss Crohn's and Colitis Association, shared a very different example from Switzerland where physicians are not placed under the same financial pressure, and view biologics and biosimilars as interchangeable. Swiss physicians are very closely involved in prescribing decisions as they have the right to sell medicines themselves like a pharmacy.



Patient Discussion

PHARMACOVIGILANCE

Neil's presentation prompted a discussion amongst attendees on the standards of pharmacovigilance (PV) in Europe and whether they ensure that patients are fully protected by accurately tracking and tracing adverse reactions to medicines. The group discussed the recent study by Professor Michael Kaeding of the University of Duisburg-Essen, who found the need across Europe for patients and physicians to be well informed about current PV requirements.

Dr Ewa Stanislawska-Biernat of the Institute for Rheumatology in Warsaw, Poland suggested that even physicians do not robustly enforce the PV system. In many cases, it is difficult to accurately identify adverse reactions because reactions may take a long time to show. Delegates agreed on the need for greater efforts to educate patients and empower them to discuss adverse events with their physician or to self-report them. The group agreed that this kind of education could come from patient groups and be shared through umbrella groups such as EFCCA. Attendees also acknowledged a variation among countries in how much they trust PV reporting systems.



Regional Best Practice for Advocacy

continued



POLAND



Dr Stanislawksa-Biernat shared the wider patient access situation in Poland, where specific guidelines dictate when a patient qualifies for reimbursement of a treatment. There is, however an added pressure on physicians, who must personally pay for any mistakes that arise with the prescription. In theory, Polish patients can be prescribed either the biosimilar or the biologic. In practice, however, the decision depends on the choice of the hospital, which is based upon the price of the medicine and the terms of the payment plan offered by the pharmaceutical company.

Dr Stanslawksa-Biernat shared the experience from her hospital where patients were wholesale switched in October 2016 from Enbrel to Etanercept, without the choice to remain on their treatment. This switch led to the originator company lowering its price, resulting in the hospital switching all patients back to the originator. This forced patients to go through two switches in the space of three months. Dr Stanislawksa- Biernat suggested that Polish patient groups are pressing for a greater role in decision making.



CZECH REPUBLIC

Representatives from the Czech League Against Rheumatism and the Czech IBD group detailed the situation in their country, where decisions on treatment change are taken by the physician, and all details are held by the health insurance companies. Patient advocates agreed that these details could be very useful to examine prescribing practices.

A patient survey undertaken in 2016 demonstrated that approximately 50% of patients do not feel that they share a role in the decision making around their treatment. To address this, the Czech group has developed 10 specific questions for patients to ask their physician around their treatment.

All Czech representatives raised the problems caused by the very low levels of public awareness around treatment options and reluctance to question the decision of the physician. This was supported by **Hana Smucrova**, a health care professional at the Institute for Rheumatology in Prague, who suggested the value that health care professionals can add around patient education as they have more time to interact with patients. Hana shared some of the advocacy work her group has undertaken, along with the Czech Society for Rheumatology and the Medical Advisor Institute developing a white paper on the treatment of rheumatoid arthritis, including specific questions from the perspective of the patient.

Renata Doanova from the Czech League Against Rheumatism explained the overall low access to biological treatments across the Czech Republic – around 5% overall. She explained that switching from a biologic to a biosimilar is allowed but should not be motivated by non-medical reasons. Renata reiterated concerns about the lack of patient involvement in the choice of treatment.



Luisa Avedano, Chief Executive Officer of EFCCA, then presented to the group the initial findings of the group's EU mapping project on innovative medicines. The goal of this project is to identify the inequality in access across Europe to new and innovative medicines and devices, while also build up a more detailed picture of the healthcare systems and level of involvement of different payers in systems across Europe.

This mapping has been put together from the findings of an online survey between October and December 2016, which asked EFCCA members to detail patients' access to different treatments, including biologics and biosimilars, in their countries. The initial countries questioned were Finland, France, New Zealand, Poland, Serbia, Slovenia and Spain.

This pilot phase identified some similar issues across the countries surveyed. A wide variety was found in the ability of different countries to identify the number of IBD patients, the exact number of patients receiving any treatment, the systems through which patients access medicines as well as the number of patients treated with biologic and biosimilar medicines. The pilot phase study concluded that there is a vast difference in access to treatments, often even within countries, such as the regional variation seen in Spain. This conclusion was difficult to come to given the lack of availability of information around the overall number of patients and the numbers receiving biological treatments.

EFCCA hopes that the second phase of this mapping, which commenced in March 2017, will provide a clearer picture of patient access. The aim of this mapping tool is to present the findings to the European Parliament in February 2018 to demonstrate to policymakers the scale of the access challenge.



K E Y T A K E A W A Y S

The key points to emerge from the meeting were:

- Working together, along with physician and health care professional groups, can amplify groups' voice when talking to policymakers.
- Protecting the physician-patient relationship is crucial, as it is ensuring that patients are confident that their physicians make decisions based on medical, not financial reasons.
- It is important for physicians to take the time to explain their treatment decisions as a way of maintaining patients' trust.
- Overall access to biologics still varies widely across Europe with very poor access in some countries. Patient groups want to be more involved in improving access to these medicines.



GAfPA and EFCCA will continue to work together to raise awareness around biologics and biosimilars in 2017 – highlighting the important issues of patient safety and pharmacovigilance, the central role of the patient in treatment and switching decisions, accurate and simple information for patients and above all, the education and empowerment of patients - be they individuals or patient groups – and healthcare professionals.



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



United We Stand

The European Federation of Crohn's & Ulcerative Colitis Associations is an umbrella organization representing 33 national patients' associations. EFCCA aims to work to improve life for people with IBD and give them a louder voice and higher visibility across Europe and beyond.

www.efcca.org

