FINAL REPORT

15 NOV 2016
BRUSSELS
BELGIUM

Patient Advocacy *and* Safety

CONFERENCE

GAfPA
Global Alliance for Patient Access

United We Stand

BUILDING ON THE BARCELONA ADVOCACY WORKSHOP ON BIOLOGICS AND BIOSIMILARS

The EU Parliament event followed the successful advocacy workshop convened by GAfPA and EFCCA in February 2016. This previous summit was attended by 60 advocates from 34 different organizations, stemming from 27 different countries. It was designed to provide patient groups with a greater understanding of the biologics and biosimilars landscape, and sharing best practice on the potential ways to increase advocate involvement in the policymaking process, with a practical focus.

O V E R V I E W

On 15th November 2016, more than 70 patient advocates and physicians from across the European Union attended the Patient Advocacy and Safety conference at the European Parliament in Brussels, Belgium. The patient and physician advocates – who came from almost every country in the EU – represented a variety of autoimmune conditions and the fields of gastroenterology, rheumatology, and dermatology.

The aim of the conference was to explore the topic of biologics and biosimilars and how different policies and practices across Europe impact on patients. Patient advocates raised concerns around **non-medical switching, tracking and traceability,** and **informed patient consent.**

The event was opened by three Members of European Parliament (MEPs), who were amongst those who kindly sponsored the room for the event: **Vladimir Urutchev** (MEP, Bulgaria), **Sergio Cofferati** (MEP, Italy) and **Andrey Kovatchev** (MEP, Bulgaria). The three MEPs reinforced the message that, while equal patient access to medicines across Europe is a priority, patient safety is an equal political and societal priority. Further MEPs and their staff also attended the session.

The second half of the conference was an interactive workshop, in which patient advocates were able to learn from each other about effective advocacy. They considered how the patient community could effectively proceed in educating policymakers, physicians and regulators about patient safety issues.

TOPICS *for* Discussion

What do patients think about switching?

Delegates heard a powerful story from **Bente Buus Nielsen**, who recounted her personal experiences of non-medical switching in Denmark. She highlighted that patients are generally opposed to non-medical switching, particularly if the decision is made on the basis of cost alone.

As Ms Nielsen described, in April 2015 patients were switched to a biosimilar medicine, having received no prior notice or information. Doctors found it difficult to explain to patients about the switch in medication, so simply avoided the topic, or even provided patients with incorrect information. Ms Nielsen described once instance in which a patient received a different information leaflet to the medicine that they were actually taking, with the doctor claiming that it was a change of product, not medication.

Ms Nielsen also noted that 25 percent of all incoming adverse event reports to medicines are generated by patients who have been switched from a biologic to a biosimilar. She referred to social media posts and enquiries from patients facing new side effects or conditions reoccurring after a switch.

Some of these patients lost confidence and trust in their physicians since the switch, Ms Nielsen explained, which would be difficult to re-establish. Dr Armuzzi raised the point that sometimes doctors have no choice in the decision about what to prescribe their patient.

On the same panel as Ms Nielsen sat **Sanna Lonnfors**, EFCCA's Scientific Adviser, who presented the results of the EFCCA Biologics and Biosimilars (BAB) survey.

EFFCA conducted the 14 question-long survey to assess patient views on biosimilars. The survey took place between November 2014 and November 2015, and had 1,181 respondents from a range of disease areas. The results found that:

- 62 percent of patients had not heard of biosimilars.
- Among those who had heard of biosimilars, the majority expressed concern about their safety profile.
- Patients had a clear desire to be involved in decisions about their treatment, with 43 percent stating that patients should be given information about their treatment.
- 27 percent said that they would accept switching on the basis of evidence-based data.

Center: Dr Alessandro Armuzzi

Why do biosimilar medicines present potential safety concerns for patients?

Dr Alessandro Armuzzi, Head of the IBD Unit at the Complesso Integrato Columbus, Catholic University of Rome, provided the attendees with an overview of the differences between biologic and biosimilar medicines.

Dr Armuzzi explained:

- Differences between biologic and biosimilar medicines that require them to be approved in different ways.
- Switching and why some healthcare systems across the EU have encouraged the practice of non-medical switching.
- How a single switch from a biologic to a biosimilar medicine – in which the patient is fully informed about the change in medication – may be appropriate, though there is not enough data on a number of switches, or switching between biosimilar products, for these practices to become established.
- That non-medical switching's long-term effects on patients are yet to be seen.

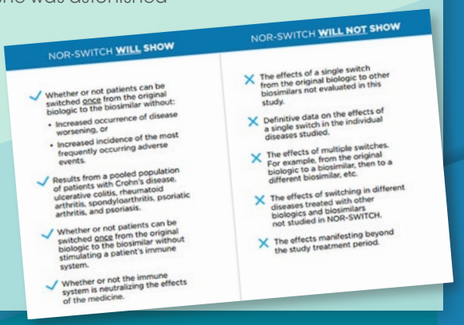
What does NOR-SWITCH show patients and physicians?

Neurologist **Dr David Charles, Chair of GAfPA's National Physicians Biologics Working Group**, gave a presentation on the NOR-SWITCH study. Dr Charles highlighted that, while the study showed that the biosimilar was "not inferior" to the originator treatment, the study had some limitations. These limitations include:

- The study is applicable only to these two specific biologics/biosimilars.
- It pools data rather than separating it by individual disease states.
- It does not take into account the effects of multiple switches
- It may not directly apply to disease areas not studied by NOR-SWITCH.
- It cannot reflect any effects manifesting beyond the study treatment period.

However, Bente Buus Nielsen stressed that she was astonished by the results of the NOR-SWITCH study which, according to her, are far from the real life experience of patients.

Dr Charles also raised in his presentation the importance of being able to track and trace biosimilar medicines to record any adverse reactions to a particular treatment.



Pharmacovigilance across the EU

Professor Michael Kaeding, of the University of Duisburg-Essen, Germany, provided delegates with an overview of his research on pharmacovigilance, set for publication in March 2017.

Professor Kaeding's research focused on the pharmacovigilance systems of six EU member states, specifically concerning biologic medicines and the reporting of adverse events.

The research included a series of interviews with relevant parties in each country, and sought to capture the challenges around pharmacovigilance and adverse event reporting as well as revealing examples of best practice. The study found:

- There are varying levels of effectiveness among pharmacovigilance systems.
- Underreporting of adverse reactions is a challenge.
- Non-serious reactions, or recurrent reactions, are rarely reported. When adverse events are reported, they are often of poor quality, missing batch numbers, brand names or patient information.
- Both doctors and patients lack awareness about reporting, time, personnel and sufficient infrastructure.

These findings underscored the importance of reporting any side effects which patients may have to their medication and ensuring that these reports provide the correct information to regulators. Accurate patient reporting will help keep biologics and biosimilars that are available as safe as possible and allow any issues to easily be traced back to the manufacturer.

Patient Involvement in Pharmacovigilance

Luisa Avedano, Chief Executive Officer of EFCCA, and **Fergal O'Regan,** the EU Ombudsman's Head of Inquiry, helped explain how patients and patient groups can work with regulators to ensure patient safety. Mr O'Regan spoke on protecting personal data for patients and the level of transparency within the EMA. Ms Avedano led the discussion of the role patient advocacy groups can play at the Pharmacovigilance Risk Assessment Committee (PRAC) at the European Medicines Agency (EMA).

Ms Avedano emphasized that:

- The EMA has engaged in dialogue with European patients since the agency was founded, and patient input is found at every level of the organization.
- Patient input to the EMA was crucial. Advocates can input into the PRAC through personal reporting, such as reporting an adverse drug reaction; taking part in consultations; and helping to integrate patients' perspective into risk management plans.
- Patient advocates are important in ensuring that PRAC outcomes are clear and understandable for patients.
- Patient advocacy organizations are important in creating strategic alliances with healthcare professionals, policy makers and other patient organizations to provide a coherent voice to PRAC.
- Patients, as ultimate users of products, are in a unique position to add value to the European pharmacovigilance framework.

C O N C L U S I O N S

Brian Kennedy, Executive Director of GAfPA, and **Luisa Avedano**, Chief Executive Officer of EFCCA led an interactive workshop session at the end of the conference. This session allowed the patient advocacy organizations – using their own experiences and the information provided throughout the day – to reflect upon learnings and discuss next steps.

The day's discussions revealed that patient concerns still remain around these issues:

- **EDUCATION –** that patients need to be given more information on biosimilar medicines.
- **EXTRAPOLATION** – some patient advocates still feel uncomfortable about the fact that biosimilar medicines are not always tested in every disease area.
- **SWITCHING** – that patients are being switched from medicines, at times without their knowledge or consent.
- **TRACEABILITY** – that proper registries need to be created to accurately track and trace the use of biologics and biosimilars in the case of adverse events.
- **PATIENT CONSENT** – that meaningful and informed patient consent is crucial when switching a patient who is well established on a treatment to a biosimilar.
- **ACCESS** – patients need access to important therapeutic treatment options.
- **STUDIES** – clinical trials are critically important to developing new medicines for patients and patients should be more involved in the process.
- **ADVOCACY** – training in effective advocacy techniques for patient representatives should remain a priority for patient groups.
- **TECHNOLOGY** – the modernization of patient organizations will foster a more collaborative environment and enable patient advocates to be much more effective in raising awareness and creating positive outcomes.

In addition, there were some clear areas of consensus for the groups to build upon in 2017. These included:

- **CREDIBILITY** – increase credibility by forging relationships with physicians.
- **UNITY** - Continuing to unify patient groups across disease areas as one voice has proven highly effective so far in presenting a unified message to policymakers.
- **EDUCATE -** Organizations would like more information – in particular, better data – about biologics to inform patients.
- **ACTIVATE** - Groups struggled in encouraging their members to be active in the organization, and often there is a lack of financial resource within groups to carry out desired activity.
- **ADVISE -** It was suggested that a scientific advisory committee for all patient groups may be helpful in providing patients with further information on complex issues in a clear and concise manner.
- **PARTICIPATE** - Increase the number of trials on biologics and biosimilars. Ensure that patients are involved in research from the very beginning.
- **HOLISTIC** - Health care should be people-centered.

GAfPA and EFFCA will continue their collaboration on the issue of biologic and biosimilar medicines in Europe in 2017.

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

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

www.efcca.org