

Biologics **AND** Biosimilars



EMPOWERING PATIENTS

Innovative therapies such as biologic medicines and their biosimilar counterparts hold promise for patients suffering from chronic diseases. In the last two years, these therapies have received substantial attention from the medical, regulatory, and patient community in Europe and beyond. Licensing rights of biological medicines used in the treatment not only of IBD but also other autoimmune modulated diseases are coming to an end and "biosimilar" medicines are being developed to compete with original biological treatment options. In various countries in the EU and elsewhere biosimilars have now entered the market.

We welcome the opportunities that affordable treatment options can bring to the patient community. At the same time we believe that under no circumstances patient safety should be compromised.

Patient safety is a very important subject for the European Crohn's and Ulcerative Colitis Associations (EFCCA) and the Global Alliance for Patient Access (GAfPA), and lies at the core of our work. **Within this framework EFCCA together with GAfPA organised an advocacy workshop on patient safety, which took place in Barcelona from 4-6 February 2016 and gathered over 60 patient representatives from a wide range of immune modulate disease groups.**

The main goals of the workshop were to create greater awareness amongst patient communities regarding the issues impacting access to biologic and biosimilar treatments and therefore to provide or improve basic understanding of the science and issues associated with biological medicines and biosimilars. Secondly, the workshop provided practical training on how to employ effective advocacy and communication strategies with the goal of raising awareness and understanding amongst key policy makers. //

Advocacy Workshop on Patient Safety EXECUTIVE SUMMARY



"Biosimilars should not be the way to reduce health costs, it should be the way to optimize health costs. The savings made, should be directly reinvested in the improvement of other aspects of patient care."

-Prof Julian Panes

THE SCIENTIFIC SCENARIO

The workshop programme included presentations by Professor Julian Panes, President-Elect of the European Crohn's and Colitis Organisation (ECCO) and Dr David Charles, MD, of Global Alliance for Patient Access giving details of the scientific scenario as concerns biosimilars and biologics.

Professor Panes emphasised the complexity of the production process of these innovative treatments and the European Union's pharmacovigilance mechanisms that are in place in order to ensure a full risk management for a newly approved biosimilar. In his view, worldwide pharmacovigilance is also needed to detect any safety or loss of efficacy signal. For this purpose, clear interchangeability rules are essential to secure the traceability of each prescription and of each product.

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THE SCIENTIFIC SCENARIO

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As concerns the access to innovative treatment options, Professor Panes pointed out that in many countries the costs for these therapies are one of the factors that, in practice, determines the access patients have to the drug. However, he stressed that "biosimilars should not be the way to reduce health costs, it should be the way to optimize health costs. The savings made, should be directly reinvested in the improvement of other aspects of patient care."

Dr David Charles also stressed that naming of biologics (i.e. distinct names for distinct medicines) is very important for patient safety. He pointed to the World Health Organization (WHO), which has a constitutional mandate for the international non-proprietary names (INN).

Concerning clinical trials, Dr Charles felt that there should be clinical trials in each of the disease groups in order to show its safety and efficacy but also potential side effects. In his view, a physician should have as many treatment options for his/her patient as possible and also be able to choose, together with the patient, the right option for them. //

PATIENT ADVOCACY

The workshop aimed to provide practical advocacy tools to raise awareness amongst key policy makers. Participants had then the opportunity to learn key elements and techniques on how to effectively advocate at European and national levels and to put this training into practice through a group exercise to develop an advocacy plan.

Effective advocacy requires people to take action. It is possible to achieve concrete results in persuading policy makers to change their position on certain health related issues, even with the the limited resources available to many small groups that are mostly volunteers.

Patient advocacy action is based on 6 key principles: messages and messengers, effective communication, finding champions, building relationships, leveraging the media, and developing alliances & coalitions. These processes require an investment of time.

Advocates have to commit themselves to building mutual trust to establish and maintain a constant flow of communication. Very often, alliances and coalitions are the solution for successful advocacy actions.

The protection of patients' safety is a thread that connects patients organisations representing different disease areas. They all share the need of raising awareness and educating policy makers on innovative medicines such as biologics and biosimilars. Patients' safety lies at the core of their work but also ensuring equal access to treatments and preserving the relationship between patients and health care providers.

In conclusion, patient advocates have an important role to play since advocacy is about informing policy makers to be able to integrate patients unmet needs into policy. //



What clearly emerged from these findings was that there is a lack of knowledge on the issue of biosimilars and an urgent need for patients to be systematically informed and involved in decision-making concerning biosimilars.



THE LEGAL SCENARIO

The scientific programme also included a presentation from the EFCCA chairman about his role of patient representative at the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC). PRAC is responsible for assessing and monitoring safety issues for human medicines and includes all aspects of the risk management of the use of medicinal products including the detection, assessment, minimisation and communication relating to the risk of adverse reactions, having due regard to the therapeutic effect of the medicinal product, the design and evaluation of post-authorisation safety studies and pharmacovigilance audits.

Patient representatives are an integral part of PRAC and key to achieving greater inclusiveness of European drug safety systems. Their role is to ensure that patient needs as a whole are taken into account in the deliberations of the Committee. The patient representatives ensure also that communication on individual medicinal products consider specific patient requirements such as health literacy and they are bridging the gap between the statistical reality of the regulatory system and the personalised reality of clinical practice. //

THE PATIENT SCENARIO

The patient scenario included a presentation of the first results from the Biologics and Biosimilars (BAB) survey, which was carried out by EFCCA under the scientific coordination of Professor Laurent Peyrin-Biroulet (Department of Hepato-Gastroenterology CHU in Nancy, France). The survey aimed to assess patients' knowledge about biosimilar medicines and gathered 1184 responses.

The findings revealed some alarming figures such as the fact that most respondents had doubts and concerns about the safety and efficacy of biosimilars, even if they were prescribed and explained by the treating physician.

What clearly emerged from these findings was that there is a lack of knowledge on the issue of biosimilars and an urgent need for patients to be systematically informed and involved in decision-making concerning biosimilars. Informing patients via therapeutic education programs is advisable, and this could be implemented with patient organization support.

Four patient associations' representatives from Poland, Spain, Norway and AGORA (the platform of organisations of people with rheumatic diseases in southern Europe) gave first hand experiences of the issues involving biosimilars and biologics in their respective countries. //

THE PARTICIPANTS

The workshop gathered nearly 60 participants primarily European based patient advocacy organizations from a variety of immune modulated disease groups treated by biologic therapies such as arthritis, rheumatic and musculoskeletal illnesses, spondylitis, psoriasis, hidrosadenitis suppurativa, pemfigo and representatives of the Chronic Intestinal Failure and Home Artificial Nutrition group.



MAIN TAKE HOME MESSAGES

From the vivid discussions and the feedback from the working groups, there emerged a list of take home messages and food for thought.

Switching from one drug to another: delegates were concerned that in some countries patients were switched from one drug to another without being informed by healthcare professionals. In some cases the prescribing doctor was also not aware of the switch at the hospital. Patient representative Bjorn Guldbrassen from the Norwegian IBD patient association, LMF, referred to the government supported "NOR -Switch" that is currently on-going. The study aims to assess the safety and efficacy of switching from innovator infliximab to biosimilar infliximab compared to continued treatment with innovator infliximab in patients with rheumatoid arthritis, spondyloarthritis, psoriatic arthritis, ulcerative colitis, Crohn's disease and chronic plaque psoriasis. Data from the study is expected in this year. Switching has been practiced by some health departments in Norway during 2014.

Tracing of a particular drug: delegates thought it was important to be able to trace back an administered drug in case there were some adverse effects.

Extrapolation (i.e. extrapolating results from clinical trials for one disease group to another disease group): many workshop participants felt uneasy about the fact that in some disease groups there was no disease-specific data available.

Access to innovative drugs: workshop representatives stressed the importance of increasing access to innovative drugs. In many countries, due to economic reasons, patients do not have access to costly but necessary treatment options. //

CONCLUSIONS

- ▶ **Need for strong collaboration amongst the patient community:** some delegates represented disease groups with very limited resource and low visibility. In order to maximise patient advocacy, it was essential that all disease groups gathered around common objectives in order to have a louder voice and high visibility in particular with policy and decision makers.
- ▶ There is a clear **need for the participation** of patients in decision-making. One group came up with this great message "no decision about me without me."
- ▶ Referring to the issue of **switching**, it is essential to **communicate with all relevant stakeholders** (dispensing pharmacist, prescribing physician and patient) in order to optimize the outcome of the patient's treatment.
- ▶ **Need for informing patients** to empower them to be involved in the decision making and management of their conditions.

Patients want to be informed about biosimilars and be aware of what they are being treated with.

This unique experience has been of paramount importance for EFCCA and the other sister organisations that have been working together with the common purpose of increasing their advocacy skills and gain visibility in claiming the protection of patients' safety and an equal access to innovative treatments.

The workshop represented a further step towards a stronger coalition where the exchange of good practices and mutual learning are the concrete sign of the importance of international networking and commitment.

The shared willingness to improve quality of life of people with chronic diseases whose causes are mostly unknown, whose voices have to be heard more, whose potential is growing to be better equipped in dealing with new treatments and new health policies in Europe and beyond any borders. //

ABOUT EFCCA

The European Federation of Crohn's & Ulcerative Colitis Associations (EFCCA) is an umbrella organisation representing 29 national patients' associations from 28 European countries and 3 associate members from outside Europe. EFCCA aims to work to improve life for people with IBD and give them a louder voice and higher visibility across Europe and beyond.

ABOUT GAFPA

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.

A full workshop report will be made available soon. For more information please contact the EFCCA office at bella.haaf@efcca.org.