

FINAL
REPORT



BIOLOGICS & BIOSIMILARS

Patient Access

WORKSHOP

WARSAW, POLAND

2017

15-16 SEPTEMBER



United We Stand

The Global Alliance for Patient Access (GAfPA) and the European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA) came together to hold a Biologics and Biosimilars Patient Access and Advocacy Workshop in Warsaw, Poland on 15th and 16th of September 2017.

The workshop was designed to build on the successful events held by GAfPA and EFCCA in 2016 in Barcelona and Brussels and to raise awareness amongst patient communities of the policy questions around the use of biologic and biosimilar medicines. The conversation built on previous discussions by bringing together patient representatives, physicians and healthcare professionals from across Europe to consider the outstanding policy questions around patient access, use of these medicines, and how to most effectively ensure that the patient voice can be heard in policy decisions. The 12 attendees from eight different countries represented specialities from across rheumatology, dermatology and gastroenterology and included members of EFCCA's European network. This was the second such meeting held by GAfPA and EFCCA that brought together representatives from a specific region to share and learn from each other's experiences with biologic and biosimilar medicines, the first of which took place in Munich in May with the third meeting taking place in Rome in November.



SCENE SETTER

Dr. Ewa Stanislawksa-Biernat,

Rheumatologist,
National Institute
of Geriatrics &
Rheumatology

Dr. Stanislawksa set the scene for the workshop by explaining the environment and use of biologics and biosimilars in Poland. She highlighted the financial challenges faced by the Polish healthcare system due to financial pressures and the constraints this has placed upon patient access to biological treatments. The Polish Ministry of Health has set specific criteria for patient access to biological treatment programmes, limiting them to the most severe patients. Treatment is not then guaranteed once a patient is on one of these programmes, as after one or two years, dependent upon disease type, patients are required to stop the treatment and only returned to the programme if there is an exacerbation of their condition. In addition to this restricted access, Dr. Stanislawksa shared her experience of the switching between biologic and biosimilar medicines taking place at a hospital level, through the tender system. Under this system patients can be regularly switched between the biologic and biosimilar, dependent upon which medicine is offered at the lowest price to the hospital. Dr. Stanislawksa expressed her concern that patients are not being informed or provided with a choice about switching their treatment, and that switches can take place multiple times if companies lower their prices. Dr. Stanislawksa hopes the introduction of biosimilars into the Polish market will facilitate greater patient access, however patients should still be as informed and involved as possible in decisions about their treatment.

INTRODUCTIONS AND WORKSHOP OVERVIEW

Brian Kennedy, GAfPA
and **Luisa Avedano, EFCCA**

GAfPA's Executive Director Brian Kennedy formally opened the workshop by building on the context provided by Dr. Stanislawksa, welcoming the life changing treatment offered by biologic and biosimilar medicines and the benefits of greater competition for increasing patient access. Luisa Avedano, Chief Executive Officer of EFCCA explained that continued barriers to patient access are of key concern to EFCCA members and has led to the group undertaking a significant project to map access to, and challenges around, biologic and biosimilar medicines.

Brian went onto identify some of the key policy questions that GAfPA has been working on around biologics and biosimilars, including the importance of robust pharmacovigilance (PV) requirements and the highest standards of testing and evidence on medicine safety. Alongside this, he said that patient choice needs to be respected and GAfPA's role will be to continue to try and ensure this by helping bring together and raise the patient and physician voice in policymaking, both within EU member states and at the European level.

PATIENT DISCUSSION: SWITCHING

Neil's presentation prompted a discussion amongst attendees on specific questions around switching. Jolanta Grygiealska, President of the Polish Rheuma Federation shared her experience in discussing switching with the Polish Minister in 2014, where she explained her concerns that switching between medicines happens too quickly due to the short length of hospital tenders. She explained that Polish patients are faced with the choice of accepting the switch or having to withdraw from the biological treatment programme entirely. Neil questioned the group on whether they believe stable patients should be forced to switch. Janek Kapper from the Estonian Inflammatory Bowel Disease Association expressed concern about the lack of certainty that any cost saving from switching to a biologic goes directly towards benefitting other Crohn's patients. Jadranka Andreic from Croatian group REMISJA shared that Croatian patients are only required to switch for medical reasons, but expressed concerns about who is accurately recording the switch, suggesting that in some cases patients have such little confidence in records they are attempting to do this themselves.

BIOLOGICS AND BIOSIMILARS POLICY ISSUES IN EUROPE

Neil Betteridge

In the first session leading UK patient advocate, and GAfPA EU representative, Neil Betteridge, detailed the policy background to the use of biologic and biosimilar medicines 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 policymakers are looking to adopt the cost saving opportunities in different ways, leading to differing levels of patient access to biological medicines across Europe and ultimately 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 patient and physicians, which can be undermined by any perception that a physician is encouraging the patient to switch medication for non-medical reasons. Neil highlighted several important policy developments with implications for patients, including the useful EU Commission 2017 guidance for physicians around switching, which reflects the importance of patient confidence.

Another key issue for patient confidence Neil identified is the system for reporting adverse reactions to treatments, known as the pharmacovigilance (PV) system. Neil highlighted the key findings of the study undertaken by Professor Kaeding of Duisburg-Essen University on how well the EU's PV legislation is being implemented in five European countries. This study identified some areas for improvement especially around educating patients, physicians and healthcare professionals on what their obligations are around reporting. Luisa agreed on the importance of a more unified approach to the issue of PV and suggested that there could be opportunity for more specialist nurses to be involved to bridge the gap between patients and physicians.

The group agreed that accurate reporting, tracking and tracing of medicines becomes even more vital when patients are being switched between multiple treatments. Neil acknowledged that in its work in Europe, GAfPA has increasingly had to move from looking at the question of the implications of a single medicine switch to multiple switching. Dr. Stanislawksa suggested that this is increasing the crucial debate as prescribers are under great pressure to make the most of their budgets and the prices between originator medicines and biosimilars are in many cases now very similar.

Regional Best Practice for Advocacy

Ahead of the workshop, participants were encouraged to consider their own experiences of their national policy environment around biologics and biosimilars and any experience they had on advocating on this question. In order to prepare for this, attendees were provided with several questions which were:

- Please give a short overview of the position in your country regarding biologics and biosimilars.
- Are patients in your country being switched to biosimilars? If so, do you know if this is just a small number of patients or the majority or all? How much are patients usually involved in the decision-making process to switch?
- What sort of information is given to patients in your country about switching? Who produces this, who gives it to them and are they able to discuss it with anyone – if so, who? Do you think this information is sufficient?
- Do you have any concerns about biologic or biosimilar medicines? If so, what are they? What could be done to address these concerns?
- Have you organised any advocacy activity in the past months? If yes, which one(s)?
- If not, what would be needed (supported by us as a group) to raise awareness and inform all relevant stakeholders (governments, patients, HCPs)?

This session was started by several members of EFCCA's network sharing their experiences.



ESTONIA

Jane Kapper (EFCCA) explained the access challenges in Estonia, with biologics only available if patients meet stringent preconditions, however beginning in 2017, all new patients must be started on the biosimilar, whilst stable patients are able to remain on their previous treatment. He raised the issue of the very low level of overall access to any biological treatment and that this is hard to address as physicians are not providing patients with sufficient information on biological options, due to a lack of funds. He reiterated that currently there is no incentive for stable patients treated with biologics to switch as the savings are not kept for treating other IBD patients, these savings are therefore not being capitalised on.



HUNGARY

Building on these opening presentations Mark Baranyai (EFCCA), from the Hungarian group MCCBE shared the current situation in Hungary where patients have also had access to biosimilars since 2014 and switching is not currently commonplace, but new patients are all being started on biosimilars. Mark highlighted the lack of patient engagement in treatment decisions, with the support of five physicians required before any biological treatment can be prescribed. He expressed similar concerns that there is a significant lack of patient awareness around these treatments and sees the role of MCCBE to be to raise public awareness about these treatments and to press for physicians to provide more information on treatment options for newly diagnosed patients.





CROATIA

Jadranka Andreic (EFCCA) then shared the experience of REMISIJA in the undertaking more developed advocacy activities. Jadranka explained that REMISIJA were also empowered to engage by a previous GAfPA-EFCCA patient advocacy event which took place in the European Parliament in November 2016. Building on the examples shared in Brussels, the group brought together a coalition of 24 different patient groups, all representing disease areas dealing with biological therapies. This group signed up to an agreed position paper on the use of biological treatments and patient access to them. The agreed position included the right for all patients to be able to access biologicals if they pass the conditional tests and the principle that a treatment cannot be switched for a non-medical reason. The group has since shared this position with the Ministry of Health and challenged them to address the issues identified.



ROMANIA

Isabella Grosu (EFCCA), from the Romania group ASOCIATIA ASPIIR explained for the group how, over the last year, a group of Romanian physicians and patients have come together to create a position document that presents an agreed position on biological products and detailed policy considerations including: indication extrapolation, interchangeability, automatic substitution and the drivers of switching. ASOCIATIA ASPIIR succeeded in securing the support for this statement from the eight Romanian Scientific Societies, the members of which are treatment prescribers.

This position statement concluded that patient safety should be the primary criterion in undertaking a therapeutic decision and that cost savings must be achieved in a way which does not interfere with the medical decision. Isabella explained that in line with this position, Romanian patients are not currently forced to switch to biosimilars. GAfPA were delighted to hear that the idea for this joint position statement came from GAfPA and EFCCA's first workshop held in February 2016. Following the initial advocacy training presented at this event, ASOCIATIA ASPIIR held an event with the Ministry of Health and other key policymakers to raise the importance of the questions around biologics and biosimilars. The joint position built on the outcomes of this meeting. The group is now looking to drive the conversation even further and is planning on holding a meeting in Transylvania in October to bring together policymakers to consider the importance of a patient centred approach to prescribing, and timely access to treatment.



LITHUANIA

Gediminas Smailys (EFCCA), a practising histologist, representing the Crohn's and Colitis Association of Lithuania, set out the situation facing Lithuanian patients, where, since their introduction in 2014, all new patients are started on biosimilars. Stable patients that were already being treated with biologics have not been forced to switch for financial reasons and the switch will only happen if the efficacy of the biologic alters for the patient. The issues identified by Gediminas include a significant lack of patient information about how to access treatments and what the treatments are. Even when the existence of biosimilar treatments and the potential they can offer for wider patient access is acknowledged, Gediminas shared his concerns that the Lithuanian reimbursement system would not facilitate increased patient access to new biosimilars for another two or three years. Sharing his experience in patient advocacy, Gediminas explained that the group has only just started engaging but have reached out to the National Health Insurance Fund, the national industry body and healthcare professionals and will now look to do more.



ALLIES AND ACCESS

Brian Kennedy then led a session on how to identify and overcome barriers in patient access through advocacy, with a particular focus on identifying and engaging with the right people. Brian talked groups through the importance of understanding who ultimately makes the decisions on policy and targeting their engagement at these key policy makers. He also emphasised the role of those who influence policy decisions, such as the media and expert groups, which in the case of healthcare decisions, is usually medical societies. Brian shared example activities and advice with attendees for them to take away and put into practice in their own countries, as some attendees had already done.



Patient Discussion

► **Need for closer working between patient and physician groups**

Another key issue identified by almost all patient advocates was a lack of reliable information being provided to patients as part of their treatment, with many representatives citing physicians' lack of time to discuss options with patients. Groups shared the different methods through which they have been trying to increase patient understanding and awareness. Dagmara Semselska from the Union of Psoriasis Associations in Poland described the video content developed by her group which aims to tackle public perceptions about patients with psoriasis and psoriatic arthritis. Jolanta similarly shared the work done by in the Polish rheumatology community, where her group has organised conferences and lectures for patients and their families from specialist physicians.

Luisa suggested that EFCCA's research has indicated that about 50% of physicians provide their patients with information about patient groups that exist and could be useful, and this is only after the physician has built up a relationship with the group. On the back of these findings EFCCA is planning on launching an EFCCA Academy to provide patient experts within EFCCA's network with the basic tools that they would need to start informing both other patients and policymakers and start advocating for policy change. The Academy is going to start with 15 patient experts as a pilot but will then look to grow and share the experience within the EFCCA network for the benefit of all patients.

► **Lack of awareness and information on treatment options**

Luisa Avedano identified the importance of patient groups working closely with medical societies, both to increase the strength of their voice in advocacy through developing shared positions, and to improve the information that is shared with patients on treatment options. The group discussed whether this type of relationship between different groups could be formalised with a type of framework or structure that could be shared with groups, setting out the ideal working relationship. Several groups suggested that there is not a strong tradition of close working between patient and medical societies in their countries, which is a barrier they must overcome. Jolanta Grygielska shared the experience of the Polish rheumatology community which has overcome this barrier and now works closely with Dr. Stanislawski's rheumatology department. In contrast, Janek Kapper suggested that in Estonia physicians are encouraged not to engage with the patient groups and don't refer newly diagnosed patients to groups as a source of information. Overall the group concluded that there is a significant variation in the patient, physician relationship and that there are distinct cultural barriers in some countries with physicians not trusting the information being provided by patient groups, therefore not recommending them to patients.

Luisa then presented to the group the initial findings of the EU mapping project EFCCA has been undertaking around 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 the access for patients to different treatments, including biologics and biosimilars, in their countries. The initial countries questioned were Finland, France, New Zealand, Poland, Serbia, Slovenia and Spain. In most cases the results were provided by patient representatives in combination with local gastroenterologists, once provided these were then fed back into EFCCA's working group.

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.

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 initial conclusions of the pilot phase study were 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 hope 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:



- Patient groups have taken away information from previous GAfPA and EFCCA workshops and put it into practice by advocating in their own countries.
- Groups appreciated the opportunity to share and can learn from each other's experiences, a process which highlights the significant disparity in patient experience in different countries.
- Patient groups agreed the importance of working together, along with physician and health care professional groups to increase their share of voice when talking to policy makers, some groups would welcome an example framework of how to make this happen.
- Widespread agreement on the importance of protecting the physician-patient relationship and ensuring that the patient is confident that their physician is making their decision based on medical not financial reasons. Also, the importance of doctors taking the time to explain to patients their treatments options and decisions and pointing patients in the direction of patient representative groups for further information.
- Overall access to biologicals still varies widely across Europe with very poor access in some countries. Patients groups want to be more involved in improving access to these medicines.



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 34 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

