

BIOLOGICS & BIOSIMILARS

Patient Access and Advocacy

WORKSHOP

FINAL
REPORT

10-11
NOVEMBER

2017

Rome
Italy



United We Stand



Introduction

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 Rome, Italy on the 10th and 11th of November 2017.

The workshop was designed to build on the successful events held by GAfPA and EFCCA in 2016, in Barcelona and Brussels, 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 primarily from Southern Europe to consider the outstanding policy questions around patient access, use of biologic and biosimilar medicines, and how to most effectively ensure that the patient voice can be heard in policy decisions.

The 17 patient delegates from 9 different countries represented specialties from across rheumatology and gastroenterology, including several members of EFCCA's European network. This was the third and final of a series of meetings jointly held by GAfPA and EFCCA in 2017, bringing together representatives from a specific region to share and learn from each other's experiences with biologic and biosimilar medicines. The first of these took place in Munich in May and the second in Warsaw in September.



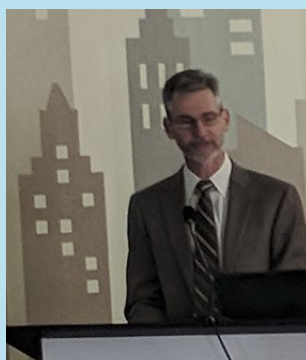
INTRODUCTIONS AND WORKSHOP OVERVIEW

Luisa Avedano, EFCCA



Luisa Avedano, Chief Executive Officer of EFCCA formally opened the workshop and encouraged attendees to engage in a frank and open conversation about the way in which biologic and biosimilar medicines are used in their own countries and how they feel about this as patients. Luisa framed the discussion as an opportunity for groups from different disease areas and countries to share the experiences they have had in advocating around these medicines and learn from each other. She went on to explain the role of EFCCA and GAfPA in supporting the sharing of best practice through these workshops, which are followed up with a report of groups' key learnings to accompany the other learning tools for patient representatives that both EFCCA and GAfPA produce.

Additionally, Luisa emphasised that there continue to be unresolved policy questions around the use of biologic and biosimilar medicines, one of which is barriers in patient access to these medicines, experienced by EFCCA members in countries across Europe. EFCCA has therefore undertaken a significant project to map access to, and challenges around, biologic and biosimilar medicines, which was shared in greater detail in the afternoon workshop.



Dr. David Charles INTRODUCTION TO BIOLOGICS AND BIOSIMILARS

Dr David Charles, GAfPA, provided an introduction to the topic by explaining the manufacturing process behind biologic and biosimilar medicines and the differences between the two. As a practising neurologist and a national leader in research into movement disorders, Dr Charles welcomed the development of biosimilar medicines as offering additional treatment options, bringing down prices by increasing competition, and overall helping to increase patient access. However, Dr Charles did urge caution around treating biosimilars in the same way as generics, as he explained, they are not identical copies and go through a different process of clinical trials to the originator medicine.

Dr Charles shared his own experience treating patients with biologic and biosimilar medicines. He suggested that there may be cases where the biosimilar could be a better treatment option for his patients; however, there is a lack of evidence on patients switching between the two for physicians to be sure. Dr Charles was clear that this can only be addressed through further clinical studies being undertaken on the impact on patients of switching, between originator medicines and biosimilar medicines; between biosimilars; and from a biosimilar to a biologic.

Dr Charles emphasised that his key concern is for patient choice in treatment options to be respected, that patients should not be forced to switch if they do not want to and should have the freedom to switch back to their original treatment if the switch doesn't work for them. He indicated that GAfPA will continue to work to try and ensure this is the case, 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: PHARMACOVIGILANCE (PV)

Dr Charles opened the floor for discussion, attendees shared their experience of PV systems in their countries and how they report any adverse events. **Mary Vella, representing the Arthritis and Rheumatism Association of Malta** shared how rheumatology patients in her country are expected to report any reaction to a rheumatology nurse, whereas **Alejandro Samhan-Arias from the Spanish Crohn's and Colitis group, ACCU España (EFCCA)**, suggested that patients are not reporting issues, but assuming it is being monitored in the hospital where they are treated. Dr Charles recognised the lack of consistency in PV practices across different countries, and argued that it is essential that this is improved in order for governments, manufacturers and regulators to have the best possible information in order to be able to make any required improvements to treatment efficacy.

An option suggested by Dr Charles to improve the tracking and tracing of medicines is to use unique International Non-proprietary Names (INN) for each medicine. Luisa set out that EFCCA fed into the World Health Organisation's (WHO) policy on this, however, the WHO's policy is only guidance for governments and EFCCA believes more should be done on a national basis to increase transparency and make patients aware of PV systems. **Dusan Baraga, from the Slovenian IBD Association, KVCB (EFCCA)**, agreed that there needs to be more information for both patients and physicians and that this should be addressed urgently, as current requirements are too complicated for many patients. Luisa suggested that one solution could be a register of all biologics and biosimilars users. EFCCA will also be looking into the issue of PV and education around PV systems through the EFCCA Academy, which is being launched next year and will include 15 patient experts as a pilot, before then looking to grow and share the learnings within the EFCCA network for the benefit of all patients.



Patient discussion: SWITCHING

The group agreed that one of the most crucial aspects of a robust PV system is to be able to track any patient response to a switch of medicine, whether this is between biologics or to a biosimilar. Attendees all recognised that their healthcare systems are under increasing pressure to deliver quick financial savings by switching patients to biosimilars. **Salvatore Leone, from Italian Crohn's and Colitis Group, AMICI Onlus (EFCCA)**, said how hard it can be for patients to become stable on a treatment and that any treatment change can be risky for the patient, suggesting that patients should therefore not be forced to switch treatment if stable. **Maria Candida Cruz, representing Portuguese IBD group, APDI (EFCCA)**, expressed her concern that the patient opinion is not valued as much as that of the physician when deciding to switch a treatment. Several attendees also expressed concern at being switched onto any treatment that has not been clinically trialled on patients in their specific disease indication. Dr Charles set out his belief that all treatments should include on their label the information on the trials that have taken place for that treatment in their specific disease state, rather than including on the label for the biosimilar just the information on the trials that took place for the biologic. Patient attendees including **Viorica Cursaru from Romanian Group, Pain Alliance Europe**, expressed reservations at being prescribed a biosimilar that had not been trialled in the exact disease state. Considering the evidence base supporting switching, **Sebastian Micallef, from the Arthritis and Rheumatism Association of Malta**, suggested there would be value in large scale trials similar to the NorSwitch study taking place in other countries, as patient reaction can be altered by factors such as weather.

Dr Charles concluded the session setting out GAfPA's position that patients should have the right to an informed discussion with their physician about their options, and their right to choose to remain on a treatment if they are stable, without being forced to switch.

Neil Betteridge: BIOLOGICS AND BIOSIMILARS POLICY ISSUES IN EUROPE

In the second 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 highlighted the latest guidance provided by the European Commission which suggests that patients should provide fully informed consent to any switch of medicine. However, the Commission does not have the ability to require that this happens on a country by country basis. Neil therefore went on to explain GAfPA's role as supporting groups to advocate in their own countries, to ensure that policies are developed clearly, recognising and supporting the rights of the patient. Neil clearly set out that the most powerful way for this point to be made is for patients to make the case for their involvement in policymaking, and to press for this change from the ground up.

Neil highlighted how far the conversation around switching to biosimilars has come since February 2016 when GAfPA and EFCCA held their first advocacy workshop on the topic. In the intervening time the conversation in Europe has shifted significantly from patients being asked to switch once, to examples of multiple switching which have been shared at several workshops. Neil suggested that one of the key questions is now whether patients have the ability to say no if they are asked to switch treatment. Attendees shared the processes for securing their consent around treatment changes, Luisa explained that in both Italy and Belgium informed consent must be secured prior to a treatment. Similarly, **Victoria Romero-Pazos, from Spanish rheumatology group LIRE-Reumatológica Española** indicated that a patient's signature is required before treatment starts. However, no signature is needed before a treatment is changed.

Neil expressed concern at some governments considering only the short-term savings available by requiring patients to switch; he argued that this approach is disrespectful to patients, dismissing their priorities, whilst at the same time asking them to carry all of the risk of a medicine change if they are stable.



GAfPA Director Chase Martin 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. Chase 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. Chase 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, and reiterated the role of GAfPA as a resource for groups to come to for information and support with advocacy ideas.



EFCCA: INNOVATIVE MEDICINES, EU MAPPING PROJECT

Luisa then presented to the group the first wave of findings of the EU mapping project EFCCA has been undertaking around innovative medicines. This project has been undertaken in order 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 which took place 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 and once provided, these were then fed back into EFCCA's working group.

This pilot phase identified some trends across the countries that were surveyed. Significant variation 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, with particular variation in Germany, France, Spain and Belgium. Conclusions were complicated by 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. Luisa suggested that the results could help feed into the development of protocols around basic levels of patient access which could be available across Europe.

EFCCA aims to present the findings of the mapping at the ECCO 2018 Congress as well as in a gastroenterological journal, and to an event at the European Parliament to demonstrate to policymakers the scale of the access challenge.

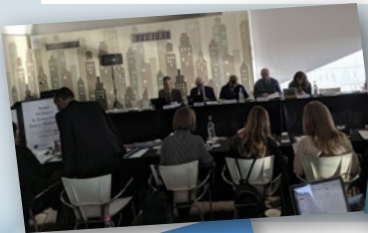
REGIONAL BEST PRACTICE FOR ADVOCACY

Portugal

Maria Candida Cruz from the Portuguese IBD patient association (APDI) and EFCCA

member shared with the group the situation that

patients experience in Portugal. She identified several key challenges facing Portuguese patients, of which the main one is a lack of information, both on what biosimilars are, and their rights around any treatment change. Information for Portuguese patients is available on an online portal from the scientific association GEDII, which welcomes the introduction of biosimilars but is clear that any switch should have patient consent. Maria suggested that currently Portuguese physicians prefer to maintain their patients on originator medicines if they are stable, but that they are coming under increasing pressure to start biologic-naïve patients on biosimilars, as centralised medicine purchasing decisions are increasingly made based upon cost. However, she suggested that Portuguese physicians are not entirely confident in the PV system and that gaps in the law and a lack of uniformity is compromising patients. In particular, she suggested that there is a lack of awareness amongst physicians of their reporting requirements. Turning to patient advocacy, Maria expressed her concern that the voice of the patient is not strong enough in the debate in Portugal and they are therefore looking for as many opportunities as possible to work with the physician group in order to influence policymaking.



Italy

Salvatore Leone from the Italian IBD patient association, AMICI Onlus and EFCCA Vice President,

explained the situation facing patients in Italy, highlighting the inequality of access, with only 20% of IBD patients receiving treatment with biologics, but these treatments account for more than 80% of overall treatment costs. Salvatore talked through the patient survey which was undertaken by EFCCA in 2010 and which found significant variation in the treatment being provided to Italian patients. The group AMICI Onlus therefore helped develop a template diagnostic pathway for IBD patients, designed to help the Italian healthcare system save money and ensure that patients are provided with the right treatment at the right time. This pathway had secured the agreement of the Italian health minister during a conference in 2014, following which, the group has successfully had it approved and put in place in several Italian regions, including Sicily and Sardinia.

Spain

Alejandro Samhan-Arias (ACCU España and EFCCA member)

presented the current situation in Spain, explaining that the decision on whether to use biosimilars is made by the pharmacist within the hospital. However, the higher-level decision on whether biosimilars are available is made at a regional level, therefore leading to different levels of access in the 17 different prescribing regions. Alejandro shared the experience of patients in one region, where ACCU España were informed of the intention to switch all patients to the biosimilar. The group therefore contacted a local politician, to whom they had to explain the topic of biosimilar medicines as the politician believed them to be the same as generics. **Isabella Haaf, (EFCCA Communications Director)** and **Victoria**, both shared their examples of attempted wholesale switching in different regions across Spain and instances of patient advocacy at a local level on the issue. Following this kind of advocacy, Spanish patients successfully pressed for a law which mandates that a stable patient cannot be switched from the originator medicine, for purely financial reasons, and that any switch must have the support of their physician.

Victoria shared the experience of her group in advocating against mandated switching. LIRE-Reumatológica Española had developed a position paper setting out the patient position, following which, the group was contacted by the Spanish physician society which expressed some concerns at some of the examples the patient group had gathered of treatment being switched at the pharmacy level, with neither patients nor physicians being made aware. LIRE-Reumatológica Española therefore worked closely with the physician group in engaging with the Government. Victoria explained the next challenge that the patient groups are facing, which is to be involved in policy making decisions. Currently, Spanish patients are not allowed to be in the room at national level policy meetings, LIRE-Reumatológica Española is therefore pressing for a council of patients to be established within the health ministry that can represent the patient voice in all policy decisions.

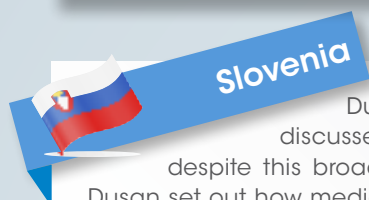
A similar example of a group successfully developing and using a policy paper was shared by **Mary Vella**, who explained how patients in Malta were switched onto a biosimilar without any choice. **In response to this mandated switch the rheumatology patient group had developed a paper which they presented to policymakers. Following this they have secured an additional three years before there is any requirement to switch.** Ms Vella thanked the GAfPA team as the idea for developing a position paper to present to policymakers had come from a previous GAfPA advocacy workshop.



Ahead of the workshop, participants had been 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 had been provided with the following questions:

- 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 they 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 sharing their experiences.



Dusan Baraga from the Slovenian IBD patient association KVCB and EFCCA member, discussed his work on a joint position paper with physicians and insurance companies, however, despite this broad approach, Slovenian patients face the prospect of being switched very regularly. Dusan set out how medicines are bought by hospitals on a tender system for one year, providing patients with no choice and the prospect of their treatment having to change every year. However, Dusan did suggest that the option remains for patients to seek treatment at an alternative hospital if they do not wish to switch treatment. Slovenian patients have expressed concerns at the potential impacts of multiple switches that have not been trialled as more biosimilars become available. To address these concerns with the system, KVCB has been trying to secure media coverage; however, they are facing a significant challenge due to the financial pressures which are being placed on hospitals to make savings on treatments. The group has also been delivering workshops for patients on adverse reactions and how to report them, however, they have yet to see a rise in reporting and believe that education around the issue needs to go wider and include policymakers. Luisa reiterated Dusan's point around wider education, suggesting that currently EFCCA members are only 20% of a disease community within a country and that they must continue to try and reach a wider audience.



The key points to emerge from the meeting were:

- Further patient groups have taken away information from previous GAfPA workshops and put them 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.
- Engaged patient advocates are aware and concerned about very detailed policy questions, in particular around areas in which they do not believe there is sufficient clinical evidence, such as around multiple switching and indication extrapolation.
- Patient groups recognise the importance of working together, along with physician and health care professional groups to increase their share of voice when talking to policy makers.
- There was widespread agreement on the importance of informed choice and protecting individual patient input into decisions about their treatment. Many groups were interested in the success in Spain of pursuing a legislative route to ensure that patients cannot be switched en masse solely on a cost basis.
- Overall access to biologicals 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. The issue of unequal access remains very pertinent in the gastroenterology community and is something that EFCCA will continue to look at.



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 organisation 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

