



13-14 JAN  
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BUDAPEST  
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# BIOLOGICS & BIOSIMILARS Self-Management

W O R K S H O P

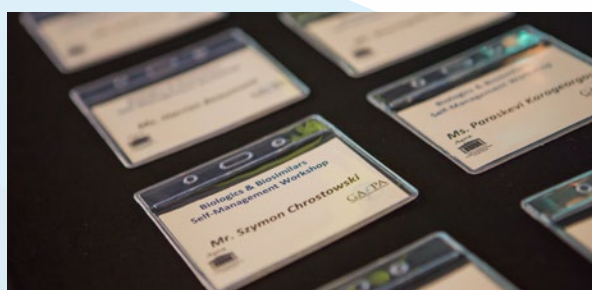
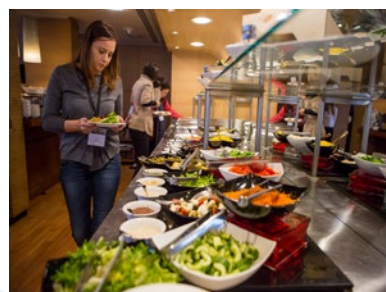




## INTRODUCTION

On January 13th and 14th, the Global Alliance for Patient Access (GAfPA) and Agora, a platform of organisations of people with rheumatic diseases in Southern Europe, held a workshop in Budapest for patient advocates. The aim of this event was to provide patient groups with a greater understanding of the current landscape for biologic and biosimilar medicines in Europe; to equip them with effective tools to inform policymakers about patient concerns; and to examine the role of self-management programmes in supporting patients with rheumatic diseases.

The workshop was attended principally by patient advocacy groups from Agora's southern European network, with additional closely engaged groups from Ireland, Denmark and Israel.





# Policy issues around biologic and biosimilar medicines

Biosimilar therapies hold promise for patients across Europe by expanding available therapeutic options, increasing the number of patients who can access innovative medicine and, in some cases, lowering the cost of treatment. As the number of these medicines available in Europe to treat autoimmune conditions increases, patient advocates are increasingly interested in issues related to the use of biosimilar medicines.

In particular, patients and health care providers have welcomed more available options for treating complex diseases, but they also want to maintain their role in decisions about patients' health care. Of particular interest, therefore, is the trend by which more states are incentivising the switching of patients from a biologic treatment to a biosimilar one.

GAfPA has engaged with patient groups across Europe and hears concerns about the role that patients play in decisions about their own treatment. These conversations have reinforced the need for patients to be central to any decision about which medicine they are treated with. This is particularly the case with biologic and biosimilar medicines, as GAfPA's previous workshops (in Barcelona, Denmark and Brussels in 2016) have demonstrated.



## The clinician's perspective



During the first day, **David Charles, M.D.**, Chair of GAfPA's Biologics and Biosimilars Working Group, explained the background of biologic and biosimilar medicines. He welcomed the choice that they bring to patients and clinicians through greater competition and lower prices. But he emphasised the need to ensure patient safety through rigorous tracking, tracing and pharmacovigilance practices.

Dr Charles explained how the complex biosimilar manufacturing process means there can be no such thing as a 'generic biologic' – as biosimilars and biologics can never be identical. He also expressed his concern around the concept of indication extrapolation – when a biosimilar may be approved for use in an indication in which it has not been clinically tested – and said he "would like to see trials in all the disease states for which I am prescribing a medicine."

Finally, Dr Charles provided the group with the latest updates on the discussion around the need for biosimilars to carry distinct non-proprietary names.





## SWITCHING

One important issue raised during the workshop was around the subject of switching between biologic and biosimilar medicines.

Dr Charles talked through the findings of the NOR-SWITCH study, a randomized, double blind study of how patients across six inflammatory diseases responded to being switched from the originator medicine Remicade® to the biosimilar Remsima®. The results suggested that treatment with the infliximab biosimilar was not inferior in terms of efficacy or safety to treatment with the biologic.

The group then discussed the findings and parameters of the study, which have been explored in detail by GAfPA in its white paper, *Nor-Switch: What will Norway's infliximab switching study tell us about the safety of switching patients from one biologic medicine to a biosimilar?* The group agreed that there is currently insufficient evidence around multiple switching – between biologics and other biosimilars, between biosimilars back to a biologics and between biosimilars – and that NOR-SWITCH did not add to the evidence base on these questions.

Delegates from the Spanish group LIRE (Spanish League Against Rheumatism) explained the current situation in Spain, where physicians are rewarded for prescribing biosimilars, leading to patients questioning the motives of their clinicians.



## DEVELOPMENT OF PATIENT PRINCIPLES AROUND THE USE OF BIOLOGICS AND BIOSIMILARS

GAfPA and Agora members then led breakout sessions that stimulated more detailed discussion of the issues raised by Dr Charles, with groups discussing their experiences of switching. To present a clear and aligned position on biologics and biosimilars, delegates helped produce these patient principles – to be adopted by Agora but also potentially by their own national patient groups – as a tool for advocating around these issues.

Delegates shared how they have addressed questions, particularly around switching, in their

own countries. A member of Inbar, the Israeli RA Foundation, led a successful legal challenge to the requirement that patients be switched to a biosimilar. Representatives from groups including the Arthritis and Rheumatism Association of Malta and the Arthritis Foundation of Greece argued that their experience has demonstrated that it is better for stable patients to stay on their originator medicine if it is working for them. Both groups also agreed that patients should be able to recognise different medicines and that all treatments must therefore have individual identifying names.





# Patient Principles

*Whereas - there is currently a lack of understanding and awareness among patient groups around biosimilar and biologic medicines;*

- I. Education should be available to patients (either through their HCPs or own patient groups) to ensure they are fully informed about biologic and biosimilar medicines. Savings made from biosimilars should be reinvested in increasing access to biosimilar therapies and should go towards educating and informing patients.**

*Whereas there is currently insufficient involvement of patient advocates throughout the process by which biologic and biosimilar medicines become available to patients;*

*Whereas patient advocates are insufficiently involved in the trial design of biologic and biosimilar medicines;*

*Whereas patient advocates are not sufficiently involved in producing information around biologic and biosimilar medicines in accessible and plain language;*

*Whereas patients do not always have access to, or know how to, find evidence-based data on biologic and biosimilar medicines;*

- II. Patient advocates have the right to be involved throughout the process through which biologic and biosimilar medicines become available to patients, and be involved in:**

- a. Trial design
- b. Producing plain language information
- c. Guiding other patients and healthcare professionals to this information
- d. Helping other patients understand this information

*Whereas some health systems may seek to switch patients from one biologic treatment to another;*

- III. Patients who are stable on a treatment should always be given the option to stay on this treatment, if they so wish.**

*Whereas patients are not always sufficiently involved in decisions about their treatment*

*Whereas patients are not always empowered to play an active part in the decision making process with their clinician;*

- IV. Shared decision making between patients and clinicians is essential when prescribing biologic and biosimilar medicines.**

*Whereas complex biological medicines sometimes cause unexpected side effects and immunogenic responses*

*Whereas accurate, timely identification of the medicine causing a patient response must be feasible to protect patient safety*

*Whereas, in communicating about prescribed medicines, clinicians and health care providers use medicines' non-proprietary names;*

- V. Biosimilars must carry distinguishable non-proprietary names that protect patient safety by ensuring that all parties, including patients, and can quickly and accurately identify which medicine is being used (ensuring it is clear to patients which brand name that this represents.)**



## SELF-MANAGEMENT

On the second day of the workshop the focus moved on to analyse self-management programmes, the purpose of which was to assess:

- The implementation of the Agora self-management programme
- How different groups have introduced the programme
- Any issues or challenges the groups faced with the programme
- Next steps to improve the programme.

Agora chair **Souzi Makri** set out the progress made by the programme and the value of the 'Train the Trainers' project. This project has seen two members of each patient organisation provided with the knowledge on both organisational and practical exercises to then run the self-management programmes for their own members. This has then been followed up through online forums and blogs through which members can share opinions and best practice.

**Claire Kinneavy** of Arthritis Ireland then presented to the group on the theory of self-management programmes as complementary treatment for RMDs. Claire went on to share evidence of the economic savings provided to healthcare systems by using these self-management systems, citing progress such as a 25% reduction in GP visits by those with chronic conditions that use self-management programmes. Claire's positive experience was in the majority of cases shared by representatives from several other groups that have introduced AGORA's programme:

- **Mary Vella** from ARAM (Malta)
- **Persefoni Markidou** from CYPLAR (Cyprus)
- **Marija Kosanovic** from ORS (Serbia).

Delegates discussed experiences from different countries, highlighting best practices and sharing considerations for groups to ensure that their training is as effective and accessible as possible. Considerations which groups suggested as critical to ensure that the self-management training can be as effective, efficient and accessible as possible, included:

- Recognition of the importance of selecting a good trainer. Just being a patient is not an automatic qualification for being a good trainer, or an effective group leader
- Trainers should themselves receive continuous updates to their training to provide the highest quality support
- Training should take place in an easily accessible location in a suitable venue
- The presence of a psychologist can be valuable in dealing with any challenges that arise in the discussions
- Greater use should be made of technology including apps, webexes and infographics to provide follow-up training
- An effective evaluation tool for self-management courses should be developed.





The importance of developing an effective evaluation tool for the AGORA self-management program was discussed during a plenary Q&A session. The delegates agreed that an effective evaluation tool should measure both quantitative and qualitative data via various methods, evaluating:

- The program itself (provided by patients)
- The desired outcomes (provided by trainers)
- The effects of the programme on the everyday life of patients (provided by patients).

Further to the development of an effective evaluation tool, the delegates highlighted the need for the current AGORA self-management program to become available, accessible and more tailored to the needs of patients. The discussion led to the realisation that an Internet-based self-management platform could provide a more personalised experience, as it allows patients to follow courses online from their own home, at their own convenience and based on their individual needs.

**Elena Tsigki**, Agora Project Coordinator, then presented the benefits of using technology and a self-management app as an aid for treating RMDs. Throughout the presentation, it was indicated that technology can play a vital role in increasing patients' knowledge and self-efficacy. An informed patient is an empowered patient and a real partner in shared decision-making. Lastly, it was indicated that the use of technology and various self-monitoring applications could reduce the unnecessary use of health care services and hospitalisations, which leads to reduced costs in health services.

Agora welcomed this feedback from this session, which will be used to develop and improve its self-management programme, including the development of a training manual, an evaluation tool and an online self-management platform with the aim of the programme being more widely adopted by its membership organisations.



## S U M M A R Y

This workshop, the first partnership of its kind between AGORA and GAfPA, was a great success that highlighted the benefits of joint working, the exchange of good practices and mutual learning.

AGORA and GAfPA will continue to work together to raise awareness around the important issues of patient safety, the central role of the patient in treatment decisions, accurate and simple information for patients and, above all, the education and empowerment of patients, be they individuals or patient groups.

Biologics & Biosimilars Self-Management Workshop  
Groups represented 13th-14th January 2017, Budapest

ACS France	France
Agora	Cyprus
APAA	Romania
Arthritis and Rheumatism Association Malta	Malta
Arthritis Ireland	Ireland
Association For Helping People With Rheumatic Diseases	Montenegro
Cyprus League Against Rheumatism	Cyprus
Global Alliance for Patient Access	USA
Hellenic League Against Rheumatism	Greece
Inbar	Israel
Liga reumatologica Galega	Spain
LIRE (Spanish League Against Rheumatism)	Spain
Patients with Rheumatic disease of the Republic of Serbia (ORS)	Serbia
Portuguese League Against Rheumatic Diseases	Portugal
Society of Information and Support for Patients with Rheumatic Diseases (ROMATURKA)	Turkey
The Arthritis Foundation of Crete	Greece
The Autoimmune Deceases Organisation	Denmark
Mifrakim Tze'irim	Israel
The Polish Cancer Patient Coalition - ECPC	Poland



**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](http://www.gafpa.org)

*Agora*



Platform of Organisations  
of people with Rheumatic Diseases  
in Southern Europe

**Agora** is an umbrella platform representing patient organizations of people with Rheumatic and Musculoskeletal Diseases (RMDs) in Southern Europe. Since its inauguration in 2011, Agora has been very active in raising awareness on RMDs aiming at creating a better quality of life not only for its member organisations, but also all people with RMDs in Southern Europe.

[www.agora-platform.eu](http://www.agora-platform.eu)

#### EVENT SPONSORSHIP

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