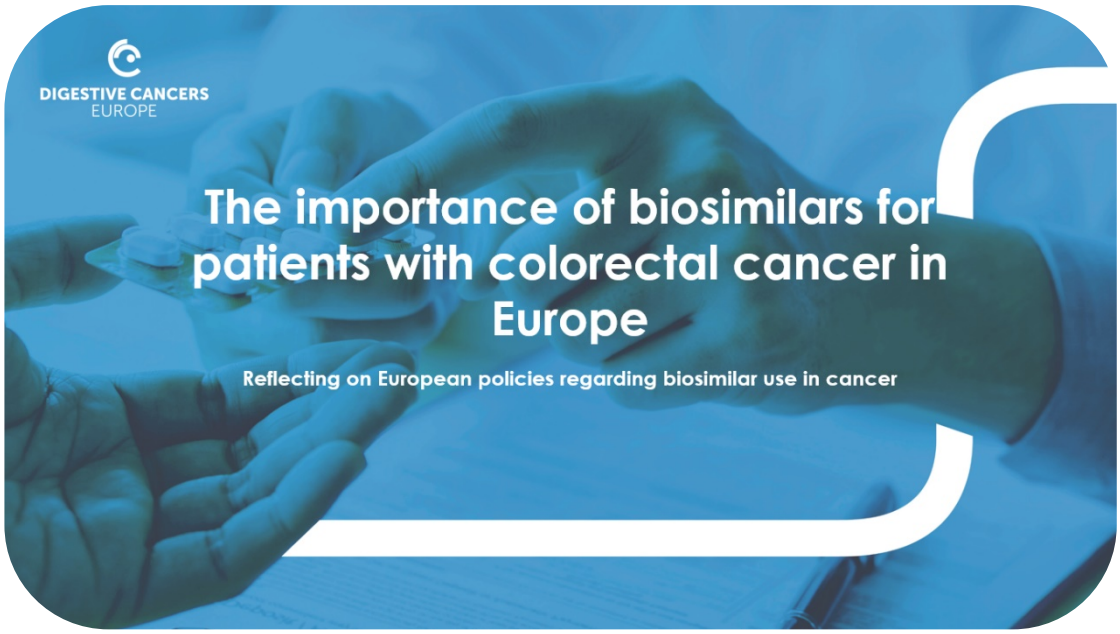
The Importance of Biosimilars for Patients with Colorectal Cancer in Europe – Reflecting on European Policies Regarding Biosimilar Use in Cancer

Tuesday 28 September, 10:00 am–12:00 pm



Event report

DIGESTIVE CANCERS
EUROPE

Introduction

On 28 September, Digestive Cancers Europe (DiCE) organised a virtual event on the importance of biosimilars for patients with colorectal cancer in Europe.

The event brought together the views of different stakeholders on biosimilar medicines, including the patient's perspective. The multidisciplinary experts demonstrated how the use of biosimilars can contribute to increasing treatment access for colorectal cancer patients and to enhancing the sustainability of European healthcare systems overall. Moreover, MEP Dolors Montserrat, rapporteur of the INI report on the Pharmaceutical Strategy, participated to share the view of the European Parliament on this important topic.
The interventions were followed by a panel discussion, involving all the experts as well as MEP Montserrat to answer questions by the audience.

Central to the event was the launch of DiCE's Call to Action, which was presented at the end. The Call to Action calls upon the individual Member States, the European Commission as well as other stakeholders to work towards improving the use of biosimilars in colorectal cancer through implementing policy change, as well as enhancing overall education about biosimilars.

Speakers and Panellists

In order of appearance

Tamsin Rose – Moderator

Barbara Moss – DiCE Patient Representative

Prof Fernando de Mora – PhD, MBA, Professor of Pharmacology, Department of Pharmacology, Therapeutics and Toxicology, Universitat Autónoma de Barcelona, Spain

Prof Zoltán Kaló – Professor of Health Economics, Eötvös Loránd University (ELTE), Budapest; founder and CEO of Syreon Research Institute, Budapest, Hungary

Dr Rosa Giuliani – Consultant in Medical Oncology, Clatterbridge Cancer Centre Wirral, Liverpool, UK & Director of Public Policy, ESMO

Yannick Vandenplas – PhD researcher, Clinical Pharmacology and Pharmacotherapy Research Unit, KU Leuven, Belgium

Dolors Montserrat Member of the European Parliament– Member of the Committee on the Environment, Public Health and Food Safety (ENVI) and of the Special Committee on Beating Cancer (BECA)

Giulia Barenghi – DiCE Policy and Public Funding Manager

INTRODUCTION TO THE EVENT, BY TAMSIN ROSE

Tamsin Rose, who moderated the event, restated the key purpose of the gathering, namely to explore how biosimilar use in cancer can be better reflected within both national and EU policies. Although since 2006 more than 70 biosimilars have been approved by the European Medicines Agency (EMA), there are many barriers that biosimilars face. To be fully accessible to those who need them, many challenges must be overcome.

BIOSIMILARS & THE PATIENT PERSPECTIVE, BY BARBARA MOSS

Barbara Moss, representing the patient perspective from DiCE, spoke about her cancer journey, what biosimilars mean for patients and why this topic is relevant for clinicians and health authorities.

She shared her story on how biological treatment saved her life when she was diagnosed with Stage IV colorectal cancer 14 years ago. Whereas Ms Moss was told upon diagnosis that she would likely survive for only 3 more months, she has been cancer-free for 13 years.

After having tried several treatment options with no sufficient effect, Barbara and her husband Mark inquired about biological treatments being used in Europe and America. These types of medicines were not available on the UK's National Health Service (NHS). **The reason for refusal by the NHS was not safety, but cost.** This moment marked the start of Barbara's determination to play an active role in the decisions revolving around her treatment, as well as media attention for her journey.

Barbara had to pay entirely out of pocket for the biological treatment (at that time only the originator was available as an option). Her story was featured in the press, taken to the UK Parliament, and it even resulted in changing the law. Specifically, in 2007 when a private medicine was added to one's treatment, one lost NHS entitlement as a whole. Barbara's story, however, helped change the law, allowing patients to purchase a private drug without losing their NHS entitlement.

Her journey has made her committed to continuing campaigning for the use of biosimilars in cancer care. Patients deserve to receive equal access to treatment options, and biosimilars must get recognised as equally safe and effective given that they are being assessed by the EMA in the exact same, rigorous way. More importantly, biosimilars can save lives, as they can be a key in increasing access to biological therapies.

BARRIERS TOWARDS THE UPTAKE OF BIOSIMILARS AT NATIONAL LEVEL, BY PROFESSOR FERNANDO DE MORA

Prof Fernando de Mora, PhD, MBA, Professor of Pharmacology, Department of Pharmacology, Therapeutics and Toxicology at Universitat Autónoma de Barcelona, Spain, explained what the barriers on national levels are when it comes to biosimilars uptake.

Two main barriers can be recognised, namely:

- **A lack of knowledge,** as there is a lack of records on the health outcomes brought along by biosimilars.
- **A lack of policies, guidance and legal action at the national level** that promote the use of biosimilars.

A few activities could provide solutions for these barriers. When it comes to the knowledge gap, education and the creation of patient registries, including data on therapeutic outcomes, should

be funded by national governments. By increasing the use of biosimilars, more data on outcomes would be available, which in turn could be used to optimise treatment and provide more targeted treatments.

As regards the lack of policies, Prof de Mora stressed that governments should implement policies that give recommendations on interchangeability and which incentivise the use and prescription of biosimilars.

- An example of this would be **gain-sharing agreements**. By increasing the use of biosimilars, funds can be accumulated, which can then be reinvested in hospitals. This would ensure that ultimate benefit is eventually offered to patients, and that the added value of biosimilars is maximised.
- Policies supporting and educating prescribers on interchangeability would guide prescribers in the switch from one product to another.

The gains that could be made from implementing these activities are both individual and collective. For the patient, it would mean among others more and earlier access to biological therapy and access to newer therapies. For healthcare systems, it would help in preventing medicine shortages and fostering innovation.

GENERAL OVERVIEW ABOUT BIOSIMILARS AND HEALTHCARE SUSTAINABILITY, BY PROFESSOR ZOLTÁN KALÓ

In a recorded statement, **Prof Zoltán Kaló,** Professor of Health Economics, Eötvös Loránd University (ELTE) in Budapest and founder and CEO of Syreon Research Institute in Budapest, Hungary, gave an explanation of how biosimilars can be a key enabler for healthcare system sustainability and how they can benefit different countries.

Prof Kaló first provided a description of how off-patent medicines can reduce health expenditure without compromising health outcomes. Off-patent medicines can improve the population's health gain by improving patient access without the need for extra budget. As such, off-patent medicines can result in overall health improvement.

When exploring patient access in different countries, **significant differences can be observed in higher and lower-income countries**. In low-income countries, utilisation of biologics is much lower as compared to middle- or higher-income countries. There is a clear disparity between Eastern and Western European countries, which is a direct result of the average lower economic status in Eastern Europe. A worrying demonstration of this is the fact that for patients diagnosed with colon cancer, the five-year survival is significantly lower in Eastern European countries as compared to Western counties. In fact, this difference can be up to 15%, showing a considerable difference in unmet medical needs.

There is more potential to improve the health status of Eastern European patients. Given the high cost saving potential of biosimilars, **Prof Kaló explained that with post-patent expiry, biosimilars can contribute to removing access barriers for patients.** He considered this is a key method to reduce the gap between higher and lower income EU Member States, as **health gain could be achieved without increasing the health budget.**

Concluding, **Prof Kaló** stated that one-size fits all does not work in terms of biosimilar policies, which should be targeted to each country according to the accessibility of patients to biological therapies before patent expiry. Thus, policies in lower income countries need to be adapted accordingly to achieve this goal.

BIOSIMILAR INCENTIVES – THE HEALTHCARE PROFESSIONAL PERSPECTIVE, BY DOCTOR ROSA GIULIANI

Dr Rosa Giuliani, Consultant in Medical Oncology, Clatterbridge Cancer Centre Wirral, Liverpool, UK and Director of Public Policy, ESMO, gave a presentation on healthcare professional view on incentives to use biosimilars and how these can best be implemented into healthcare practices. Before starting her presentation, Dr Giuliani emphasised the extent of agreement among the experts that had spoken so far with respect to the great potential of biosimilars.

She explained the importance of value-based oncology care as essential in our healthcare systems today, and that this requires four key pillars:

- **Science**: the extent of evidence gathered on biosimilars to date is indisputable. There is a solid scientific base for their use.
- **Regulatory science** is needed in order to assess medicines properly.
- **Oncology community,** including not only professionals but also patient advocates, as all stakeholders have a role in promoting access to beneficial intervention.
- **Value sustainability and access,** to provide the best outcomes for individual patients, while supporting overall healthcare systems.

Many patients do not have access to important cancer medicines. Ensuring access to effective therapies is crucial, also from the oncologist's point of view, as they should be able to provide suitable treatment options. Dr Giuliani expressed that biosimilars fit very well in the objective of improving access to cancer treatment. This would require defining a targeted policy. She stressed that the oncology community should receive consensus guidelines on the use of biosimilars.

Specifically, Dr Giuliani brought forward the following policy recommendations:

- The need to fill the knowledge gap in education about biosimilars to abolish ungrounded fear, given that they are of the same quality and have the same safety and efficiency as the reference products.
- Address the lack of financial incentives to switch to biosimilars from reference biological products.
- Transparency on the reallocation of resources generated by biosimilar use.
- Avoidance of any type of administrative burden.

THE IMPORTANCE OF BIOSIMILARS IN CANCER - EDUCATION & COMMUNICATION STRATEGIES FOR HEALTHCARE PROFESSIONALS & PATIENTS, BY YANNICK VANDENPLAS

Yannick Vandenplas, PhD researcher, Clinical Pharmacology and Pharmacotherapy Research Unit, KU Leuven, Belgium, reported on how education and communication on biosimilars can best be approached.

Mr Vandenplas explained that educating and informing professionals and patients requires a different and targeted approach. Healthcare professionals are confronted with biosimilars on a daily basis, so they are familiar with their properties. For patients, on the other hand, biosimilars will only become actual when they are confronted with them by their healthcare provider.

Mr Vandenplas described five main points of attention when informing patients:

- Provide understandable and up-to-date info.
- Communicate the positive aspects of biosimilars and show an open attitude.
- Speak with one voice and similar terms to avoid confusion (the 'one-voice' principle).
- Provide information tailored to the individual's needs. The language used should be adapted to their knowledge and understanding.
- Use supportive audio-visual material, such as leaflets and/or videos.

Clear communication towards patients will build trust, increase the chances of higher acceptance reduce the nocebo effect, which will lead to better clinical outcomes in the patient community.

Post-graduate initiatives by medical and scientific associations, as well as regulatory agencies, can support the training of communication around biosimilars for healthcare professionals. However, here also lies a responsibility for universities, as education on biosimilars can already be addressed within the curriculum.

THE VIEW FROM THE EUROPEAN PARLIAMENT, BY MEMBER OF THE EUROPEAN PARLIAMENT DOLORS MONTSERRAT

Dolors Montserrat (EPP, Spain), Member of the European Parliament and rapporteur of the own-initiative report on the Pharmaceutical Strategy presented the view from the European Parliament on biosimilars.

She referred back to presentations held so far and reminded the positive impact of biosimilar medicines in increasing access for cancer patients and in contributing to healthcare system sustainability. As such, she noted the valuable role biosimilars could have in one of the Pharmaceutical Strategy's main objectives, namely ensuring access to biological medicines. She expressed her commitment to driving this conversation and ensuring that the value of biosimilars is considered in the Strategy's implementation.

She recognised DiCE's activities as key for policymakers to learn about the added value of biosimilars and the barriers to their acceptance. She gave her endorsement for the Call to Action and acknowledged the need for its recommendations to be implemented.

PANEL DISCUSSION

Featuring:

- ***Barbara Moss*** *– DiCE Patient Representative*
- ***Prof Fernando de Mora*** *– PhD, MBA, Professor of Pharmacology, Department of Pharmacology, Therapeutics and Toxicology, Universitat Autónoma de Barcelona, Spain*
- ***Dr Rosa Giuliani*** *– Consultant in Medical Oncology, Clatterbridge Cancer Centre Wirral, Liverpool, UK & Director of Public Policy, ESMO*
- ***Yannick Vandenplas*** *– PhD researcher on sustainable policy for best-value biologicals in Belgium*
- ***Dolors Montserrat*** *– Member of the European Parliament and rapporteur of the own-initiative report on the Pharmaceutical Strategy*

Throughout the event, the audience had shared various questions with the speakers which were answered during the panel discussion:

- *Do you believe that savings from biosimilars can be used to improve patients' quality of life?*

Mrs Moss confirmed that savings from biosimilar use would be very suitable to support patients and this could be done in many ways, especially at the beginning of the treatment. Based on her experience, advice with regards to diet and mitigating the psychological effects of having to leave work should receive special attention through an individualised approach. For instance, investments could be used to put in place specialised colorectal cancer nurses.

- *What can governments do to increase education and awareness among patients?*

Mrs Moss said that governments should support patient organisations in offering education to patients, as they are perceived trustworthy and reliable. Such organisations can put patients in contact with each other, which can be very supportive for them.

Governments can also help simply by making it known that biosimilars are completely safe.

- *Do we have good examples of national governments who managed to boost acceptance?*

Prof de Mora referred to an example in the UK, which was the first country to foster gain-sharing agreements. In the South Hampton general hospital, for every patient prescribed with a biosimilar in gastroenterology, the department would receive €500 – which could be reinvested further for instance in purchasing higher technology equipment for the hospital.

Also, in Italy (Catánia), it was agreed that savings from biosimilars were reinvested in the hospital and could be used for purchasing innovative medicines.

A couple of questions were directed specifically to Dr Giuliani:

- *What can you share about your experiences in biosimilars' acceptance?*

Dr Giuliani once again stressed that *one size does not fit all,* and that transparency is very important. Different models exist in allocating savings from biosimilars; some engage with people and have a more democratic nature, whereas others do not have this. In either case, clear communication on savings allocation is key.

- *How do you approach the conversation of switching to biosimilars with patients?*

Dr Giuliani responded that not all patients require the same level of information. Some patients automatically trust everything we as oncologists say, while others need further explanation. In any case, it is very important to discuss the science during these conversations while keeping it rather easy to follow.

- *What are some best examples of national or hospital-level incentives to train and educate healthcare professionals and patients?*

Mr Vandenplas provided a couple of examples, including the brochure and video published by the European Commission that provide very useful information for both patients and healthcare professionals.

Moreover, he mentioned the toolkit by the International Alliance of Patients' Organisations and the ESMO brochure toolkit. When looking at national initiatives, he recommended the factsheets under Australia's biosimilar awareness initiative and the output from the Dutch initiative group biosimilars.

- *Do we need regulators to do something before getting the full trust of professionals?*

Mr Vandenplas confirmed that indeed, regulators are on top of the pyramid to provide information since they evaluate biosimilars from the regulatory point of view. It is a necessary condition for healthcare professionals to have trust in what they are prescribing, because only then they can provide the right information to their patients. For this reason, regulatory agencies should be at forefront of providing information on biosimilars.

Dr Giuliani added that associations also have an important role to play, for instance in developing guidelines and by confirming that questions around biosimilars are unnecessary given the clear science behind them.

- *How do low- and middle- income countries deal with something like biosimilars in their country context and limitations?*

[Given that Prof. Kaló was best-suited to answer the question, the below answer was shared after the event]

The best available scientific evidence unanimously suggests the use of biosimilars over more expensive biological medicines. Unfortunately, the implementation of evidence-based health policy is less advanced in lower-income compared with higher-income countries. Health care professionals may not follow so strictly therapeutic guidelines, and they are more

likely influenced by hypothetical concerns about biosimilars generated by marketeers and advocates of originator medicines. As a consequence, the uptake of biosimilar medicines is not as strong in lower-income countries as in Denmark, Norway or the United Kingdom, and so these countries with highly limited health care resources do not maximise benefits from the patent expiry of expensive biological medicines. This is truly unfortunate for patients, as highly limited patient access to (even reimbursed) biological medicines can be alleviated by more affordable biosimilars.

A few questions were specifically addressed to MEP Montserrat:

- *In our approach to pharmaceuticals, how can we put biosimilars in the Pharmaceutical Strategy as something we can have trust in and should be encouraged as a use?*

MEP Montserrat reported that the Strategy will be adopted in the next plenary, taking place in November. Currently, the groups are negotiating the last changes. She highlighted that as a rapporteur, she is of the opinion that the following four aspects should be embedded in the final strategy:

1) It should be stressed that biosimilars are accessible treatments and that they contribute to the budgetary sustainability of healthcare systems, whereas this sustainability aspect is one of the Strategy's key objectives.
2) The strategy should call on the Commission to support measures for a bigger market presence of biosimilars and harmonise this at the EU level.
3) Moreover, the Commission should be called upon to design routes for the industry that promote research and development of generics and biosimilars and propose EU protocols for the interchangeability of biosimilars.
4) Given the importance of improving education on biosimilars, the Commission should be called upon to promote educational activities as well as an EU-wide resource centre.

- *When you were drafting the report on the Pharmaceutical Strategy, did your fellow policymakers know about them? How much do we still need to get the message across?*

MEP Montserrat stressed that the Strategy will have a big role in that as it will decide upon the next Directive. Moreover, the Strategy can promote the dialogue to share best practices, facilitate partnerships, share knowledge, and integrate the cost-savings benefit. Accordingly, the Strategy will be a great opportunity to make Member States familiar with biosimilars.

- *Does the fact that a thriving biosimilar ecosystem would be good for the overall competitiveness for Europe's Lifesciences sector from an additional element of relevance?*

MEP Montserrat indeed saw this as being of great relevance, especially in light of the European Health Union. In the most coordinated approach this initiative aims to achieve, biosimilars would fit in greatly in helping to bring about patient-centeredness.

Relating to this final question for MEP Montserrat, it was asked whether the use of biosimilars could foster innovation in terms of Europe's strategic autonomy in the development of medicines and medical supplies.

Prof de Mora considered biosimilars indeed as a perfect means to contribute to this through higher savings and by fostering the development of new medicines.

PRESENTATION OF THE CALL TO ACTION AND NEXT STEPS, BY DiCE

The following speaker was Giulia Barenghi, DiCE's Policy and Public Funding Manager, who presented the Call to Action on improving the use of biosimilar medicines in colorectal cancer through the adaptation of EU policies.

The Call highlights the fact that important inequalities persist across Member States in relation to patient access to biological treatments. For this reason, and given the EU's power to mitigate these differences, the Call to Action calls upon the European Commission to:

- Support transparent and tangible benefit-sharing practices across Europe, to allow any savings arising from biosimilar prescriptions to be reinvested in the national healthcare systems.
- Build a dedicated Europe-wide online resource centre to support the exchange of best practices on biosimilar savings reinvestment together with Member States.
- Set up a dedicated Europe-wide online resource centre for healthcare professionals and patients including continuous education, to provide adequate information on the value of biosimilars.

Moreover, it asks Member States to:

- Adjust national policies to ensure that biosimilar-related savings are reinvested locally in a tangible and transparent way.
- Introduce incentives to encourage hospitals and healthcare professionals to consider biosimilars in all purchasing processes.
- Invest in educational and communication activities for healthcare professionals, support patient organisation initiatives.
- Invest in the creation of national patient data bases.

Finally, it calls on all stakeholders to support patient organisations in raising overall awareness about biosimilars and to actively call on the MS to organise communication campaigns to reinforce patients' knowledge, acceptance and trust in biosimilar medicines.

The Call to Action will be open to endorsement and support until the end of November and will be publicly shared with all interested stakeholders (mainly DiCE Members, policy makers from the European Commission and European Parliament, not-for-profit organisations with an interest in cancer, patient advocacy, and/or equitable access to care and treatments for patients) during the occasion of the Global Biosimilars Week in November.

CONCLUDING REMARKS BY TAMSIN ROSE

Closing the event, Ms Rose referred back to the Call to Action as a great opportunity for all stakeholders to become active players to change the situation.

She concluded by pointing out once more the added value of biosimilars, as was shown by all speakers present, and that there were only good reasons for biosimilars to become more widely available. With this, she invited all speakers and participants to use all arguments mentioned during the event to drive change and strive for improved use of biosimilar medicines in colorectal cancer.