

Education in Biosimilars

Whitepaper
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Hypothesis

The general impression in the marketplace is that because biosimilars have been available for quite a while, they are well known and understood by patients and HCPs alike.

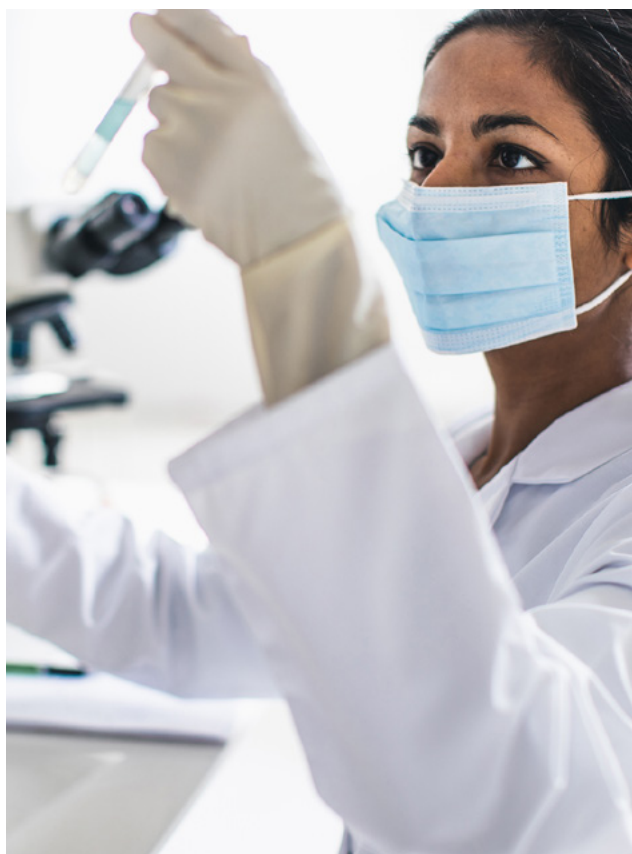


Executive Summary

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Samsung Bioepis decided to test this hypothesis and, to identify any fundamental information gaps and unmet needs in the biosimilar space, commissioned an independent research to ascertain the media and key opinion leader perspectives on the use of biosimilars across the EU5 countries of France, Germany, Italy, Spain and UK. The research was guided by the following questions:

- **What do HCPs and professional organisations say publicly about biosimilars and biologics? Has this changed over time?**
- **What is the perception of biosimilars?**
- **Are there concerns when moving patients from biologics to biosimilars?**
- **Are biologics seen as problematic in certain therapy areas?**

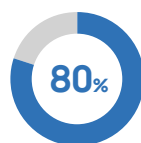


The answers to these questions were determined using a two-step approach. Firstly, through media analysis across over 200,000 outlets and secondly, through identification and mapping of more than 250 key opinion leaders (KOLs). These KOLs were a mixture of healthcare professionals, medical academics, journalists, plus patient groups and drug policy experts.

We then mapped them; using their online social profiles and conversations, to show who is connected and talking to who, and what they are talking about. From this, we were then able to analyse all of their conversations, posts and interactions to understand the shape and the direction of the conversation about biosimilars in Europe.

To support this analysis, we also held three virtual expert panel sessions to gain professional insight into: experiences with biosimilars to date, perceptions of biosimilars compared to biologics and attitudes to biosimilars in Europe in general.

We found that a lack of understanding prevails across all countries, with HCPs aware that the prescription rules are shifting at pace but unsure what comes next. Information gaps in particular exist in Germany, Spain and Italy.



In Italy, 80% of HCPs questioned stated they felt they needed much more information on biosimilars, as they were unsure as to how they functioned and what they contained.

We also see patients often do not understand the difference between a biologic and its biosimilar equivalent, or what the drivers behind switching medication might be.

This whitepaper explores the need not only for increased access, but for better education on the innovation, quality and value of biosimilars. Furthermore, it addresses a specific need to educate patients and HCPs on the reason for switching to biosimilars in order to counteract any resistance to change, or even the nocebo effect.

Patient Education

“ A national survey of individuals with rheumatic diseases found that 28.91% of patients weren't sure whether they have been prescribed a biosimilar, indicating that there is a lack of knowledge about biosimilars and how they compare with reference products. ”

Rheumatic Disease Awareness Month 2020 and the American College of Rheumatology (ACR)

Patients are more educated about treatments today than ever before. In many circumstances, patients often discuss medications with healthcare professionals before treatment is prescribed and are involved in the decision over which therapy they will receive. Therefore, it is important to provide patients, and their carers, with easily digestible and accessible information to enable these decisions to be made confidently.

In our KOL analysis, we found that Patient Advocacy Groups (PAGs) are the most vocal on biosimilars, particularly when there are new treatments in their therapy area. They are often 'filling the information gap' that exists when it comes to patient education, but often with mixed results.

PAGs in Italy, UK, and Germany specifically, are focused on single-treatment campaigns through media outreach e.g. trastuzumab and aflibercept, and have often been successful in driving high-profile coverage amongst patients and the scientific community about changes in treatments. They have also successfully crowd sourced patient feedback on biosimilars, as they try to better understand patient options and drug efficacy.

However, it is important that the role of educating patient is not left to solely to PAGs. A statement

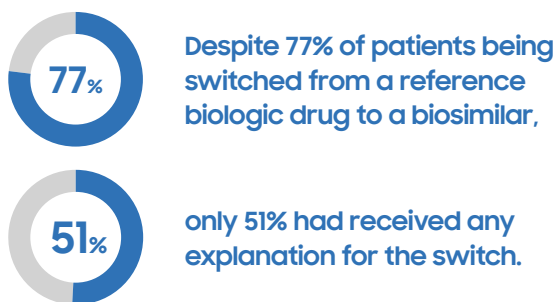


published by the American Society of Clinical Oncology (ASCO) in the Journal of Clinical Oncology suggested that there is a greater need for biosimilar education for prescribers and patients, particularly as more biosimilars come to market in the next several years, and their role in the future care of patients with cancer grows in importance.



ASCO has stated that it will continue to work to provide education, from webcasts and online practice guidelines, to social media updates potentially via ASCO university.ⁱ These resources have the potential to be available for prescribing clinicians to use when speaking to patients, and could help to facilitate dialogue between patients, carers and HCPs.

In one of the virtual panel discussions hosted by Samsung Bioepis, Serena Mingolla, Communications Consultant at Associazione Nazionale Persone con Malattie Reumatologiche e Rare APMARR, highlighted an Italian survey showing that:



As biosimilars become more widely adopted patient education is more important than it has ever been; to ensure that patients receive the correct information about biosimilars, what they are and how they are used.

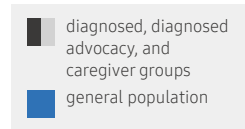
An international study in 2016 on patient understanding of biosimilars found that awareness about biologic therapies was significantly higher in diagnosed, diagnosed advocacy, and caregiver groups (45–78%) versus the general population (27%; $p < 0.05$).ⁱⁱ Only 6%

of the general population reported at least a general impression of biosimilars, whereas awareness was significantly higher in the diagnosed advocacy group (20–30%; $p < 0.05$).

Awareness:



General impression:



Knowledge gaps were identified in biosimilar safety, efficacy, and access; there were also many who had never heard of biosimilars. From those who had heard of biosimilars, participants often thought that biologics performed better than biosimilars, but that patients had better access to biosimilars and that they were cost effective.

The report concluded that there was an immediate need for patient education about biosimilars and clinical trials to ensure educated and informed decisions are made about biosimilar use.

Through various education initiatives, such as providing workshops for patients in specific disease areas, or online guidelines and animations for disease awareness and treatment information, patients can become more aware of symptoms to look for, and what to expect before, during and after diagnosis and treatment.

Doctor Education

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The Nocebo effect:
Patients are not happy to switch simply because a clinician tells them to, they need education prior to switching and support while on their new medication to prevent the nocebo effect

The consensus from the virtual panel discussions hosted by Samsung Bioepis is that the understanding of biosimilars is often poor among HCPs. Many believe that the more you pay for a drug, the better it will perform. This lack of understanding leads to further miscommunication about biosimilars.

There is a need for education on the quality, innovation and value of biosimilars, including the reduction in batch to batch variation compared to older originator biologics. Educating on the robustness of the clinical trials programmes and the approval system may also help to dispel many of the myths related to biosimilar quality.

Doctors and nurses need to be educated on the best way to discuss biosimilars with patients in order to avoid the 'nocebo effect'. The nocebo effect is when an individual expects a specific treatment to have a negative effect, resulting in the patient experiencing negative symptoms during treatment.ⁱⁱⁱ This poor expectation of a treatment usually originates from a lack of understanding, such as how the treatment will be administered or the common side effects.



Clare Jacklin, Chief Executive Officer, National Rheumatoid Arthritis Society, UK, stated in our virtual roundtable that one of the biggest obstacles in biosimilar switching as: **"Patients are not averse to using biosimilars, but good communication is critical, allowing patients to have a say in their treatment, and leading to a more positive treatment outcome"**.

Jacklin also highlighted that if HCPs fail to mention minor differences in the switched treatments, such as changes in administration, side effects and pain at the site of administration to the patient, that these minor differences can lead to the patient experiencing a build-up of anxiety and concern surrounding the treatment, which can often lead to the nocebo effect.

During the EULAR 2020 virtual congress, Professor of Physiology and Neuroscience, University of Turin Medical School, Fabrizio Benedetti, described the importance of effective communication to counter the nocebo effect.^{iv} Benedetti compared 'open' and 'hidden' administration, observing how patients found treatment to be less effective when their HCP had not communicated with them prior to administering a drug, in comparison to when a patient that was fully briefed prior to administration.

Benedetti mentioned that a number of enhanced communication strategies have been developed and are recommended to help manage patients' beliefs and experiences, in order to decrease the nocebo effect. These include providing detailed information to patients, increasing empathetic attitudes, distributing information in a suitable manner, reducing anticipation



of adverse events and promoting social contact between successfully treated patients. Together, it is recommended that these should be routinely used when considering communication with patients.

Effective communication between HCPs and their patients is paramount in ensuring a positive treatment outcome. All implications of switching must be communicated with patients, along with the differences that can be expected.


Building trust between pharmaceutical companies and physicians is also vital for acceptance and uptake of biosimilar drugs. It is essential for manufacturers to foster alliances with advocates and key opinion leaders (KOLs) with experience of using biosimilars to promote their widespread adoption.

Many physicians are too busy to study in depth clinical trials data and would prefer to see easily digestible educational materials on biosimilars' safety, equivalence, and cost savings. Reasons for the development of biosimilars should be clearly explained, as well as the robust testing and approval processes to ensure quality standards of these medicines.

International scientific conferences, such as EULAR, remain major platforms to form partnerships for spreading awareness over all aspects of the science behind, and therapeutic uses of, biosimilars, for example videos, podcasts, and workshops are perennially popular among attendees.

Digital formats are essential with conferences turning to virtual gatherings because of COVID-19 restrictions on travel and meetings.



A woman with dark, curly hair is smiling and looking towards a man whose back is to the camera. She is wearing a green cardigan over a striped top. The background is a plain, light-colored wall.

““ Doctor to patient education and communication needs improvement...time should be allocated for discussion and improvement in doctors’ attitudes towards biosimilars. Increasing patient education will ensure patients are confident in their medicine and that they have greater control over their treatment options and journey. ””

Serena Mingolla, Communications Consultant at Associazione Nazionale Persone con Malattie Reumatologiche e Rare APMARR, Italy

Nurse Education

European Specialist Nurses Organisations (ESNO) published a guideline in 2018^v aimed at assisting nurses in the management of switching a patient from a reference biologic to a biosimilar

The ESNO guide focuses on tools for nurses to better inform and communicate on biological and biosimilar medicines to patients. The guide has been developed by the ESNO community based on similar initiatives across Europe where switching programmes are already in place.



Nurses play integral roles in patient education; they are highly trusted in their role and often are the first point of contact for a patient. Nurses can influence the adoption of biosimilars through patient education and can impact the future of the field in their expanding roles within health care systems.

With nurses positioned at the forefront of healthcare provision, it is extremely important that they are able to discuss and explain biologic medicines to patients, especially when patients are being switched from biologics to biosimilars.ⁱ Ensuring that nurses are properly trained and educated about biosimilars is vital; this information can then be relayed to alleviate patient concerns, and to maximize potential public health benefits. However, according to the expert panel sessions, many nurses consider they are overlooked in terms of education and communications plans.



In 2018, European Specialist Nurses Organisations (ESNO) attempted to address the important interactions that nurses have with patients through the launch of an informative guide for the specialised nursing community. Building on existing European Community guidelines, the document includes points around how to better inform and clearly communicate information about biologics and biosimilars.^v

Specifically, the guidelines contain talking points around the benefits of biosimilars such as increasing patient access to drugs, how to address patient questions or concerns if they are hesitant about switching and exercising proper pharmacovigilance.

Commenting on the launch of the report, Ber Oomen, Former Executive Director and advisory committee member at ESNO, said: “switching between similar biological medicines needs good management. Nurses play a crucial role in communicating with patients and providing support and reassurance, before, during and after the switch. This is built on nurses’ many years of education, and their experience with patients in different therapies. It is a process that requires time, patience and care.

It’s clear that nurses want better education about biosimilars and especially aspects of switching so that they can better communicate with patients. As a result, pharmaceutical manufacturers are ideally placed to provide education materials about biosimilars for nurses and pharmacists.

Furthermore, COVID-19 has greatly impacted everyday practice and nurses, who now potentially have less face-to-face patient contact, should be equipped to deal with any effects on healthcare provision and effectiveness.

Nurses have a critical role to play in supporting patients who may be transitioning from treatment with reference biologics to biosimilars, and their support for patients is vital to the success of biosimilar treatment in general.

Ensuring that nurses are properly trained and educated about biosimilars is vital; this information can then be relayed to alleviate patient concerns, and to maximise potential public health benefits.^{vi} Through education, patient confidence and treatment success with biosimilars is more likely to improve, resulting in an increased adoption of biosimilars by healthcare agencies worldwide.

Future Outlook



While the uptake of biosimilars is different between countries for many different reasons, one reason that appears consistent is that the role and suitability of biosimilars is not as clearly understood by both HCPs and patients as the general impression would suggest.

A number of organisations are involved in developing educational materials to support switching to biosimilar drugs, from the US Food and Drug Administration^{vii} which licenses drugs in the United States, to professional organisations such as the European League Against Rheumatism (EULAR),^{viii} and Medicines for Europe.^{ix}

However, what is clear is that while many organisations have attempted to address the gap in knowledge by developing educational materials, it is far from comprehensive, easily accessible or digestible for patients, doctors and nurses alike.

While the tested hypothesis has been found to be incorrect, clear and effective solutions have been identified that can make a difference. Independent research, combined with group dialogue with respected European experts, has confirmed that there is still a job to be done to ensure that HCPs and patients are fully aware of, and understand the role of, biosimilars. It is not enough to expect the markets to adopt biosimilars based on the simple knowledge that a biosimilar is available.

HCPs are keen to know more about available biosimilars relevant to their specialty and to have more, but concise, information regarding safety, efficacy, equivalence and cost-effectiveness. This education will enable them to make informed decisions. Professional support organisations have been, and will continue to be, central to providing guidance, though there is still more that could be done.

Similarly, educating on the robust nature of the clinical trials programmes and approval processes can be an important aspect in convincing HCPs of the quality and suitability of biosimilars.

Patients also need to fully appreciate the merits of a biosimilar being recommended to them and this will help manage their treatment expectations and support treatment adherence. Patient organisations have been, and will continue to be, central to the provision of supporting information.

One specific educational need will be to support HCPs and patients when the decision is made to switch a patient from a biologic to a biosimilar. It is crucial that all involved fully understand the rationale for switch, how the biosimilar will be administered, and what to expect from the new treatment.

The opportunity exists for leadership that built on consensus and cooperation to develop a focussed, comprehensive educational programme that will benefit all involved.

Conclusion

Overall, our findings show that the biosimilar conversation in both the media and amongst KOLs is immature. Information gaps in particular exist in Germany, Spain and Italy. In Italy, 80% of HCPs questioned stated they felt they needed much more information on biosimilars, as they were unsure as to how they functioned and what they contained.

Despite the importance of the prescribing clinician, and how they should be the one to explain biosimilars as a treatment option to patients, sometimes, this is not feasible.

We have also found that patients often do not understand the difference between a biosimilar treatment, or what the drivers behind switching medication category might be. This could provide the opportunity to provide patient education materials, particularly around the “nocebo effect”.

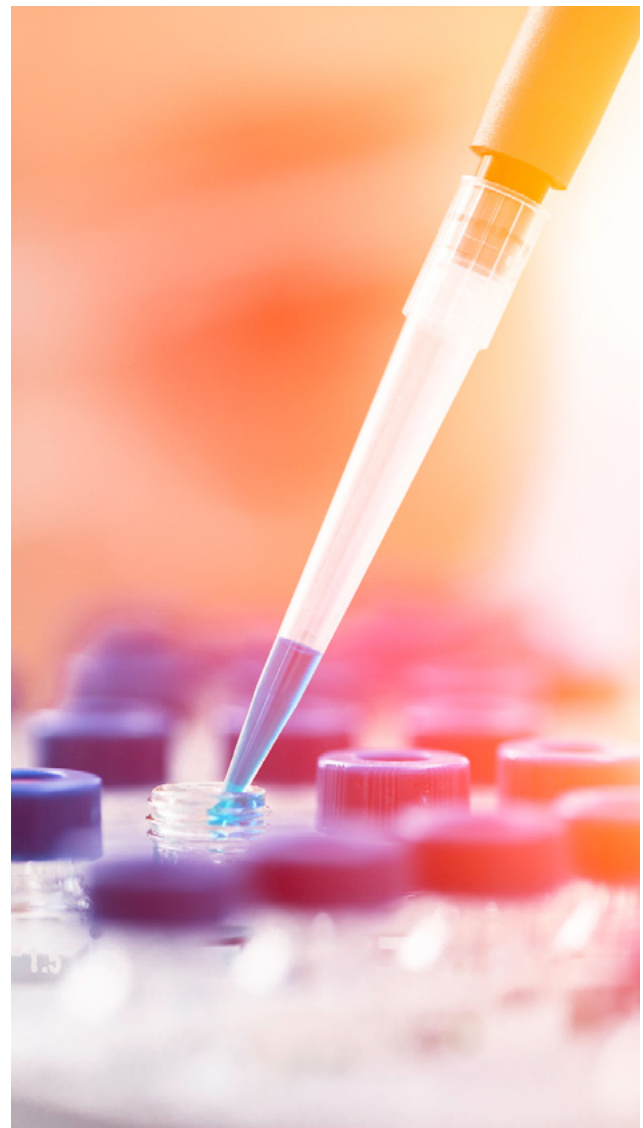
Patient education on biosimilars is vital to their success in being implemented as a treatment option in healthcare systems worldwide.

Biosimilar education for HCPs and patients remains one of the keys to unlocking the true potential of biosimilars in Europe. Put simply, HCPs need to fully understand the merits and value of each individual biosimilar, while patients need to feel confident in the treatment that they are prescribed. Many approaches to education are already available, but based on our research, there are knowledge gaps and these current approaches are not necessarily leading to improved access by patients. Similarly, there appears to be a lack of leadership in this area that a fresh, focused, yet comprehensive approach could address.

Samsung Bioepis is a biopharmaceutical company with the well-being of patients at the centre of everything we do. Through innovations in high quality product development and ensuring that healthcare professionals have all the information required to make informed prescribing decisions we aim to increase

access to biological medicines for all patients who need them. The educational needs identified for HCPs and patients confirms that there is still work to do, but is in line with our stated commitment.

Through education, patient confidence and treatment success with biosimilars are more likely to improve, resulting in an increased adoption of biosimilars by healthcare agencies worldwide.





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