A COMMUNICATION AND
INFORMATION GUIDE FOR NURSES

Switch Management between Similar Biological Medicines

ESN
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CONTENTS

Foreword

Today's nurses, with their increased knowledge, experience, competencies and level of autonomy, play a major role in sharing responsibility; in some countries they have prescribing authority in close cooperation with physicians[1]. Nurses are high-level professionals tackling the current and future challenges side by side with physicians. This phenomenon is welcomed by patients and evidence has shown that users and consumers are very satisfied with this new and shared responsibility. ESNO took the initiative to establish an efficient communication document on biosimilar medicines for nurses in Europe.

This information and communication guide on the safe and efficient switching between similar biological medicines addresses a highly relevant issue with healthcare professionals and patients and is an example of cooperation in an interdisciplinary context. It provides insights about biosimilar medicines and switching practices between biological medicines. It also provides answers to the most frequently asked questions coming from patients.

This educational and practical guideline indicates the shared interest in good switch management in the use of reference and biosimilar medication. It contributes to clear understanding and prevents misinformation.

Based on evidence and collective experience at all levels, this guideline will serve patients and physicians and, above all, nurses, when confronted with the terms 'biosimilar' and 'switching'.

For those new to biosimilar medicines, having a useful guideline such as this, in a nurse's narrative, will prove an essential aid when communicating with patients and other healthcare professionals. It is an excellent tool for ensuring the best possible care for patients during switching of their biological medication.

May I congratulate all nurses in Europe who contributed to this guide for their insights, knowledge and collaboration over the past 2 years.

Adriano Friganović,

ESNO President

1 https://www.nuphac.eu/

Introduction to the second edition

This Communication and Information Guide for Nurses is an upgrade of the first edition published in 2018. Our aim is to provide a guide for the nursing profession, as nurses are increasingly becoming more involved in guiding treatment policy, prescribing medication, and providing patients with information. This is demonstrated by the Nurse and Pharmaceutical Care (NuPhaC) international network that strengthens evidence, policy, practice and education in nurses' contribution to interprofessional pharmaceutical care initiatives[2].

Many of the updates in the 2022 guide are based on feedback from nurses. We have included more real-world examples and case studies, with an emphasis on personal examples and experiences. We have increased the focus on education and communication, to ensure good practice and support professional competencies. We also included examples to show how biosimilar medicines can benefit health systems beyond price alone. Those who have been leaders in the use of biosimilar medicines have found that they can use savings generated to invest in hospital and/or care infrastructure.

Ber Oomen and Hanneke Voorneveld

2 Nurse and Pharmaceutical Care (NuPhaC) Available at: https://www.nuphac.eu/

About this guide

This information and communication guide on biosimilar medication for nurses is designed to provide support and information for nurses working with patients who are switching between similar versions of biological medicines. This could be a switch between the original biological medicine (known as the reference biologic, reference product or originator product) and a biosimilar medicine, between a biosimilar medicine back to the originator medicine, or between biosimilar medicines of the same reference medicine.

The guide provides examples of projects and best practices based on different specialities and disease areas. Its aim is to contribute to the safe use of and trust in all biological medicines, including biosimilar medicines. It also gives nurses tools to implement switching decisions in a clinical context and deal with possible patient concerns, drawing on the learnings from real-life experiences.

One of the most important elements in nursing is the relationship between the patient and the nurse and prescriber. As professionals in close contact with patients, nurses play a key role in supporting communication between patients and physicians, especially when treatment regimens and medications are initiated or changed. Their experience and their communication skills mean that they are ideally placed to explain to patients the rationale for and impact of changes to their treatment. This can be particularly important in the transition between versions of a given biological medicine.

While the physician is most commonly the authorised prescriber, nurses can take the lead in implementing the transition between therapeutic alternatives of a given biological medicine (originator and biosimilar versions). This includes managing the process before, during and after the switch. However, this isn't the case everywhere, and the role and responsibility of the nurse can vary between hospitals, regions and countries. For example, in the Netherlands, some specialist nurses can prescribe within their own specialty.

The guide provides sample FAQs. These may need to be adapted by country, region, hospital or speciality.

Who is this guide for?

The main audience for this guide is specialist nurses. This guide, however, is also important for managers and CEOs in healthcare institutions, to create awareness on this important topic, to support investment in nurses, and to ensure that training, education and support for nurses at all levels is embedded in policies and budgets.

The European Commission and European Medicines Agency (EMA) has created a patient Q&A on biosimilars (https://ec.europa.eu/docsroom/documents/26643) and a guide for healthcare professionals (https://www.ema.europa.eu/en/documents/leaflet/biosimilars-eu-information-guide-healthcare-professionals_en.pdf), and these publications will provide further information on this important issue.

> **I only just learned about this Information Guide; I wish I had known about it before. This topic is a much-discussed issue in my hospital when biosimilar medications are introduced. I'll bring this guide to the attention of other specialists such as the Oncology, IBD and Neurology nurses.**
>
> *Lurdus Barbosa, Rheumatology Nurse, Hospital Almada, Lisbon Portugal*

CHAPTER 1

BIOLOGICAL AND BIOSIMILAR MEDICINES

Chapter 1. Biological and biosimilar medicines

- Biological medicines are complex and are produced in living cells
- Biosimilar medicines can be developed and marketed once the original biological molecule – the reference biologic – has lost its patent protection
- Biosimilar medicines are highly similar to the reference biologic, and are just as safe and effective

What are biological medicines?

> Biologics began with insulin for the treatment of diabetes. This was originally isolated from animals, and then genetically engineered insulin allowed us to treat diabetes with a much purer form. Insulin was followed by blood factors such as erythropoietin (EPO) and growth hormone, taking away the risk of the impurities and infections that came with the natural forms of the product. The next major breakthrough, based on our underlying knowledge of disease processes, were the monoclonal antibodies. These target specific proteins allowed us to block certain specific disease processes, something we could never have done with small molecules. Producing biologics is a complex process; it involves reprogramming the cell by manipulating its DNA so that it makes the proteins that we want. The development of biologics takes time, energy and money. As with small molecules, when biologic patents expire, the molecules can be copied, and reach the market as biosimilar medicines. Biologics have become standard of care for some diseases and can treat diseases that have previously been untreatable. This improves the quality of life of patients and can mean they spend less time in hospital and more time with friends and family, or at work.
>
> *Professor Arnold Vulto, former hospital pharmacist at Erasmus MC and advisor to the Dutch Biosimilars Op Maat (BOM) Initiative, which provides education in biosimilars.*

What are biosimilar medicines?

Originator biosimilar medicines are patented for 20 years from their discovery, though a lot of this time can be taken up by clinical trials. As originator biological medicines reach the end of their patent life, other companies can make their own versions, called biosimilar medicines. These biosimilar medicines are as similar as possible to the originator biologic, also called the reference biologic medicine. In the same way that companies produce generic versions of small molecule drugs, companies can market approved biosimilar versions of originator biological medicines once the patents and market protection (ten years from the approval of the originator biologic) expire.[3, 4]

3 European Medicines Agency and European Commission. Biosimilars in the EU: Information guide for healthcare professionals. 2017. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Leaflet/2017/05/WC500226648.pdf

4 Bruce Love. US plays catch-up with Europe over biosimilar patents. Financial Times 17 June 2021. Available at: https://www.ft.com/content/3f7ca3f4-8256-4570-a6a3-b255e185f162

Nurse FAQ 1

Is this medicine a biosimilar medicine?

- Check section 5.1 of the summary of product characteristics (SmPC) for the biological medicine.
- If you want to know more, go to the medicines section (https://www.ema.europa.eu/en/medicines) of the European Medicines Agency website.

Nurses need to know about biosimilar medicines because they will be involved in switches between reference medicines and biosimilar medicines and will often be the key source of information for patients.

Patient FAQ 1

Why are you changing my current treatment to a biosimilar medicine?

- Once the patent on the original biological medicine expires, companies can produce their own versions, called biosimilar medicines.
- The biosimilar is just as safe and effective as the original medicine, which means that we can be confident we can keep you on this treatment for as long as it works for you.
- The availability of multiple versions of a biological medicine means that the treatment will be more cost-effective.
- Because it is more cost-effective, it doesn't mean it is any less effective for you.
- This may mean we can give you and other patients earlier access to biological medicines, a wider choice of medicines, or better support at home and in hospital in the future.
- If you have to pay for all or part of your medicine, the cost may be lower for the biosimilar medicine.

Biosimilar medicines are highly similar

Biological medicines (both reference and biosimilar medicines) are produced in **batches** in living cells. No two batches of living cells are exactly the same, so no two batches of biological medicines will be exactly the same. Each batch has an identification number, which means that the batch of medication on the European market that has been approved by the EMA (European Medicines Agency) is traceable to the product, the factory and how it was transported. This process is extremely well documented and regulated[5].

Every company uses its own processes and strains of cells to produce biological medicines. This means that there will be slight differences between the original product (the reference biologic) and the biosimilar medicine. This is why biosimilar medicines are described as **highly similar** and not as **identical**. Before they are approved for use in patients, biosimilar medicines are tested to make sure that these small differences do not affect the effectiveness and safety. There have been many studies comparing the efficacy and safety of reference biological medicines and biosimilar medicines, and on the chances

5 https://www.pall.com/en/biotech/blog/batch-definition-traceability-bioprocessing.html

of biosimilar medicines triggering immune responses. These confirm that there is no difference in safety and efficacy, and no increased risk of immunogenicity[6].

Case Study 1

Data from the real world supports the safety and efficacy of biosimilar medicines

- Omnitrope, a biosimilar medicine of Genotropin (somatropin) was well tolerated and effective in the treatment of a wide range of paediatric conditions in the PATRO Children study, a multicentre ongoing observational, longitudinal, non-interventional, global post-marketing surveillance study of the long-term safety and efficacy of Omnitrope® in children requiring growth hormone treatment[7].
- DANBIO is a research register and data source for rheumatologic diseases (rheumatoid arthritis, axial spondyloarthritis, and psoriatic arthritis) for monitoring clinical quality at the national, regional, and hospital levels. Data from 802 patients with inflammatory arthritis switching from Remicade® (infliximab) to the biosimilar medicine Remsima® showed no negative impact on disease activity[8].
- In two real world studies of patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA), axial spondylarthritis (SpA) or ankylosing spondylitis (AS) carried out by Biogen, disease activity was largely unaffected in RA, PsA and SpA, and the rate of discontinuations was low[9].
- The NOR-SWITCH Phase 4 study included patients with a variety of diseases: Crohn's disease, ulcerative colitis, SpA, RA, PsA and chronic plaque psoriasis. There was no inferiority in outcomes for patients switching from the reference infliximab to an infliximab biosimilar medicine, compared with the patients who stayed on the reference biologic medicine[10].

Nurse FAQ 2

How do we know that biosimilar medicines are safe?

- The European Medicines Agency (EMA) assesses the safety and efficacy of all medications that you give to your patients before it grants its approval.
- The EMA monitors the long-term safety of all approved medicines once they are on the market.
- When medicines are approved, the EMA publishes a summary, called the European Public Assessment Report (EPAR) on its website. This includes a patient-friendly overview.
- Your country's national regulatory authority will also provide information on biosimilar medicines in your local language.

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6 Kurki P, van Aerts L, Wolff-Holz E, et al. Interchangeability of Biosimilars: A European Perspective. BioDrugs 2017;31(2):83-91. Available at: https://pubmed.ncbi.nlm.nih.gov/28120313/

7 Iughetti L, Tornese G, Street ME, et al. Long-term safety and efficacy of Omnitrope(R), a somatropin biosimilar, in children requiring growth hormone treatment: Italian interim analysis of the PATRO Children study. Ital J Pediatr 2016;42:93. Available at: https://ijponline.biomedcentral.com/articles/10.1186/s13052-016-0302-3

8 Glintborg B, Sorensen IJ, Loft AG, et al. A nationwide non-medical switch from originator infliximab to biosimilar CT-P13 in 802 patients with inflammatory arthritis: 1-year clinical outcomes from the DANBIO registry. Ann Rheum Dis 2017;76(8):1426-1431. Available at: https://pubmed.ncbi.nlm.nih.gov/28473425/

Is the biosimilar medicine a different medicine to my initial medicine?

Patient FAQ 2

- The biosimilar medicine and the originator medicine are alternative and equivalent versions of the same medicine.

Can I finetune my dose or titrate myself as I did with the reference biologic?

Patient FAQ 3

- This depends, because some biosimilar medicines are packaged differently (the box shape and colour, or the name of the drug, may be different), or the drugs may have different delivery systems, such as syringes, autoinjectors or pens. The best thing to do is to talk to me, one of the other nurses, the nurse or doctor who prescribed your medication, or your pharmacist, and take the first dose with someone there if you are unsure.

How do you know it's as good as the medicine I was taking until now?

Patient FAQ 4

- Your biosimilar medicine is available to you only because it was approved for use by the EMA after having showed that it is the same quality, safety and efficacy as the originator medicine.
- Your biosimilar medicine will be tracked by the EMA's surveillance system, just like any medication that your doctor prescribes for you.

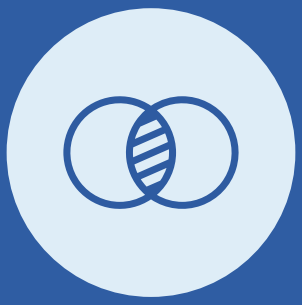
What are the side effects of the medication?

Patient FAQ 5

- The biosimilar medicine is equivalent to the previous version of the medication that you received and will share similar benefits and side effects. Talk to me, the other nurses or to your doctor or pharmacist if you have any new or different side effects.
- You or your nurse, doctor or pharmacist can tell the national authority if you experience any new or different side effects. Your experience is important.

9 Russell B. Real World Data Being Presented At EULAR 2017 Demonstrate Acceptance And Confirm Sustainability Of Effectiveness, Safety And Adherence Among Patients Switching To BENEPALI (Etanercept Biosimilar Of Biogen) From Reference Etanercept. 14 June 2017. Biogen. Available at: http://www.businesswire.com/news/home/20170614005666/en/Real-World-Data-Presented-EULAR-2017-Demonstrate.

10 Jørgensen KK, Olsen IC, Goll GL, et al. LB15 - Biosimilar infliximab (CT-P13) is not inferior to originator infliximab: Results from the 52-week NOR-SWITCH trial. Abstract presented at the United European Gastroenterology (UEG) Week meeting 2016, 15-19 October, Vienna, Austria 2016. Available at: https://acrabstracts.org/abstract/biosimilar-infliximab-ct-p13-is-not-inferior-to-originator-infliximabresults-from-a-52-week-randomized-switch-trial-in-norway/



CHAPTER 2

EXTRAPOLATION OF INDICATIONS

Chapter 2. Extrapolation of indications

- Because biosimilar medicines are highly similar to their reference biologic, they can be used for the same indications

Biosimilar medicines are developed in comparison to their reference medicines. Many tests are carried out to establish a scientific 'bridge' between the two molecules. The similarity between the biosimilar medicine and the reference medicine is demonstrated by collecting evidence that shows, for each test carried out, that the biosimilar and its reference medicine are comparable, both in terms of their structure and how they function.

The regulators assess the scientific evidence. Once they are satisfied that the biosimilar medicine and its reference product are comparable (that is, a version of the same molecule), they can confirm that the biosimilar medicine can be approved for all of the same indications for which the reference medicine is approved. This is known as **extrapolation** of indication. It means that there is no need to carry out additional clinical trials. This is similar to the process used to extrapolate indications from subcutaneous medications to intravenous medications, for adult drugs to paediatric drugs. Extrapolation of indication is not automatic.

As an example, a study comparing the rituximab reference medicine MabThera® and the biosimilar medicine Ruxience™ in CD20-positive, low-tumour-burden follicular lymphoma (LTB-FL) showed that the efficacy, safety, immunogenicity, pharmacokinetics and pharmacodynamics of the two versions of rituximab were similar over a year[11].

11 Sharman JP, et al. A Randomized, Double-Blind, Efficacy and Safety Study of PF-05280586 (a Rituximab Biosimilar) Compared with Rituximab Reference Product (MabThera ®) in Subjects with Previously Untreated CD20-Positive, Low-Tumor-Burden Follicular Lymphoma (LTB-FL). BioDrugs. 2020 Apr;34(2):171-181. Available at: https://pubmed.ncbi.nlm.nih.gov/31820339/

Nurse FAQ 3

If a biosimilar medicine is only studied in one condition, how do you know it will work for another condition?

- Biosimilar medicines are approved after studies that show that:
  - The structure is the same as the reference biological medicine[12].
  - The way the molecule works is the same.
- These two combined sets of studies confirm that the reference biologic and biosimilar are as similar as possible, are behaving the same way in one indication, and are safe and efficacious. Based on this scientific demonstration, the regulators can scientifically deduce that the two versions will act the same way in all the reference biologic's approved indications. This is known as extrapolation of indication.
- Using infliximab and inflammatory bowel disease as an example[13, 14]:
  - The original version of infliximab is **approved** in inflammatory bowel disease (IBD), psoriasis, ankylosing spondylitis and rheumatoid arthritis.
  - **A multitude of laboratory studies** confirmed that the biosimilar version of infliximab is highly similar to the infliximab reference biologic.
  - **Clinical studies** in ankylosing spondylitis and rheumatoid arthritis confirmed that the safety and efficacy was highly similar to the reference biologic in these indications.
  - The combination of **laboratory** and **clinical** data confirmed that the infliximab reference biologic and its biosimilar medicine were versions of the same molecule.
  - Establishing 'sameness' between two versions of a molecule means that all of the reference biologic indications could be **extrapolated** to the biosimilar version. In this case, this means that both versions can be used in the treatment of IBD and psoriasis, as well as ankylosing spondylitis and rheumatoid arthritis.

12 Kurki P, van Aerts L, Wolff-Holz E, et al. Interchangeability of Biosimilars: A European Perspective. BioDrugs 2017;31(2):83-91. Available at: https://pubmed.ncbi.nlm.nih.gov/28120313/

13 London Medicines Evaluation Network. Answers to commonly asked questions about biosimilar versions of infliximab. 2015. Available at: www.medicinesresources.nhs.uk/en/Communities/NHS/SPS-E-and-SEEngland/LNDG/London-Wide-Reviews/Answers-to-commonly-askedquestionsabout-biosimilar-versions-of-infliximab/

14 British Society of Gastroenterology. BSG guidance on the use of biosimilar infliximab CT-P13 in inflammatory bowel disease. 2016. Available at: www.bsg.org.uk/images/stories/docs/clinical/guidance/bsg_infliximab_guidance_16.pdf

CHAPTER 3

WHY SWITCH? THE IMPACT OF BIOSIMILAR MEDICINES ON PHARMACEUTICAL BUDGETS AND INVESTMENT IN HEALTHCARE

Chapter 3. Why switch? The impact of biosimilar medicines on pharmaceutical budgets and investment in healthcare

- Biologics can be safer and more effective than conventional drugs, however cost significantly more to develop and manufacture
- All biological medicines comply with the same standards, originator and biosimilar medicines included
- The introduction of biosimilar medicines creates competition, as different versions of a medicine are available. Competition triggers a downward evolution of the medicines and treatment cost across all versions of the medicines, and sometimes even across a larger set of medicines available to treat a given disease
- The budget savings mean that, to treat the same number of patients, the corresponding healthcare budget will go down over time. This can also lead to changes in policy and decisions to treat more patients or treat patients earlier, as medically appropriate, by removing restrictions in how expensive biological medicines are prescribed or reimbursed (for example guidelines)
- Finally, where policy supports it, the savings can be re-deployed in other areas of the healthcare system, for example increasing staff numbers, acquiring equipment, financing supporting care, prevention campaigns or diagnostics, or allowing access to innovative therapies for patients not responding to standard of care.

Making access to biologics equitable for all patients and sustainable for healthcare systems

In the EU, member states spend up to 11.5% of their income on healthcare (2018)[15]. The percentage spent on drugs varies between states, from 7% in Denmark to 34% in Bulgaria[16].

Biologics can be higher cost than new and existing small molecule drugs because of the technology involved, which means that they have higher development and manufacturing costs. Companies need to earn back these costs during the patent life of the medicine. Around 40% of the total medication budget in the EU is spent on biologics[17].

Developing a new reference biologic can take over a decade and cost billions of Euros. Developing a biosimilar medicine can take between five and nine years, and cost between €150 million and €250 million, because its development follows a different paradigm focused on comparing the two versions of a given medicine. As such, it requires fewer studies because it does not need to re-establish Safety and Efficacy (Figure 1)[18, 19]. This means that, on launch, most biosimilar medicines are more affordable than their reference biologic, while offering the same therapeutic value in terms of safety and efficacy.

15 Eurostat. Healthcare expenditure statistics. December 2021. Available at: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Healthcare_expenditure_statistics

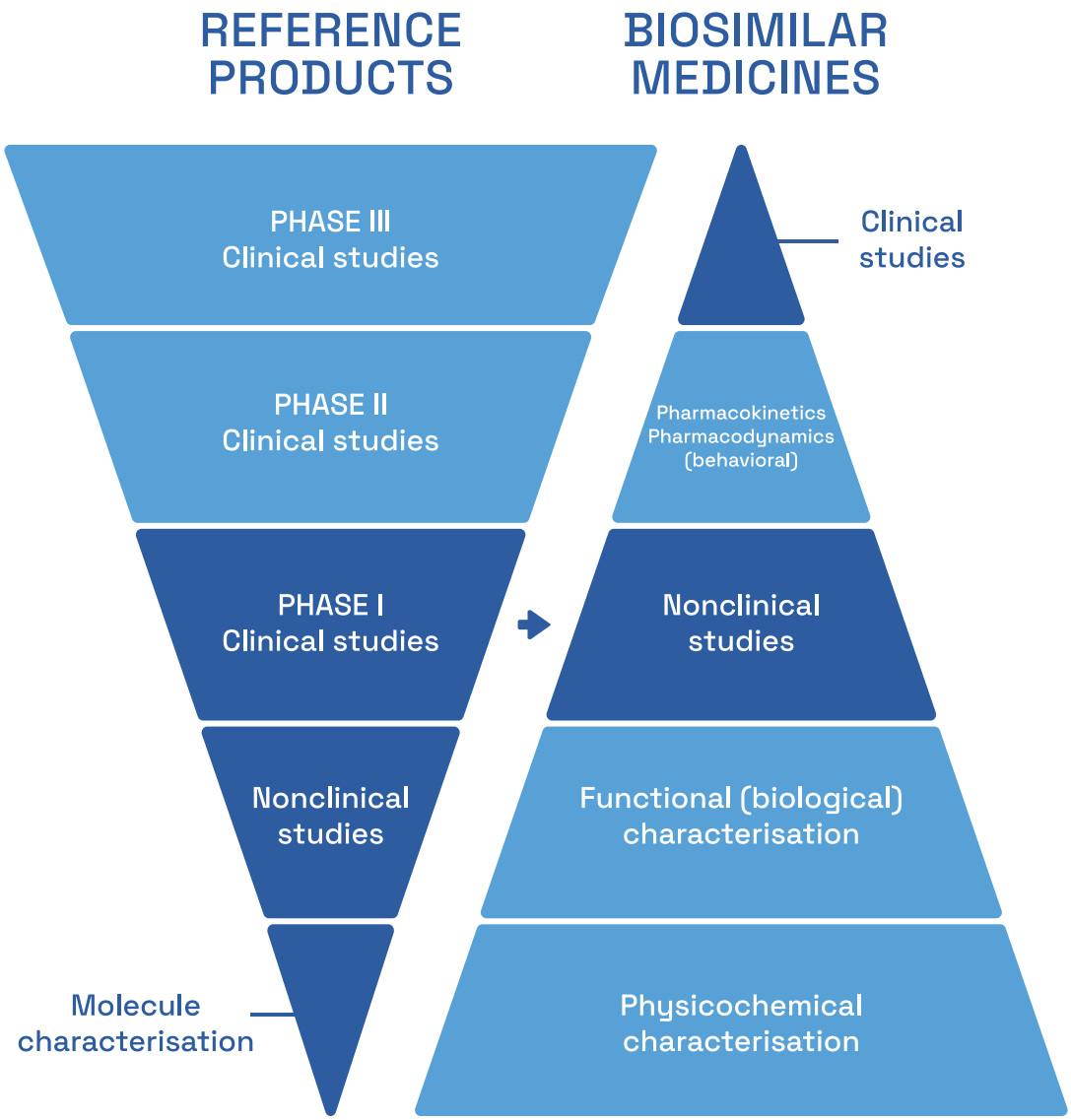
16 OECD. Pharmaceutical spending. Available at: https://data.oecd.org/healthres/pharmaceutical-spending.htm

17 IQVIA. Spotlight on Biosimilars: Optimising the sustainability of healthcare systems. June 2021. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports/spotlight-on-biosimilars

18 Pfizer. Let's see how biosimilars are developed. https://www.pfizerbiosimilars.com/biosimilars-development

19 Simon Kucher & Partners. September 2016. Available at: https://www.medicinesforeurope.com/wp-content/uploads/2016/09/Simon-Kucher-2016-Policy-requirements-for-a-sustainable-biosimilar-market-FINAL-report_for-publication.pdf

Figure 1: Comparison of the development process for reference products and biosimilar medicines



Width of pyramid represents level of effort

High regulatory emphasis

Low regulatory emphasis

Source: Unni[20]

It's important to think about biosimilar medicines as cost-effective, budget-efficient or budget-friendly rather than cheap. Using the term "cheap" may be counter-productive and misrepresent biosimilar medicines as "inferior" medicines. Patients may be led to believe that biosimilar medicines are of a lower standard or lower quality, whereas there is only one regulatory standard in Europe for all biological medicines.

In turn, the shift from a monopoly situation (where only the reference medicine is available) to a market where several biosimilar medicines are available triggers competition among manufacturers and

20 Unni, N. Biosimilars in Oncology: Internal Medicine Grand Rounds. 24 January 2020. Available at: https://utswmed-ir.tdl.org/bitstream/handle/2152.5/7884/123_012420_Protocol_UnniN.pdf

pushes down the cost of all versions available.[21, 22] This means that patients may be switched between versions of a given biological medicine including, sometimes, from the biosimilar back to the originator biologic.

Nurse FAQ 4

Some biosimilar medicines are cheaper – why is that?

- It costs a lot to develop the original biological medicine (reference biologic) because of the in-depth research and (often huge) clinical trials. When a new medicine is developed, little is known about its effect on the disease or on the body, so there needs to be a lot of research to ensure safe use. A lot of drugs also fail before they get to the clinic. To help companies cover their costs, the newly developed medicines may cost a lot, and they are protected by patents for a specific time.
- After the patents expire, the market is open to competition from biosimilar medicines.
- Companies developing biosimilar medicines need to prove that they have equivalent safety and efficacy profiles to the reference biologic, but they do not need to repeat all the clinical studies as the researchers already know a lot about the molecule. This means that their development cost is less (see Figure 1).

Nurse FAQ 5

If the biosimilar is cheaper, does that mean it is lower quality?

- The biosimilar is as similar as it can be to the original reference biologic.
- The quality will be the same because the European Medicines Agency uses exactly the same rules to approve biosimilar medicines as it does to approve all other medicines.

Case Study 2

Cost savings from implementing biosimilar medicines: An example from the UK

- The York Teaching Hospital Foundation Trust switched from the reference infliximab biological medicine to biosimilar infliximab in September 2015 and saved around £450,000 (approximately €516,600) in the first year. The IBD nurses played a central role, both in informing and supporting patients, and in working with the staff in the day unit where the infusions were administered.[23]

21 Goldman DP and Philipson TJ. STAT. 8 October 2021. Available at: https://www.statnews.com/2021/10/08/biosimilars-competition-helps-patients-more-than-generic-competition/

22 IQVIA. The Impact of Biosimilar Competition in Europe. January 2021. Available at: https://www.iqvia.com/library/white-papers/the-impact-of-biosimilar-competition-in-europe

23 Read C. Specialist nurses support cost effective drugs for treatment. HSJ, 2017. Available at: https://www.hsj.co.uk/nursing/specialist-nurses-support-costeffective-drugs-for-treatment/7015632.article

Making the switch economically viable: An example from Denmark

Case Study 3

- In a Danish study, the estimated savings for a switch to a biosimilar product in patients with rheumatoid arthritis, ankylosing spondylitis or spondyloarthritis were between around DKK8,900 and DKK64,600 (about €1,195 to €8,675) per patient, depending on the type of administration. The process of switching itself was not cost-intensive.
- The study concluded that, in this case, "the cost of implementing switching was very limited and savings incurred by the significantly lower prices of biosimilar compared to originator made the switch instantly economically viable".[24, 25]

The savings associated with the introduction of biosimilar medicines can be re-deployed into patient care, such as healthcare products and services:[26, 27]

- **Healthcare can remain affordable.**
- **More patients can be treated thanks to increased treatment cost-effectiveness.**
- **The savings generated can be used to increase specialist nursing staff, which is needed as more patients are being treated.**
- **Increased nursing staff means that patients will receive better care, contributing to improved health outcomes.**
- **The savings are available for the healthcare budget or the treatment of other patients and other diseases.**

The benefits of cost savings: Earlier treatment, more choice or better outcomes

Access to biological medicines can be restricted for patients because of the pricing and reimbursement procedures of the individual government and healthcare system. The introduction of competition from biosimilar medicines provides an opportunity for governments throughout Europe to increase patient access to treatment, while at the same time supporting the sustainability of healthcare budgets.

Generic medicines (off-patent versions of small molecule medicines) can significantly decrease inequalities in healthcare.[28, 29] Similarly, the introduction of biosimilar medicines had led to an increase in patient access to biological medicines.[30]

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24 Syrop J. 4 Studies Address Successes, Failures, and Strategies in Non-Medical Biosimilar Switching. The Centre for Biosimilars. 2017. Available at: http://www.centerforbiosimilars.com/conferences/acr-2017/4-studies-addresssuccesses-failures-and-strategies-in-nonmedical-biosimilar-switching

25 Jørgensen TS, Skougaard M, Asmussen HC, et al. Communication strategies are highly important to avoid nocebo effect when performing non-medical switch from originator product to biosimilar product: Danish results from applying the parker model-a qualitative 3-step research model. American College of Rheumatology 2017 meeting; November 7, 2017; San Diego, California; Abstract 2260. Available at: http://acrabstracts.org/abstract/communication-strategies-are-highly-important-to-avoid-nocebo-effect-when-performing-non-medicalswitch-from-originator-product-to-biosimilar-product-danish-results-from-applyingthe-parker-model-a-q/

26 NHS England. Principles for sharing the benefits associated with more efficient use of medicines not reimbursed through national prices. 2014. Available at: https://www.england.nhs.uk/wp-content/uploads/2014/01/princ-shar-benefits.pdf

27 Read C. Specialist nurses support cost effective drugs for treatment. HSJ, 2017. Available at: https://www.hsj.co.uk/nursing/specialist-nurses-support-costeffective-drugs-for-treatment/7015632.article

28 Elek P, Harsanyi A, Zelei T, et al. Policy objective of generic medicines from the investment perspective: The case of clopidogrel. Health Policy 2017;121(5):558- 565. Available at: https://pubmed.ncbi.nlm.nih.gov/28343810/

29 IMS Health. The Role of Generic Medicines in Sustaining Healthcare Systems: A European Perspective. 2015. Available at: http://www.medicinesforeurope.com/2015/06/01/ims-health-2015-the-role-ofgeneric-medicines-in-sustaining-healthcare-systems-a-european-perspectivejune-2015/

30 IMS Health. The impact of biosimilar competition on price, volume and market share - update 2017. 2017. Available at: http://ec.europa.eu/growth/content/impact-biosimilar-competition-price-volumeand-market-share-update-2017-0_en

With the introduction of biosimilar medicines, as shown in the following case studies, many payers and health authorities have decided to change their treatment, prescription, or reimbursement guidelines. This includes potential to allow biologic therapy to start earlier, or to give prescribers and patients more treatment options. However, the re-deployment of savings into access has not been seen in all parts of the EU. It requires active policy making and implementation efforts to allow the use of biosimilars to translate into being able to provide better care.

Case Study 4

Changing policy can make biosimilar medicines more accessible: An example from Sweden

- In Sweden, before biosimilar filgrastim was launched, Neupogen® (the originator filgrastim) could only be administered to patients after the consent of three physicians. Because of the reduction of the treatment costs due to biosimilar competition, the authorities relaxed the restrictions on prescribing, requiring consent from only one physician. This resulted in a five-fold increased use of filgrastim.[31]

Case Study 5

Changing policy can allow biosimilar medicines to be used in more indications: An example from the UK

- The UK's National institute for Health and Care Excellence (NICE) updated its treatment guideline with the introduction of biosimilar infliximab to allow adult patients with non-radiographic axial spondyloarthritis to be treated. This indication had previously been restricted because of the high cost of the originator biologic (Remicade®). [32]
- After the launch of biosimilar erythropoietin, NICE assessed the treatment as cost-effective for cancer patients with treatment-induced anaemia. [33]

Case Study 6

Changing policy can improve convenience for patients and reduce workload for community nurses: An example from the UK

- District nurses in Somerset were involved in a project to identify patients who could switch to biosimilar insulin. In 2017, the community nurses were carrying out 300 visits a day to administer insulin to patients who were mostly in twice daily regimens of either twice daily mixed insulin or twice daily basal insulin. By 2018, this had reduced to 166 visits per day, with 23 patients stopping insulin altogether. Patients were also moved from twice daily to daily biosimilar insulin glargine. This has potential to save £473,000 in terms of visits saved.[34]

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31 Simon Kucher & Partners. Payers' price & market access policies supporting a sustainable biosimilar medicines market. September 2016. Available at: https://www.medicinesforeurope.com/wp-content/uploads/2016/09/Simon-Kucher-2016-Policy-requirements-for-a-sustainable-biosimilar-market-FINAL-report_for-publication2.pdf

32 NICE. TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis. February 2016. Available at: https://www.nice.org.uk/guidance/ta383

33 NICE. Erythropoiesis-stimulating agents (epoetin and darbepoetin) for treating anaemia in people with cancer having chemotherapy. Available at: https://www.nice.org.uk/guidance/ta323/resources/erythropoiesisstimulating-agents-epoetin-and-darbepoetin-for-treating-anaemia-in-people-with-cancer-having-chemotherapy-pdf-82602485230021

34 Down S. Experience of using biosimilar insulin glargine. BBA.

In the 'treat-to-target' approach in rheumatoid arthritis and psoriatic arthritis, the aim is to keep disease activity as low as possible by carrying out regular tests and using the results to tailor treatment choices and doses. This improves outcomes for patients, but the costs are higher. Because the arrival of biosimilar medicines has reduced the drug costs, this has made treat-to-target less expensive and more realistic.[35]

The benefits of cost savings: Increase nursing staff

Where the savings are fed back into the department, hospitals may be able to expand their teams, offering more support from colleagues or access to more hours for specialist nurses, and better training and support for non-specialist healthcare professionals.

Case Study 7

Benefit-share can mean extra nurses: Examples from the UK

- A benefit share agreement with the manufacturer following an infliximab switch allowed York Teaching Hospital Foundation Trust to employ an IBD specialist nurse in Scarborough. The savings were used as the argument to create the new role and mean that patients did not have to travel so far.
- At the Royal Free London Foundation Trust in the UK, a benefit share agreement and savings of £2.5 million (around €2.9 million) with the use of biosimilar medicines in gastroenterology has allowed the recruitment of a couple of new IBD nurses. While the time of the agreement is limited, the additional support provided by the nurses will hopefully allow their roles to be extended.[36]
- At the University Hospital Southampton NHS Foundation Trust, switching from Remicade® to the biosimilar medicine Inflectra® saved an initial £300,000 without adverse effects to patient care. This was reinvested in staff (IBD nurses, clerical support and pharmacists) and IT (such as the UK IBD registry patient management system).[37]

35 Coates LC, et al. Treat-to-target in psoriatic arthritis—cost-effective in the biosimilar era. The Lancet. 2018;4(6):E390-E391. Available at: https://www.thelancet.com/journals/lanrhe/article/PIIS2665-9913(22)00101-1/fulltext

36 Read C. Specialist nurses support cost effective drugs for treatment. HSJ, 2017. Available at: https://www.hsj.co.uk/nursing/specialist-nurses-support-costeffective-drugs-for-treatment/7015632.article

37 Razanskaite V and Cummings F. Hospital Pharmacy Europe Issue 80 Winter 2015. Available at: https://hospitalpharmacyeurope.com/news/editors-pick/biosimilar-remicade-the-cost-saving-benefits/

CHAPTER 4

BIOLOGIC PRODUCT EXCHANGE: THE DIFFERENCE BETWEEN SWITCHING AND SUBSTITUTION

Chapter 4. Biologic product exchange: The difference between switching and substitution

- Once the EMA and national regulatory authorities approve a biosimilar medicine, it can be prescribed to patients
- Different countries have different regulations on how biosimilar medicines are prescribed

Once the EMA and national regulatory authorities approve a biosimilar medicine, it can be prescribed to patients. The option of changing from a reference biologic to a biosimilar is performed by the clinical decision-maker and can vary between countries and regions according to national and local policies.

- **Interchangeability** is a medical term in the EU and describes the possibility of exchanging one medicine for another medicine that is expected to have the same clinical effect. This could mean replacing a reference biologic with a biosimilar (or vice versa) or replacing one biosimilar with another. In Europe the European Medicines Agency confirms that safety and efficacy are the same between the biosimilar and the reference biologic. However, the policy on interchangeability is set by the national authorities.
- Replacement may be by:
    - **Switching** – the authorised prescriber (doctor or specialist nurse) decides to exchange one medicine for another medicine with the same therapeutic intent.
    - **Substitution** (automatic) – the practice of handing out (dispensing) one medicine instead of another equivalent and interchangeable medicine at pharmacy level without consulting the authorised prescriber. Substitution of biological medicines is not applied in most EU Member States.

See the further reading section for examples of national policies regarding the introduction and substitution of biosimilar medicines and reference biological medicines.[38]

For a nurse, it is important to understand that there is no such thing as a 'one size fits all' approach for the use of biosimilar medicines. Different countries have their own policies and regulations, and this can vary between regions and even between hospitals and institutes. Nurses and other healthcare professionals must be familiar with, and follow, the policies in their country, region or hospital, and use these to guide the process and communicate with healthcare professionals and patients.

38 Biosimilar Medicines. Positioning statements on physician-led switching for biosimilar medicines in Europe. 2021. Available at: https://www.medicinesforeurope.com/docs/20210825%20FINAL%200verview%20of%20switching%20positions.pdf.

CHAPTER 5

SWITCHING TO A BIOSIMILAR OR A DIFFERENT VERSION OF A BIOLOGICAL MEDICINE

Chapter 5. Switching to a biosimilar or a different version of a biological medicine

- Changing medication can be challenging for patients
    - Nurses play a crucial role in supporting, reassuring and educating patients – this is before, during and after the switch

Nurses know from experience that changing medication can be challenging for patients who may already be struggling to come to terms with diagnosis and treatment. The process of change involves a journey from doubt and worry to understanding and acceptance.

Managing the exchanges

Nurses play a crucial role[39] in communicating with patients and providing support and reassurance, before, during and particularly after switching between reference products and biosimilar medicines. This relies on their years of education, experience and competencies with patients in different situations. It is a process that requires time, patience and care.

The nurse's role in building patients' confidence and commitment to the switch can be summarised in eight steps (Table 1):[40]

Table 1: Communicating the switch in eight steps

Steps in building patient confidence and commitment	Role of the nurse	Patient's response
Step one: Contact	Provide clear information, create awareness	"I've heard about it"
Step two: Awareness	Build on the information provided	"I'm aware of it and I need to know more"

39 Read C. Specialist nurses support cost effective drugs for treatment. HSJ, 2017. Available at: https://www.hsj.co.uk/nursing/specialist-nurses-support-costeffective- drugs-for-treatment/7015632.article

40 Conner D. The Eight Stages of Building Commitment. 2011. Available at: http://www.connerpartners.com/blog-posts-containing-downloadable-tools/theeight-stages-of-building-commitment

Steps in building patient confidence and commitment	Role of the nurse	Patient's response
Step three: Understanding	Show examples, answer questions and deal with challenges as patients begin to understand how the change will affect them	"I understand it and what it will mean for me"
Step four: Positive perception	• Reinforce the positive benefits of the change for the patient • Talk about the care that they will receive	"I support it"
Step five: Experimentation	• Talk patients through the processes of administration, particularly if there are any changes • Let them see the new medicines and the information that will come with them • Provide any new skills that they may need	"I will try it out"
Step six: Adoption	• Begin treatment with the biosimilar medicine, and answer questions as they arise • Continue to confirm that the biosimilar medicine is still the same treatment	"I want it to happen"
Step seven: Institutionalisation	• Reinforce the previous steps, as the treatment begins to become 'normal' • Follow-up any questions previously asked, and deal with new post-switch questions	"It's how we do things"
Step eight: Internalisation	• Emphasise and reiterate the information already passed on • Continue to reassure patients as they have treatments and counter any negative thoughts to avoid the nocebo effect (the worsening of symptoms induced by the switch to another active therapy)[41] • Continue to deal with questions as they arise. Monitor adherence and compliance as the treatment with the biosimilar becomes routine • Link up patients who have fully accepted the change with patients who are still unsure	"It's ours"

Source: Adapted from Conner[42]

41 Rezk MF, Pieper B, Treatment Outcomes with Biosimilars: Be Aware of the Nocebo Effect. Rheumatol Ther 2017;4(2):209-218. Available at: https://link.springer.com/article/10.1007/s40744-017-0085-z

42 Conner D. The Eight Stages of Building Commitment. 2011. Available at: http://www.connerpartners.com/blog-posts-containing-downloadable-tools/theeight-stages-of-buildingcommitment

Introducing the switch

Good communication plays a very important role in introducing biosimilar medicines to patients.[43, 44] When talking to patients, nurses and all members of the healthcare team need to be sure that they know enough about biosimilar medicines and have confidence in the role that biosimilar medicines and similar biological medicines play in treating patients.

The flow chart in Figure 2 (page 28) shows the steps to ensure that the members of the multidisciplinary team are fully informed and prepared for the implementation of switching.

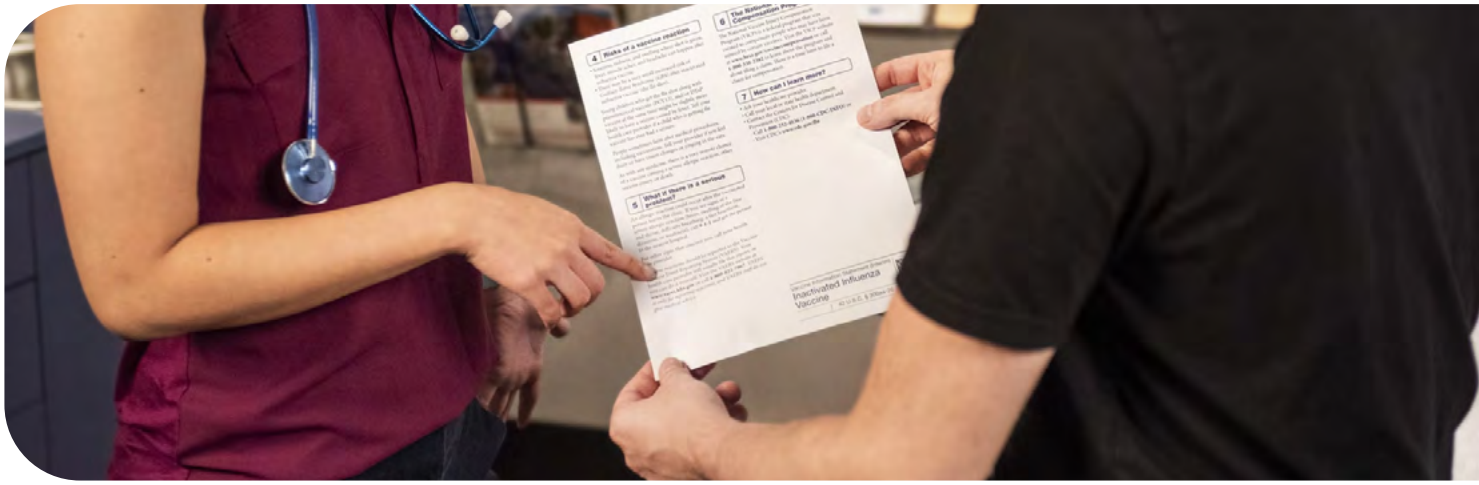
Once the decision for the switch is made, whether from reference biologic to biosimilar (or vice versa) or between different biosimilar medicines, and the implementation plan is in place, the next step is to implement the switch (see Figure 3 - page 29).

Patients may be concerned about the changes. It's important to be honest and use positive language when answering. This provides confidence and reassurance. Patients need to know that their healthcare professionals are knowledgeable and competent, that they understand the reasoning behind the change and that they are confident that it is the right thing to do: trust is key.

To avoid confusion, the team of nurses and other healthcare professionals should have a consistent explanation that is used by all.

Communication with patients throughout the process is vital. This can be through face-to-face meetings, phone calls, and (in some regions) e-health solutions. See the Example letter on switching in the appendix for a sample letter for patients.

Information for patients should also talk about the importance of adherence and compliance, and provide them with a route for reporting adverse events with their doctors, nurses and pharmacists.



43 Syrop J. 4 Studies Address Successes, Failures, and Strategies in Non-Medical-Biosimilar Switching. The Centre for Biosimilars. 2017. Available at: http://www.centerforbiosimilars.com/conferences/acr-2017/4-studies-addresssuccesses-failures-and-strategies-in-nonmedical-biosimilar-switching

44 Jørgensen TS, Skougaard M, Asmussen HC, et al. Communication strategies are highly important to avoid nocebo effect when performing non-medical switch from originator product to biosimilar product: Danish results from applying the parker model-a qualitative 3-step research model. American College of Rheumatology 2017 meeting; November 7, 2017; San Diego, California; Abstract 2260. 2017. Available at: http://acrabstracts.org/abstract/communication-strategiesare-

Figure 2: Biosimilar medicine introduction flow chart

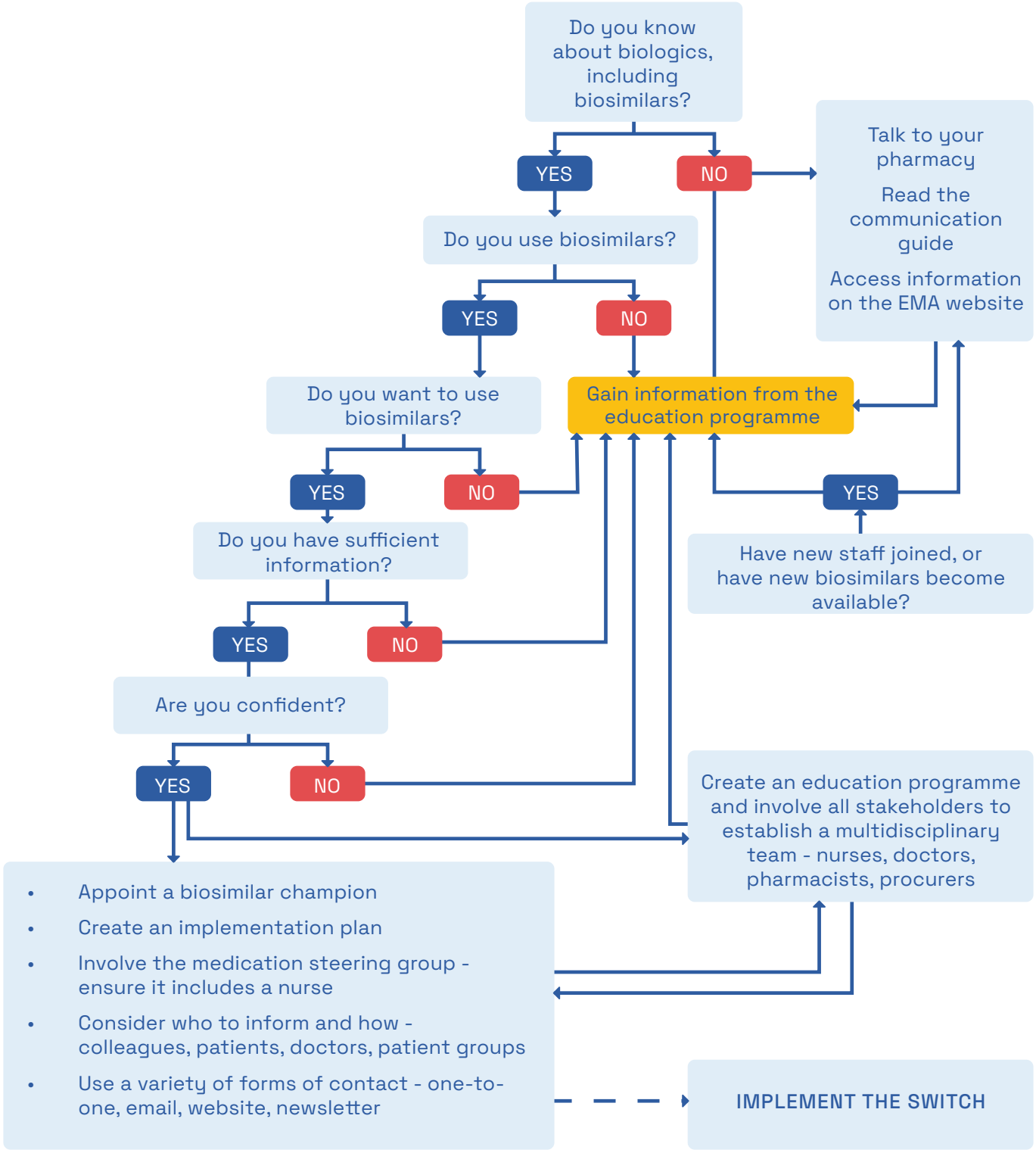
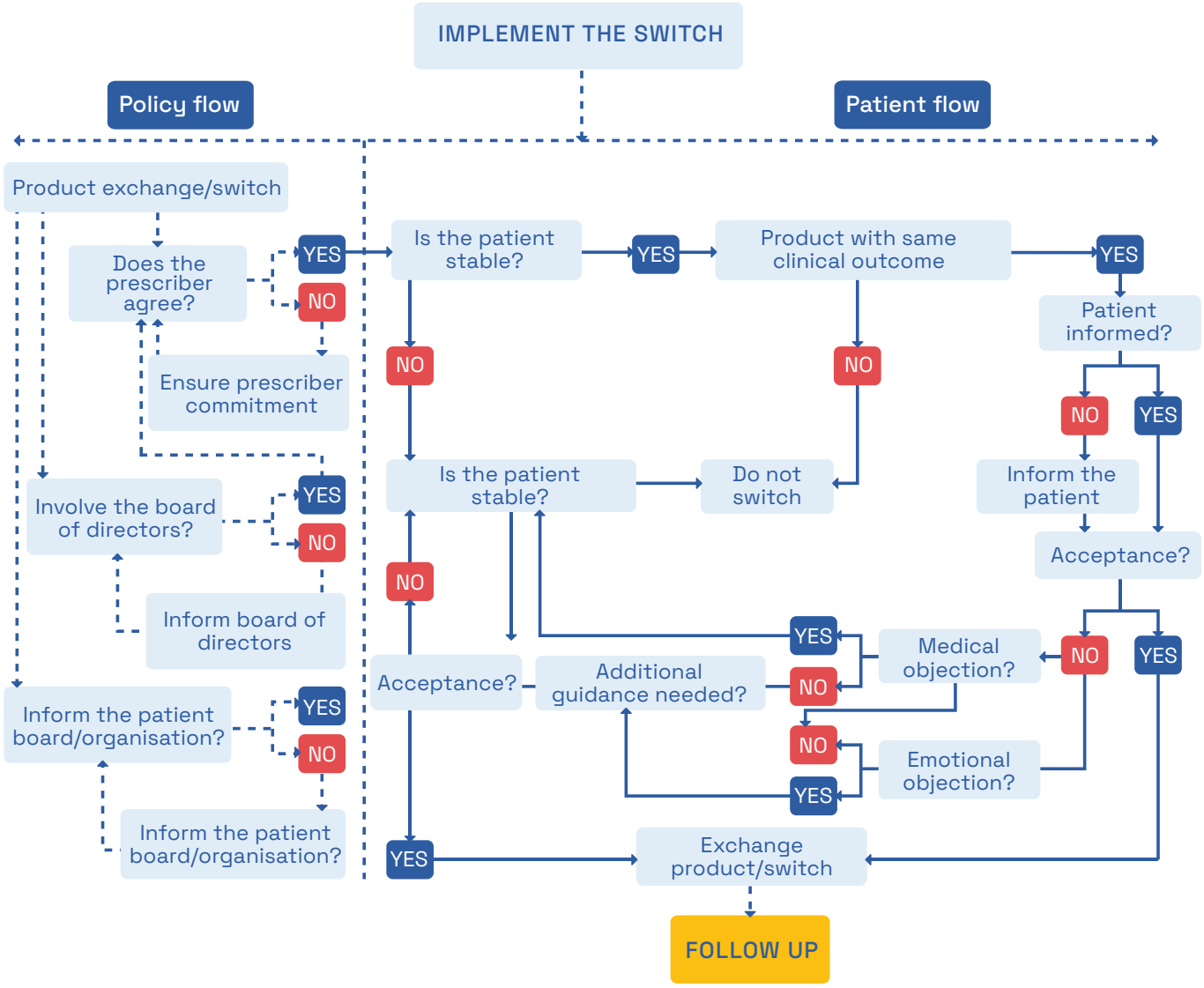


Figure 3: Biosimilar medicine switch implementation flow chart



Nurse FAQ 6

Can the biosimilar medicine look different or have a different packaging or delivery system?

- Biosimilar medicines may have different packaging or delivery systems to the reference biologic. This however will not affect the safety and efficacy of the biosimilar medicine.
- Check the package insert, leaflet or electronic product information (ePI) to see if the delivery system has changed and find out more about how it works. [45]
- You can also check the online 'Electronic Product Information (ePI)'

45 https://www.ema.europa.eu/en/documents/presentation/presentation-71-update-electronic-product-information-eu-medicines-e-scanlan_en.pdf

Patient FAQ 6

I am stable and don't want to switch medications

- The biosimilar medicine that you are going to receive is just as safe and effective as the original medicine and is just as high quality.
- Switches between reference medicines and biosimilar medicines have been taking place successfully since the first biosimilar was launched in Europe in 2006.
- We don't expect to see any change in your response to your medication – we expect you to remain stable. We will monitor your disease before and after the switch, so that we can confirm that nothing has changed.

Patient FAQ 7

Are there going to be any more changes?

- As more companies produce biosimilar forms of biological medicines, and competition in the market increases, there may be another biosimilar version of your medication, or the price of the reference biologic may fall.
- If we do switch you to a different biosimilar medicine or to the reference biologic, we will monitor your disease before and after the switch, so that we can confirm that nothing has changed.

Nurse FAQ 7

My patient says that they are not going to change

- In some countries and regions, the change to biosimilar medicines is mandated. As a nurse, you will need to explain the changes and support your patients. In other countries and regions, you may be able to keep individual patients on the reference biological medicine.
- Keeping communication open is important because, as patients learn more about biosimilar medicines and increase their understanding and trust, they may be more open to change.
- This is particularly important for patients who have had to change medications a lot to find the one that works best for them, and their disease is finally stable. This process may have damaged their trust in the process (see also Patient FAQ 6: I am stable and don't want to switch medications and Patient FAQ 8: Will the medicine lose its effect after the change?).
- In some countries, patients can stay on their original medication, but must pay the difference in cost out of their own pocket.

Will the medicine lose its effect after the change?

Patient FAQ 8

- We will monitor with you before and after you switch between biological medicines and keep a close eye on you during the process.
- If you have questions or concerns, please talk to me, the other nurses, your doctor or the pharmacist.
- If you are worried about the switch, this may make your symptoms seem worse, so it feels as if the medicine isn't having as much of an effect. This is understandable and normal. This is what we call the nocebo effect.[46] The medicine is just as safe and effective as the version you had before.
- In very rare cases the effectiveness of the biological medication can be lost. This isn't because of the switch, it's just a coincidence that it has happened at the time of the switch. It happens because your body can create antibodies to biological medicines, and this can happen with any biological medicine, whether it's the reference medicine, or a biosimilar medicine.

Why are you doing more tests?

Patient FAQ 9

- We monitor your disease before and after the switch, so that we can confirm that nothing has changed.

What happens if a patient has the reference medication by accident after switching to the biosimilar?

Nurse FAQ 8

- To minimise risk, all biosimilar medicines are prescribed by brand name, and their safety monitored through pharmacovigilance systems, under the supervision of the health authorities, so this should not happen
- The batch number and trade name must be recorded, in accordance with pharmacovigilance rules
- As all biological medicines, whether reference biologics and biosimilar medicines, are safe and effective, there should be no impact on the patient. However, if this does happen, monitor the patient after the switch, report it to the prescriber, and to your national pharmacovigilance centre.

46 Rezk MF, Pieper B, Treatment Outcomes with Biosimilars: Be Aware of the Nocebo Effect. Rheumatol Ther 2017;4(2):209-218. Available at: https://link.springer.com/article/10.1007/s40744-017-0085-z

Case Study 8

A managed switching programme to biosimilar infliximab: An example from the UK

Southampton General Hospital developed a managed switching programme. This was carried out with support from the local IBD patient panel, gastroenterologists, pharmacists, and the IBD nursing team, in order to switch patients from the reference infliximab biological medicine to Inflectra® (biosimilar):[47]

Patient approached by IBD nurse at the time of the reference infliximab infusion ► Patient given biosimilar medicines information sheet and an opportunity for discussion ► Patient has oppurtunity for questions and discussion before switching to biosimillar infliximab ► Reviewed at each infusion

Working with the patients

The patient panel, a group of 8-10 patients, met with the IBD clinical team every 6-8 weeks to provide the patient's perspective for both the service and the research projects. While the patients were concerned about gaps in the evidence base around the use of biosimilar medicines in IBD, and around switching, they were reassured by the increase in monitoring built into the managed switching and the risk management programme. The patients were keen to see savings invested in development of the IBD service, including dietetic support and specialist nurses.

Working with the healthcare professionals

The healthcare professionals discussed biosimilar medicines at the gastroenterology departmental meeting, with a focus on the scientific information about biosimilar medicines and ways to improve the IBD service. The physicians were universal in their support, based on the reassurance provided by the risk management plan, which included robust pharmacovigilance procedures and prescribing biological medicines by their specific brand names. The physicians also stated clearly that they would need further investment to be able to deliver the programme, as they did not have sufficient capacity.

Funding the project

The programme was funded through a 'gainshare agreement' between the University Hospital Southampton NHS Foundation Trust and local clinical commissioning groups, and any savings were shared. This included:

- Funding the managed switching programme
- Investing in the nurse-led IBD biologics service
- Developing an inpatient IBD nursing service

New posts included an IBD specialist nurse post, a 0.5 full time equivalent (FTE) clerical post, a 0.2 FTE pharmacist and a 0.2 FTE dietitian.

The outcomes

All of the infliximab-treated IBD patients who were looked after by the adult IBD service were given the chance to take part. Those who agreed were switched to Inflectra® at the same dose and frequency as the reference infliximab biological medicine.

After the change: follow-up and support

Patients can become very anxious during and after changes of any medications, and particularly between biosimilar and reference biological medicines. Support, reassurance, communication and information from nurses and other healthcare professionals are especially important, particularly when patients have struggled to get a diagnosis and find an effective treatment in the past. This can be an emotional process for the patient and needs time and patience.

Nurses need to be available to answer questions once patients have changed their treatment and knowing that they can have their questions answered will make patients feel more confident and comfortable. Figure 4 shows a flow chart looking at the follow-up strategy after a switch.

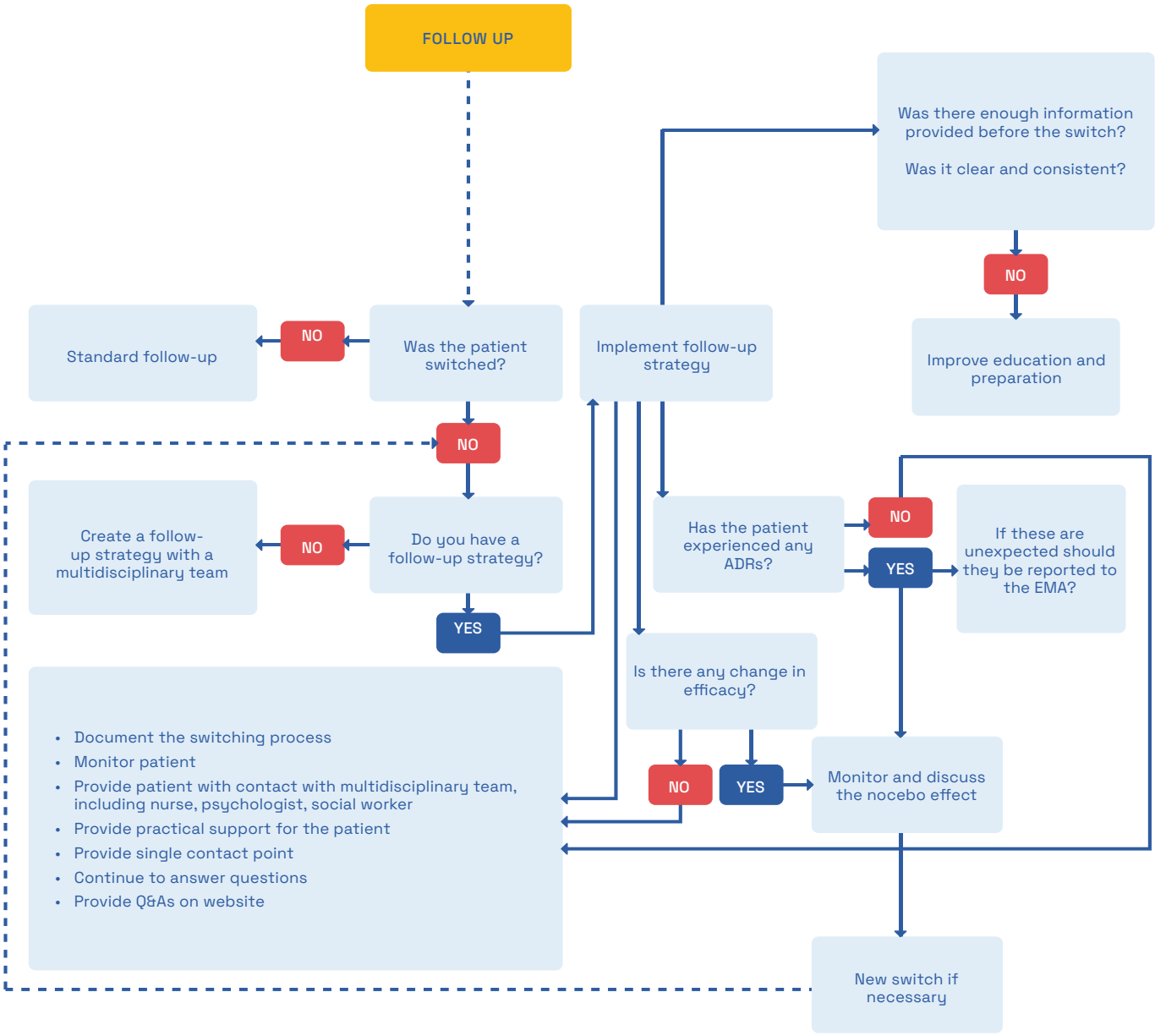
Some patients may worry that they feel worse on the biosimilar. This is likely to be a psychological effect called the nocebo effect, where patients are afraid of becoming ill again and focus on symptoms or adverse effects that they didn't notice before, or they misinterpret normal disease progression as side effects.[48] Studies show that there is no difference in rates or severity of adverse events after changing from reference biological medicines and biosimilar medicines.[49]

47 Taylor NS, et al. The impact of an inflammatory bowel disease nurse-led biologics service. Frontline Gastroenterology 2016;7:283–288. Available at: https://fg.bmj.com/content/7/4/283

48 Rezk MF, Pieper B, Treatment Outcomes with Biosimilars: Be Aware of the Nocebo Effect. Rheumatol Ther 2017;4(2):209-218. Available at: https://link.springer.com/article/10.1007/s40744-017-0085-z

49 Kurki P, van Aerts L, Wolff-Holz E, et al. Interchangeability of Biosimilars: A European Perspective. BioDrugs 2017;31(2):83-91. Available at: https://pubmed.ncbi.nlm.nih.gov/28120313/

Figure 4: Biosimilar medicine follow-up flow chart



Patient FAQ 10

Will the side effects be different?

- All versions of a given biological medicine (both reference and biosimilar medicine) share a similar profile – how they work, their efficacy and safety, and any possible side effects.
- Each patient may experience all, some, or none of the side effects.
- If you are worried about the switch, this may make your symptoms or side effects seem worse. This is what we call the nocebo effect.[50] The medicine is just as safe and effective as the version you had before.

50 Rezk MF, Pieper B, Treatment Outcomes with Biosimilars: Be Aware of the Nocebo Effect. Rheumatol Ther 2017;4(2):209-218. Available at: https://link.springer.com/article/10.1007/s40744-017-0085-z

Educating patients about the normal course of their disease is particularly important to avoid the nocebo effect.[51] A patient's report of side effects should still be taken seriously and reported as required by nursing standards. The trade name and batch number must be included when reporting any side effects, according to EU law.

Case Study 9

Explanations help to stop treatment failures: An example from Denmark

- In a study carried out in Denmark looking at treatment failures when switching between reference etanercept (Enbrel®) and the etanercept biosimilar Benepali®, patients believed that it was 'obvious' that adverse events and loss of efficacy were a result of the switch to the biosimilar medicine. Explaining that the reference and the biosimilar medicine are the same treatment was effective in about 90% of cases.[52, 53]

Patient FAQ 11

What should I do if I think the biosimilar medicine is causing new side effects?

- All versions of a biological medicine, including the reference and the biosimilar versions of the medicine, should have similar patterns of side effects.
- There have been no reports of safety issues specifically related to biosimilar medicines.
- If you think any medicine is causing side effects, especially if they are new side effects, you should tell your doctor, nurse or pharmacist.
- You can report side effects through the patient reporting system provided by your country's national authority. You must include the trade name and batch number.

51 Rezk MF, Pieper B, Treatment Outcomes with Biosimilars: Be Aware of the Nocebo Effect. Rheumatol Ther 2017;4(2):209-218. Available at: https://link.springer.com/article/10.1007/s40744-017-0085-z

52 Syrop J. 4 Studies Address Successes, Failures, and Strategies in Non-Medical-Biosimilar Switching. The Centre for Biosimilars. 2017. Available at: http://www.centerforbiosimilars.com/conferences/acr-2017/4-studies-addresssuccesses-failures-and-strategies-in-nonmedical-biosimilarswitching

53 Hendricks O, Horslev-Petersen K. When etanercept switch fails-clinical considerations. American College of Rheumatology 2017 meeting; November 7, 2017; San Diego, California; Abstract 2484. 2017. Available at: http://acrabstracts.org/abstract/when-etanercept-switch-fails-clinicalconsiderations/

CHAPTER 6

EDUCATION AND COMMUNICATION

Chapter 6. Education and communication

- Education and communication on biosimilar medicines are important because they are linked to safe use and better health outcomes
- Educating patients helps them to understand why they are being switched to a biosimilar medicine
- Including nurses in biosimilar education projects is essential

Why are education and communication so important?

Unfortunately, up to half of all medications[54] for long term conditions aren't taken properly. This affects patients' outcomes and long-term health. Switching can affect whether patients take their medications properly (safe use and **adherence**)[55], so explanations and support from nurses is particularly important to improve patients' adherence to medication. According to the IQVIA 'Spotlight on Biosimilars',[56] patient education and awareness are linked with better health outcomes, which means that nursing education on this topic is important.[57, 58]

54 NICE. Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence. 28 January 2009. Available at: https://www.nice.org.uk/guidance/cg76/chapter/introduction

55 Edwards CJ, et al. Switching to biosimilars: current perspectives in immune-mediated inflammatory diseases. Expert Opinion Biol Ther. 2019:19(10):1001-1014. Available at: https://www.tandfonline.com/doi/full/10.1080/14712598.2019.1610381

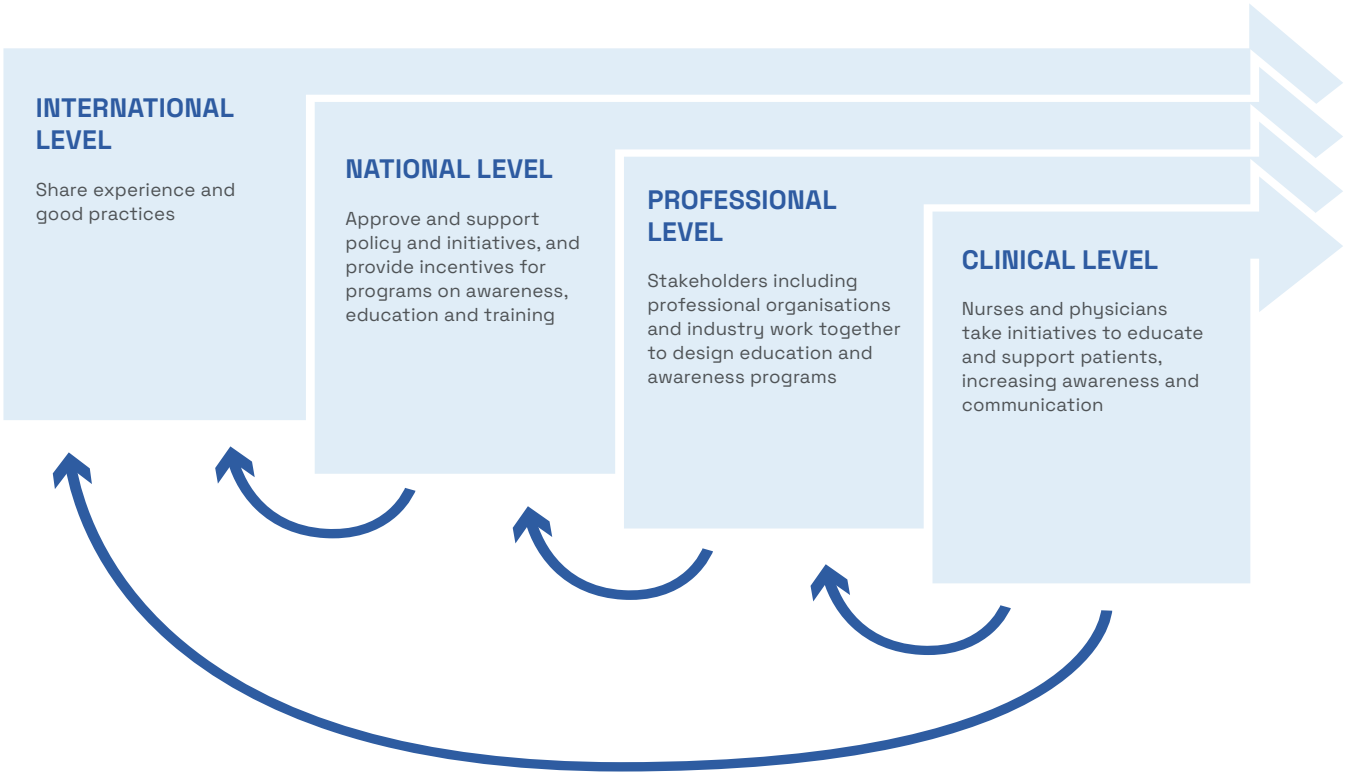
56 IQVIA. Spotlight on Biosimilars: Optimising the sustainability of healthcare systems. June 2021. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports/spotlight-on-biosimilars

57 Syrop J. 4 Studies Address Successes, Failures, and Strategies in Non-Medical-Biosimilar Switching. The Centre for Biosimilars. 2017. Available at: http://www.centerforbiosimilars.com/conferences/acr-2017/4-studies-addresssuccesses-failures-and-strategies-in-nonmedical-biosimilar-switching

58 Jørgensen TS, Skougaard M, Asmussen HC, et al. Communication strategies are highly important to avoid nocebo effect when performing non-medical switch from originator product to biosimilar product: Danish results from applying the parker model-a qualitative 3-step research model. American College of Rheumatology 2017 meeting; November 7, 2017; San Diego, California; Abstract 2260. 2017. Available at: http://acrabstracts.org/abstract/communication-strategiesare-

A good education policy must be supported at national level. This needs support and political will at all levels (see Figure 5).

Figure 5: The process of education policy



Case Study 10

Communication is key: An example from Denmark

- In another Danish study, researchers who were looking at a switch to a biosimilar product in patients with rheumatoid arthritis, ankylosing spondylitis or spondyloarthritis, concluded that communication strategies were an important part of the process.

Case Study 11

Training together is important: An example from the Netherlands

- We created a training program and invited our own clinical staff and the outpatient clinic team because patients who receive an intravenous infusion are mainly seen by them. They tell their story, ask questions, and are involved in the entire conversion process. I think it is good that we all tell everyone the same thing, not that one person says, “it is a different cheaper drug,” and the next says, “this is exactly the same drug, but only from a different manufacturer”. This has strengthened the solidarity among the healthcare staff. We also trained with actors to role play what happens when people say, firmly, “I don’t want this,” and how you deal with that. That really helped.

Talking to patients who refuse can change minds: An example from the Netherlands

Case Study 12

- For biosimilar use and switching to be able to succeed, nurses must be able to talk to their patients about them. We always try to explain to patients that the process of manufacturing reference biologics and biosimilar medicines is very strictly controlled. This ensures that while reference biologics and biosimilar medicines can't be completely identical because they are made in living cells, they are as close to identical as possible.
- We conducted a switch study in 600 patients. Of these, 40 were not happy with the switch and five refused completely. The objections were based on the assumption that they were entitled to 'the best remedy'. We sent a letter to the patients who refused, with more explanation about biosimilar medicines.
- Nurse: 'We have had a year of experience with biosimilars and we have not seen any differences. Perhaps you just should try it."
- Patients: "Well, now that it's explained better to me, I'll give it a try."

Communicating one-to-one: An example from Portugal

Case Study 13

- I start by assessing my patient's level of understanding. If I realize the message is not being understood, I ask them to bring someone with them next time. Then I look at their needs and concerns. I try to be objective and speak as simply as possible. I also use a guidebook prepared by my team. I explain what I am reading and address their doubts. I tell them about possible side effects – what to look out for, and who to contact. I tell them to read the book at home and make a list of concerns so that we can talk about them. Whenever the patient goes for treatment, we evaluate whether the teaching has changed their behaviour or not. Sometimes the teaching is carried out during the treatments, it depends on the patient's psychological condition. The more they know about their treatment the better their participation in the treatments will be and the better the outcomes will be.
- Effective communication involves listening, understanding and taking the time needed. I think that spending extra time with patients and listening to their doubts is the secret. This is not easy to achieve. Not giving all the information at once is also very important. The patient won't be able to memorize everything and will be under stress. It should be a gradual learning. And of course, speak plainly and clearly. It's very important, whatever their level of knowledge.

Repeating information when needed: An example from the Netherlands

Case Study 14

- The most common method is face-to-face explanation. Most of my patients are usually very grateful for the information they receive. However, sometimes it turns out that the information needs to be repeated after a while.

Creating an education program for nurses and other healthcare professionals

Including nurses in biosimilar education projects is essential. Figure 6 shows the process of setting up a sustainable program.

Figure 6: Creating an education programme

1
- Find the nurses interested in the project
- Find an organisation or group that will support the project financially
- Connect with nurses, medics and pharmacists
- Identify goals, for example:
    - Making nurses aware of biosimilar medicines
    - Ensuring that nurses can communicate on biosimilar medicines to patients and colleagues
    - Putting together learning activities in relation to swich management

2
- Design a survey to gain insight and trigger interest
    - Create questions that find out what nurses need to know, for example communication, education, prescribing
- Include a tick box to ask if respondents would like to get follow-up information

3
- Publish the survey
    - Set a two-week deadline for completion
- Send reminders

4
- Make a report on the outcomes to communicate with participants
    - Identify learning gaps
    - Make conclusions and recommendations
- Include goals

5
- Create tailored versions of the report, targeting different audiences:
    - Press release
    - Articles for print and online publication
    - Presentations
- Create social media posts

6

- Create a follow up activity such as a webinar or training course based on the survey outcomes
    - Identify a working group for the webinar or training, which includes experts and nurses
- For a national program, ensure that there are nursing representatives from the specific country

7

- Seek means for sustainability in education at a national policy level.
    - Campaign to have biosimilar medicines included in student education and Continuing Professional Development
- Organise local education activities

The value of creating a program: An example from Poland

Case Study 15

- In the past we have seen a lot of projects but have had little follow-up. What we have found best is to create a specific program that has a clear outcome, and that can then differentiate into small projects. Ours focused specifically on the switch management of medication for patients. This can be from the reference biologic to the biosimilar, or from the biosimilar to the reference biologic, depending on availability and markets. Nurses need to understand the dynamics of switching and how to communicate the topic. This is important not only because it will be the future of the roles and responsibilities of nurses but also because nurses move to different specialist areas or to different member states. If this program works well, it could be an excellent example for other countries.

Using nurses as communicators: An example from Norway

Case Study 16

- In Norway, the rheumatology nurses don't prescribe medication. The rheumatologist has to prescribe the medication that is selected for the year. The patients can't choose between different biosimilar medicines and the reference biologic. The specialist nurse often has to explain this to the patients. This makes communication easier. I think that when the nurses are familiar with the biosimilar medicines, we can give useful information about switching. A lot of patients accept the fact that the rheumatologist has to prescribe a specific medication. We explain that when we started to use biosimilar medicines, it became possible to treat five patients instead of one.
- When patients contact the nurse's helpline, it may be because they have experienced a flare up after switching to a biosimilar, but it is rare. These patients, just a few, can go back to the treatment they had prior to biosimilar medicines. We do not wish to stress the patients. We give the patients who call us information about rheumatic diseases and how they can fluctuate. But we listen carefully, explain thoroughly for those who need extra information, and sometimes ask the rheumatologist for advice.
- When patients start with a new biological medication, we use the substance name in the written information – for example, talking about infliximab or rituximab, as well as the corresponding brand names (Remicade®, Remsima®, Inflectra®, Zessly®, MabThera® or Rixathon®). When they have been to the nurse or rheumatologist, we write infliximab (Zessly®) or rituximab (Rixathon®).

Case Study 17

Successful switching for patients with inflammatory bowel disease: An example from Belgium

After running a hospital tender for infliximab (biosimilar and reference biological medicine) at the AZ Delta Hospital, Roeselare, Belgium, the hospital decided to perform a mandatory switch for inflammatory bowel disease (IBD) patients, moving all patients from a reference biological medicine to a biosimilar.

The key to the changeover was information and education. The important first step was to inform the patients, and so the team sent all patients a personal letter, as well as explaining it to them face-to-face. The focus was on the advantages for the patients.

The IBD team felt it was crucial to work with and inform all of the healthcare professionals involved in the switch process. At AZ Delta, this included the pharmacists, day clinic nurses, physicians and inpatient nurses. The consultant IBD nurse played a central role in this interdisciplinary journey.

The team wrote personal letters to the patients' general practitioners, as patients may raise questions and concerns after the switch. There was also an interdisciplinary lecture for all stakeholders based on some of the questions that patients were likely to ask:

- What is a biosimilar?
- What is the difference between a biosimilar and the reference biological medicine?
- Are biosimilar medicines equally effective?
- Can effectiveness be lost after the exchange between the reference biological medicine and the biosimilar?

The team created a pocket dictionary for the nurses that included frequently asked questions.

The conclusion is that it is important to communicate with patients before, during and after the switch. Comparing patients' results from before and after the switch was helpful.

While the switch to the biosimilar biological medicine was mandatory, the team found a number of positive outcomes:

- Benefits to the nurses (and the patients):
    - The program was run by the interdisciplinary team and nurse lead.
    - The process allowed the team to re-examine the administration procedure to make it simpler.
    - Nurses were included in education, training and communication.
    - It increased the self-esteem of nurses
    - It triggered follow up project engagement at local, national and European levels.
- Benefits to the patients
    - This resulted in shorter waiting times, harmonising procedures, improving pre-delivery procedures, etc.
    - Thanks to the savings, the hospital was able to increase from one part-time to one full-time IBD nurse to support patients during their clinic visits.
    - The team could provide support to help with problems or questions at home.
    - The team improved the organisation of the care pathway.
- Benefits to the hospital and the healthcare system:
    - The biosimilar was less expensive than the original biological medicine so, by using the biosimilar medicines, the team could make more biological medicines available to more people.
    - The team could maintain the financial viability of the healthcare system for longer.

CHAPTER 7

NURSE ROLES AND RESPONSABILITIES IN RELATION TO BIOSIMILAR MEDICATION

Chapter 7. Nurse roles and responsibilities in relation to biological and biosimilar medication

- Nurses play a role in assessing, managing and monitoring biological therapies
- This includes delivering safe care, reporting on adverse effects, working as part of a multidisciplinary team, managing risk, providing patient training and education, and collecting data

Depending on their location in Europe, nurses are increasingly involved in prescribing.[59, 60] Even where they have no specific prescribing roles or responsibilities, they should still be involved in the decision process of prescribing biosimilar medicines, as it will help them communicate the reasons behind the switch with their patients.

According to the UK's Royal College of Nursing's guidance, nurses' roles as service providers in assessing, managing and monitoring biological therapies include:[61]

- Delivering safe and effective care assuring the safe administration and monitoring of biological therapies
- Reporting and acting on any adverse effects, errors or near misses following local guidelines
    - For biosimilar medicines it is important to report by the product name not the substance, for example Remsima® not infliximab, and include the batch number
- Supporting ongoing monitoring and management
- Working as part of a multidisciplinary patient-centred approach where all members of the health care team, including patients, are valued and have a voice
- Managing risk as part of a safe service
    - This includes consulting local policies and ensuring that all potential risk areas have been addressed
- Promoting best practice in prescribing
- Ensuring the shared decision-making process is tailored to the patient, carer or family's needs and wishes
- Providing appropriate training and educational resources to support patients with the self-administration of the biosimilar medicines
- Undertaking the collection of data and reporting to support effective local commissioning and the management of patients on biosimilar medicines

59 International Council of Nurses. Guidelines on prescriptive authority for nurses. 2021. Available at: https://www.icn.ch/system/files/2021-09/ICN_Nurse_prescribing_guidelines_EN_WEB.pdf

60 NuPhaC. Development of a framework for nurses' role in interprofessional pharmaceutical care in Europe. Available at: https://www.nuphac.eu/single-post/development-of-a-framework-for-nurses-role-in-interprofessional-pharmaceutical-care-in-europe

61 RCN. Assessing, managing and monitoring biologic therapies for inflammatory arthritis. 2015. Available at: https://www.rcn.org.uk/-/media/royal-college-of-nursing/documents/publications/2015/february/pub-004744.pdf

CHAPTER 8

RECOMMENDATIONS

Chapter 8. Recommendations

Introducing biosimilar medicines and moving patients between biosimilar medicines and the reference medicines can be of benefit to patients, healthcare teams and the healthcare system as a whole, but it has to be handled with care. Nurse-led programmes often ensure the continuity of information and education before, during and after the change of medication. Working together in interdisciplinary teams and ensuring clear and consistent communication and information at all levels, from management to patients, can result in gains in care quality and costs.[62]

62 Taylor NS, Bettey M, Wright J, et al. The impact of an inflammatory bowel disease nurse-led biologics service. Frontline Gastroenterol 2016:7(4):283-288. Available at: https://fg.bmj.com/content/7/4/283

63 European Medicines Agency and European Commission. Biosimilars in the EU: Information guide for healthcare professionals. 2017. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Leaflet/2017/05/WC500226648.pdf

CHAPTER 9

APPENDIX

Glossary

Adherence	Taking medicines according to recommendations
Batch	An amount of drugs manufactured in a single cycle
Benefit share	Collaborative processes set up between the stakeholders – the healthcare commissioners and providers – that support the use of less expensive medicines, where cost savings are distributed to the healthcare teams and groups involved. Also known as gainshare
Biological medicine	Biological medicines (including biosimilar medicines) are produced from living organisms, such as mammalian cells, bacteria or yeasts. Biological medicines are usually larger and more complex than chemically synthesised compounds
Biosimilar	A medicine highly similar to a marketed biological medicine (reference medicine or reference biologic)
European Medicines Agency (EMA)	To make biological, including biosimilar, medicines available to patients in Europe, a company needs the green light from the European Medicines Agency (EMA). The EMA recommends to the European Commission that the medicines can be marketed. The EMA continues to monitor the medicine while it is on the market
European public assessment reports (EPAR)	Full scientific assessment reports of medicines approved for the market by the EMA
Extrapolation of indications	Approving a biosimilar for the same indications as the reference medicine. If a biosimilar is highly similar to a reference medicine, with the same safety and efficacy in one therapeutic indication, safety and efficacy outcomes data may be used for other indications approved for the reference medicine
Interchangeability	Interchangeability refers to the possibility of exchanging one medicine for another medicine that is expected to have the same clinical effect. This could mean replacing a reference biologic with a biosimilar (or vice versa) or replacing one biosimilar with another (see also switching and substitution)
International non-proprietary name (INN)	The name of the active ingredient in a medicine. It is also described as the generic name or common substance name
Nocebo	The idea of worsening of symptoms that may be seen when patients switch to another active therapy, such as a biosimilar. This as a result on patient's perception regarding -in this case biosimilars cause the treatment- to have a more negative effect than it otherwise would have
Pharmacovigilance	Monitoring, detecting and reporting adverse effects and other issues relating to medicines

Real-world data	Information collected on medicines in every-day use
Real-world evidence	Evidence created from analysis of real-world data
Reference biologic or reference medicine	The original version of a biological medicine
Substitution	The practice of dispensing one medicine instead of another equivalent and interchangeable medicine at pharmacy level without consulting the authorised prescriber – this can be an automatic process
Switching	When the clinical decision maker decides to exchange one medicine for another medicine with the same therapeutic intent

Definitions of biosimilar medicines

The formal definition of biosimilar medicines

Biological medicine can have an inherent degree of minor variability (microheterogeneity). This minor variability must fall within the acceptable range to ensure consistent safety and efficacy. This is done by adjusting the manufacturing process to guarantee that the active substance fits into the desired specifications range.

This degree of minor variability can be present within or between batches of the same biological medicine, particularly when manufacturing processes are modified during the commercial life of the medicine (e.g., increasing production scale). Strict controls are always applied to ensure that, despite this variability, there is batch-to-batch consistency and that the differences do not affect safety or efficacy. In practice, variability (within a batch or batch-to-batch) is very low when using the same manufacturing process.

Due to the natural variability of the biological source and to the manufacturing process unique to each manufacturer, minor differences can occur between the biosimilar and its reference medicine and between batches of the reference medicine. Strict controls are always in place during manufacturing to ensure that minor differences do not affect the way the medicine works or its safety. Thus, these differences are not clinically meaningful in terms of safety or efficacy.

From **Biosimilars in the EU: Information guide for healthcare professionals**[63]

63 European Medicines Agency and European Commission. Biosimilars in the EU: Information guide for healthcare professionals. 2017. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Leaflet/2017/05/WC500226648.pdf

Specific appearance of biosimilar medicines[64]

'Highly similar to the reference medicine'	The biosimilar has physical, chemical and biological properties highly similar to its reference medicine. There may be minor differences from the reference medicine which are not clinically meaningful in terms of quality, safety or efficacy.
'No clinically meaningful differences compared with the reference medicine'	No differences are expected in clinical performance. Comparability and clinical studies that support the approval of a biosimilar confirm that any differences will not have an effect on safety and efficacy.
'Variability of biosimilar kept within strict limits'	Minor variability is only allowed when scientific evidence shows that it does not affect the safety and efficacy of the biosimilar. The range of variability allowed for a biosimilar is the same as that allowed between batches of the reference medicine. This is achieved with a robust manufacturing process to ensure that all batches of the medicine are of proven quality.
'Same strict standards of quality, safety and efficacy'	Biosimilar medicines are approved according to the same strict standards of quality, safety and efficacy that apply to any other medicine.

Approved biosimilar medicines

Since the introduction of the first biosimilar into clinical use in 2006, an increasing number of biosimilar medicines have been approved and safely used in the EU. A list of approved biosimilar medicines in Europe can be found on the EMA website. By 2021, EU approved biosimilar medicines had delivered over 2 billion patient days of treatment.[65]

Further reading

Europe

Biosimilar Medicines Group, Medicines for Europe

- Reading list (https://www.medicinesforeurope.com/wp-content/uploads/2022/04/M-Biosimilars-Reading-list-20220413_for_publication.pdf)
- Overview of European positioning statements on biosimilar medicines (https://www.medicinesforeurope.com/docs/20210825 FINAL Overview of switching positions.pdf)

64 European Medicines Agency and European Commission. Biosimilars in the EU: Information guide for healthcare professionals. 2017. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Leaflet/2017/05/WC500226648.pdf

65 https://www.medicinesforeurope.com/wp-content/uploads/2020/12/BIOS5.pdf

Professionals and Biosimilars

- Biosimilars in oncology key role of nurses , Friganovic and Waller (https://fonse.eu/wp-content/uploads/2021/04/Biosimilars_in_oncology_key_role_of_nurses.pdf)
- European Stakeholder Learnings Regarding Biosimilars: Part I—Improving Biosimilar Understanding and Adoption (https://link.springer.com/epdf/10.1007/s40259-020-00452-9?sharing_token=1LWBB5_-2CgZGHTcTxbQS_e4RwlQNchNByi7wbcMAY6frUxSUa4jpf5kvlUlsQkBV3kEl-CHZigdzfZaFUEONEN98JQRYefHmK1DxLSjdbmV4YeDzjb2J78B3WgQKJ43KMmy5Xl6lDA7GzGkPn_jzVLJfOcUFP5eWu1HECLy2tI%3D)
- European Stakeholder Learnings Regarding Biosimilars: Part II—Improving Biosimilar Use in Clinical Practice Liese Barbier (https://link.springer.com/epdf/10.1007/s40259-020-00440-z?sharing_token=H8BgU5b8yun2rJm4cDFXcPe4RwlQNchNByi7wbcMAY67I7M1veDDtIxz6yeJHe8SKI7IMJ1DsPy9LxY3615r0TaL70ytd1-1BEFtg1exol3EEYBbTgptw4US3qLYo3RByH7JA8PDXte-NBsexq8ebLdF17ahZdQZv8Pr5EjuiL5I%3D).
- Perceptions About Biosimilar Medicines Among Belgian Patients in Ambulatory Care , Yanick Vandenplas et al (https://www.frontiersin.org/articles/10.3389/fphar.2021.789640/full)

IGBA

- A Vision for the Global Generic and Biosimilar Medicines Industry (https://igbamedicines.org/doc/IGBA_Whitepaper_A Vision for the Global Generic and Biosimilar Medicines Industry_registered-user.pdf)
- Whitepaper – May 2021

Effective strategies to Advance Access to Biologic therapies for Non-Communicable Diseases– A Biosimilar Access Policy Blueprint (https://www.globalbiosimilarsweek.org/2021/doc/A-Biosimilar-medicines-Access-Policy-Blueprint-IGBA.pdf)

- Policy paper - October 2021

Frederike Voglsamer Head of Market Access bei Pro Generika / AG Pro Biosimilars BIOSIMILARS IN GERMANY – ZUM KALENDERJAHR IN ZAHLEN (Biosimilar in Numbers) (https://probiosimilars.de/img_upload/2021/07/Biosimilars-in-Zahlen_2020-1.pdf)

IQVIA

- Spotlight on Biosimilars, Optimising the Sustainability of Healthcare Systems (https://www.iqvia.com/en/insights/the-iqvia-institute/reports/spotlight-on-biosimilars)
- The Impact of Biosimilar Competition in Europe (https://www.iqvia.com/library/white-papers/the-impact-of-biosimilar-competition-in-europe)
- Video – 15 December 2021: Webinar on the impact of biosimilar competition in Europe (https://vimeo.com/659326182/9fc48a4825)
- Report: The Impact of Biosimilar Competition in Europe December 2021 (https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/the-impact-of-biosimilar-competition-in-europe-2021.pdf?_=1640198387326)

Biosimilar Biologics in Canada 'ARTHRITIS CONSUMER EXPERT'

- What inflammatory arthritis patients need to know. Third Edition September 2021 (https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/the-impact-of-biosimilar-competition-in-europe-2021.pdf?_=1640198387326)

EMA

- Adverse Reactions Responses Page (https://www.adrreports.eu/)
- Clinical Trials Register (https://www.clinicaltrialsregister.eu/index.html)
- Terms Used Glossary Clinical Trials (https://www.clinicaltrialsregister.eu/doc/EU_Clinical_Trials_Register_Glossary.pdf)

CHAPTER 10

CONTRIBUTORS

Chapter 10. Contributors

The ESNO biosimilars focus group involved in the development of this communication guide represents five of its member organisations.

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About ESNO

ESNO: The European Specialist Nurses Organisation (ESNO) is a non-profit organisation, and the goal is to provide and facilitate an effective framework for communication and co-operation between the European nursing organisations and the individual members. ESNO also represents the mutual interests and benefits of these organisations to the wider European community. ESNO contributes to health themes and threats, and puts together innovative activities, all in the interest of European public health.

Notes

Notes

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