Introducing the:

ESNO Communications and Information Guide for Nurses

Switch Management between Similar Biological Medicines

ESN
EUROPEAN SPECIALIST NURSES ORGANISATION

Agenda

About ESNO

The European Specialist Nurses Organisation (ESNO) is a non-profit organisation, and the goal is to facilitate and provide an effective framework for communication and co-operation between the European Specialist Nurses Organisations and its constituent members.

ESNO represents the mutual interests and benefits of these organisations to the wider European community in the interest of the public health.

Members of ESNO consist of individual European specialist nurses organizations.

About this presentation

As the COVID-19 pandemic has shown, nurses play a critical role in our healthcare systems - they're even increasingly prescribing medicines.

- With that in mind, ESNO wanted to establish an efficient communication document for biosimilar medicines for nurses in Europe - covering key facts, benefits, and important considerations that all nurses should know.
- This presentation will summarize the findings and highlight key areas for how the full guide can be applied in practice.

About the guide

Based on evidence and collective experience at all levels, the full guide serves patients, physicians, and above all nurses, when confronted with the terms ‘biosimilar’ and ‘switching’.

The ESNO Biosimilars guide provides a multitude of examples, best practices, and guidelines for how nurses should handle understanding, dealing with on a day-to-day basis, and communicating about biosimilars.

It is divided into 8 main chapters, then recommendations and findings.

This Communication and Information Guide for Nurses is an upgrade of the first edition published in 2018. 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 also increased the focus on education and communication, to ensure good practice and support professional competencies.

FAQs and best practices

Throughout the guide, we provide concrete examples of FAQs and communication best practices for how to talk about these topics.

Let's begin! →

Patient FAQ 4

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

- 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.

1. Biological and biosimilar medicines

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The development of biologics began with insulin, for the treatment of diabetes. Originally a compound isolated from animals, genetically engineered biosimilar insulin allowed us to treat diabetes with a much purer form.

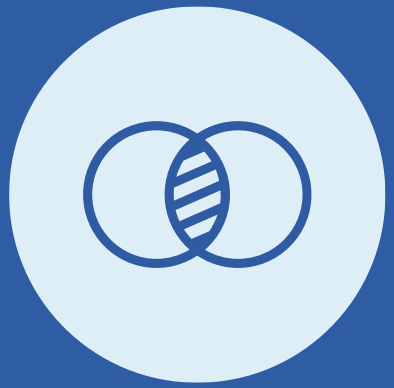
This has led to creation of a multitude of different biologics.

- Originator biologics are patented for 20 years from their discovery. After this period, other companies can make their own versions, called biosimilar medicines.

1. Biological and biosimilar medicines

- Biological medicines are complex and are produced in living cells
- Biological vs. Biosimilars:

  - Biosimilars can be **developed and marketed once the original molecule has lost patent protection**
  - Biosimilar medicines are **just as safe and effective** as the original



2. Extrapolation of indications

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Biosimilar medicines are approved after studies that show that:

- The structure is **the same as the reference biological medicine**
- 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.

3. Why switch?
Budgets and investment in healthcare

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- Biologics can be safer and more effective than conventional drugs, however they cost significantly more to develop and manufacture.
- Biosimilars bridge the budget gap:

Developing a new reference **biologic**:

- can take over a decade and cost billions of Euros.
- Around 40% of the total medication budget in the EU is spent on **biologics**

Developing a **biosimilar** medicine:

- can take between five and nine years, and cost between €150 million and €250 million

3. Why switch? Budgets and investment in healthcare

The introduction of biosimilar medicines creates competition and reduces costs.

- 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.

3. Why switch? Budgets and investment in healthcare

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.
- The **savings can also be re-deployed in other areas** of the healthcare system, such as on staff, equipment, prevention campaigns or diagnostics, and more.

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

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Once the EMA and national regulatory authorities approve a biosimilar medicine, it can be prescribed to patients, often replacing a biologic.

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.

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

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Nurses play a crucial role in communicating with patients and providing support and reassurance, before, during and particularly after switching between reference products and biosimilar medicines.

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**.

5. Switching communication – in practice

The findings of the guide are not just theoretical, but include practical guides for how these conversations play out:

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"
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"

6. Education and communication

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Unfortunately, up to half of all medications for long term conditions aren't taken properly, highlighting the importance of getting this right.

- 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

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

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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.

8. Recommendations

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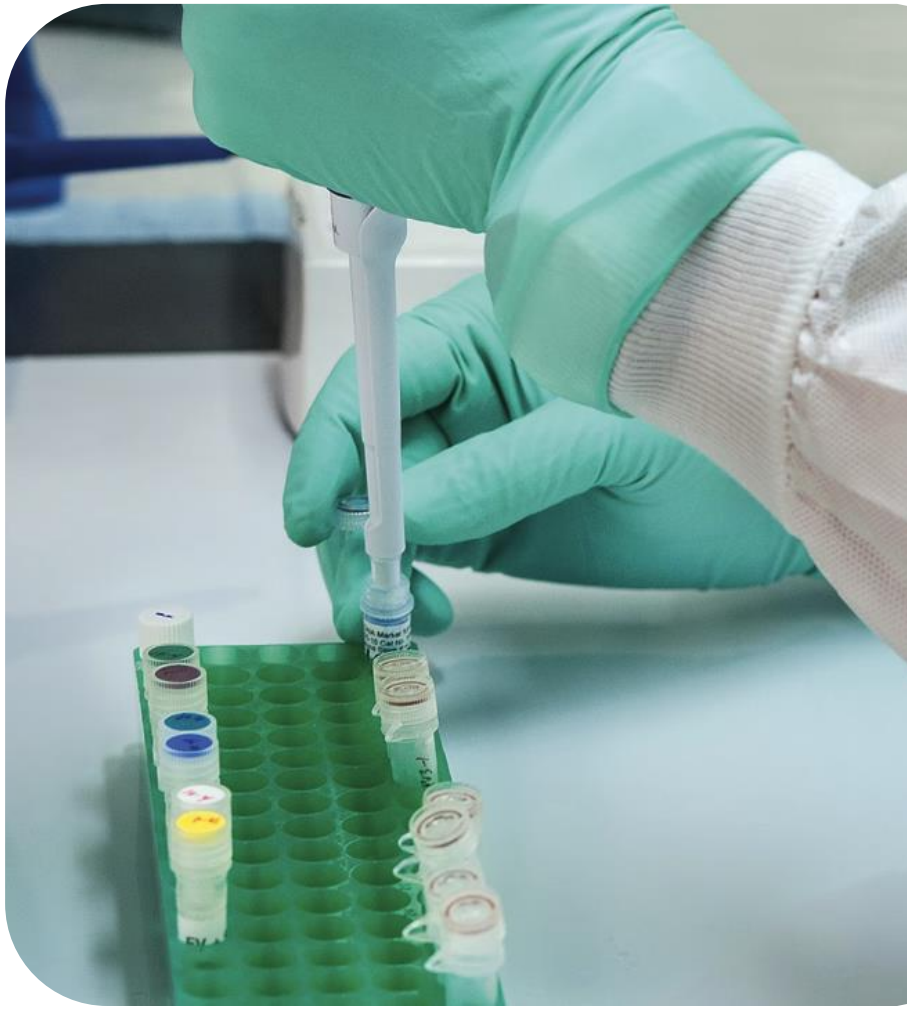
Introducing biosimilar medicines and moving patients between them and the reference medicines can be of benefit to patients, healthcare teams and the healthcare system as a whole, but it has to be handled with care.

Nurse-led programmes often ensure the continuity of information and education before, during and after the change of medication.

Working together and ensuring clear and consistent communication and information at all levels, from management to patients, can result in gains in care quality and costs.



The importance of education

- Beyond the specifics given earlier, we highlight **how critical education is**, first for nurses, and then from nurses (and other sources) to patients.
- Biosimilars offer **incredible advantages in efficacy, cost savings**, and more, but only if they are properly used.
- **Education** makes that happen.

The importance of education

Well done education initiatives are multi-tiered, and require engagement throughout the sector:

Join the discussion!

The main audience for this guide is specialist nurses.

The guide, however, is also important for managers and CEOs in healthcare institutions, to **create awareness** and **communicate 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**.

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