BIOSIMILARS – an information brochure for patients with colorectal cancer

DIGESTIVE CANCERS EUROPE

When colorectal cancer (CRC) has metastasised (cancer cells have spread from the colon into or other organs), a combination of chemotherapy with either **immunotherapy** or **targeted therapy** can be used as a treatment option. Immunotherapy and many types of targeted therapy rely on biologics.

What are biologics?

Biologics are big molecules produced in living cells or organisms. They have a complicated structure and are complex to manufacture.

How are biologics regulated in the European Union?

As with every medicine in Europe, each biologic undergoes rigorous and strict procedures that check and ensure the medicine's safety and efficacy.
In the European Union (EU):

A biologic is developed

A biologic must meet EMA's **regulatory requirements**, by showing that:

- ✓ it is safe for the patient
- ✓ it has the expected beneficial effect

A biologic is granted **market authorisation**

EMA continuously checks and monitors the **safety** and **effectiveness** of biologics

Efficacy: *a term that means that the medicine has the expected beneficial effect under ideal conditions (before it becomes approved)*

Effectiveness: *a term that means that the medicine has the expected effect under real-world conditions (after it becomes approved)*

European Medicines Agency: *the EU body responsible for the evaluation and supervision of all medicinal products*

Market authorisation: *the permission granted to medicinal products to become available in the EU*

Regulatory requirements: *a set of strict procedures that each medicine in Europe must meet before being approved by EMA*

Safety: *a term means that the risk that may arise from the use of the medicine is negligible compared to the therapeutic benefit*

What are biosimilars?

All **innovative** - or **originator** - medicines are **patented**, which means that during a specific period (~15–20 years) no other product with the same active substance can enter the market. When this term of exclusivity rights expires, new products with the same active substance can gain market access. This can only happen when the new products comply with the same strict regulatory requirements imposed by EMA.

In the case of biologics, these new products are known as **biosimilars** to differentiate them from the initial-patented biologics that are known as **originators. The active substance of a biosimilar is essentially the same as the originator's active substance, and the biosimilar matches the originator in terms of safety and efficacy, assessed and approved by EMA.**

Biosimilars and colorectal cancer

The first biosimilar was approved by EMA in 2006, and since then biosimilar production and approval have grown. Currently more than 70 biosimilars have been approved by EMA, and we now have more than 14 years of positive experience with biosimilar use. In 2017, the first biosimilars for patients with lymphoma (rituximab) and breast cancer (trastuzumab) were approved.

For patients with metastatic CRC (mCRC), EMA has approved a biological medicine known as **bevacizumab**, which is indicated for the treatment of mCRC in combination with chemotherapy drugs. In addition to the originator, EMA has approved seven bevacizumab biosimilars to be used for the treatment of patients with mCRC (as of March 2022).

What is the benefit of using a bevacizumab biosimilar?

For a patient, there is no additional treatment benefit or downside to using a (bevacizumab) biosimilar rather than the originator. Both types of products have undergone rigorous testing and comply with the same strict, high-standard safety and efficacy criteria set by EMA (discussed above). However, as with all biosimilars, the availability of bevacizumab biosimilars to European health systems and hospitals offers several advantages for the patient community and society, as they contribute to more **sustainable** and **affordable** healthcare systems.

- funding new, innovative treatments for patients, using released resources to improve patient support programs, hiring additional nurses in the hospital, or investing in new treatment and researchthey offer the opportunity for more patients to have access to biological treatments
- helping reduce the waiting time to be treatedhelping reduce the waiting time to be treated
- more patients to have access to biological treatments

What is switching?

If you have been treated with the originator and your physician proposes to replace the originator with a biosimilar medicine, this is called **switching**. Switching should always be discussed upfront between you and your physician. If you and your physician choose to switch, remember that your treatment will not change. Switching may help you get a better service and access to other treatments and may help more patients have access to biological treatments. Switching does not only refer to a change from an originator to a biosimilar, but also to a change from a biosimilar to another biosimilar, or a biosimilar to the originator.

To sum up

- Biosimilars are biological medicines with the same active ingredient as the originator medicine.
- Biosimilars undergo the same rigorous checks as the originators through EMA, guaranteeing equivalent quality, safety, and efficacy with their originator product.
- Biosimilars offer more patients the possibility of biologic, targeted treatment.
- As always, please contact your physician, nurse or pharmacist if you have any questions or concerns about the suggested treatment or "switch" to a biosimilar medicine.

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