BIOSIMILARS –

A guide for healthcare professionals to address any questions patients with colorectal cancer may have on biosimilars

1. What are biological medicines?

Biological medicines, also called biologics, are big molecules that are produced in living cells or organisms. They have a complicated structure and are complex to manufacture. In digestive cancers, biologics are used as **immunotherapy** and **targeted therapy treatments.**

A biologic with an active substance not previously used to treat any disease is known as an **originator.** Originators are patented, and when the patent expires, usually after some 15–20 years, other new products with the same **active substance** can enter the market. These new products are known as **biosimilars.**

2. What are biosimilars?

A **biosimilar** is a biological medicine that has essentially the same active substance and the same indication as the originator. Biosimilars match their originators in terms of quality, safety and efficacy.

3. Are biosimilars as safe and effective as the original medicines?

Yes! Biosimilars are as **safe** and **effective** as the originators. Biosimilars are assessed by the **European Medicines Agency (EMA)**, the EU body responsible for the evaluation and supervision of medicinal products, are approved if they comply with the same strict regulatory requirements applied to all biological medicines.

4. How is the safety and efficacy of biosimilars ensured?

The EMA monitors the **safety and efficacy** of biosimilars before approval and then continuously. Over the last 15 years, the EU monitoring system for safety concerns has not identified any differences in severity or frequency of treatment-related side effects between biosimilars and originators.

5. Are biosimilars the same as generics?

No. **Generics** have a simple structure and contain exact copies of chemically made active substances. Unlike generics, all biologics, including biosimilars, are made in living cells, so no two batches of any biologic are the same. This is normal and tightly controlled. Both biosimilars and generics are versions of brand-name products with the same efficacy and safety.

6. How long have biosimilars been on the market and how many biosimilars have been approved for colorectal cancer?

EMA has currently approved more than 70 biosimilars (up until September 2021).

When it comes to the treatment of metastatic colorectal cancer (mCRC), EMA initially approved a biologic originator with an active substance called **bevacizumab**. Currently, EMA has approved seven bevacizumab biosimilars (up until September 2021).

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7. What are the benefits of using a (bevacizumab) biosimilar?

There are no additional treatment benefits when using biosimilars compared to the originator. **Both are equally safe and effective.**

Biosimilars have been proven to be advantageous to European health systems, hospitals and ultimately the patient community, as they contribute to more **sustainable and affordable** healthcare systems.

The use of biosimilars offers the opportunity for:

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

8. What are the downsides of biosimilars?

There are no downsides in using biosimilars.

9. What is switching?

A change between two products with the same active substance is called switching. For example, switching occurs if you have been treated with the originator and your physician proposes to replace the originator with a biosimilar. Switching does not result in treatment change. However, as with all medicines, you should discuss and decide with your physician your treatment and choose together the best option for you. Remember you can always ask about anything you do not understand or seems unclear.

10. How is this new treatment different from what I was taking before?

The efficacy of a biosimilar is the same as that of the originator. Your treatment will continue to be the same in terms of **quality, safety and efficacy**. After the switch, your disease progression and treatment efficacy will continue to be monitored as before. As for any biological treatment, you should always report any unexpected side effects.

11. Will I have any additional side effect(s)?

No. Biosimilars and originators cause the same **side effects**, all of which are included in the package insert description. As for any treatment, if you believe you are experiencing any additional side effect(s), you should contact and discuss this with your physician and/or your pharmacist.

Remember:

- ☐ **Use simple language when explaining medical terminology.**
- ☐ **Choose a private and quiet place for the discussion.**
- ☐ **Tailor your messages to the patient and consider specific factors when talking about biosimilars, such as the patient's age or cultural background.**
- ☐ **When describing biosimilars, emphasise that there are no differences compared to originators in terms of quality, safety and efficacy. If the conversation leads to it, outline the benefits biosimilars offer to patients and the healthcare systems.**
- ☐ **Answer questions until the patient begins to understand how the treatment works. Encourage the patient and his/her family to ask additional questions.**
- ☐ **For any further questions, provide the patient with a healthcare professional's updated contact details.**
- ☐ **Provide the patient with reliable and trustworthy information/tools on biosimilars (e.g. DiCE's information brochure for patients with colorectal cancer, Biosimilar Medicines Information for patients document by the European Commission).**

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For further information:
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