ESMO

UNDERSTANDING BIOSIMILARS

For Cancer Patients

This infographic explains what 'biosimilars' are and what kind of opportunities they may bring for cancer patients and their treatment.

Please note that this infographic is only for educational purposes. It does not replace the advice of your doctor.

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What are biosimilar medicines?

Biological medicines are complex medicines made from living organisms such as human and animal cells, yeast or bacteria. Hormones, vaccines, and monoclonal antibodies used in cancer therapies are examples of biological medicines.[1]

Biosimilar medicines are highly similar copies of existing biological medicines (originators) that work in the same way.[2]

Generic medicines are identical copies of simple medicines. Paracetamol and ibuprofen are examples of generic medicines.[2]

You may have heard of generics or biomarkers – these are not biosimilars!

What are the opportunities?

Biosimilars **improve access** to much needed **cancer treatments**[3] by:

Providing additional **treatment options**

Decreasing prices of biological medicines

Creating savings that may be redistributed to continue **financing the healthcare systems**

Even more biosimilars will reach cancer patients as of 2020...

...because more existing biological medicines will **come off patent***.[3]

*Off-patent medicines are no longer subject to intellectual property exclusivity and can potentially be produced by an unlimited number of companies.

Are they safe?

EUROPEAN MEDICINES AGENCY

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Biosimilars are safe and work just as well as originator biological medicines, as they go through a rigorous assessment prior to being approved by healthcare authorities.[4]

The European Union is a pioneer in approving biosimilars. Between April 2006 and October 2018, the European Medicines Agency has approved **47 biosimilars**, including rituximab and trastuzumab.[5]

BIOLOGICS BIOSIMILARS

The authorisation of biosimilars requires an extensive set of preclinical and clinical tests. These tests are aimed to demonstrate there are **no meaningful differences between the biosimilar and the originator** biological medicine.

You may not be aware, but these **minimal differences** already exist among the various batches of the originator biological medicine.[6]

The **label of a biosimilar reflects the label of the originator** product. You and your doctor can find all necessary information about the product, its safety and efficacy on the label.[6]

You should know about...

1 Immune reactions and other side-effects

All biological medicines, as they are made from living organisms, could cause your body to have an immune response, e.g. a high fever. Biosimilars have similar side-effects to their biologic counterparts, except for slight potential differences in immunogenicity (see definition below). Your treating physician will inform you about that. All potential immune responses and other side-effects are **closely studied and analysed** during the approval process for all biological medicines, including biosimilars.[7]

Your nurse and medical staff will closely monitor any immune reactions that might occur during your treatment. As with any other medicine, your role in monitoring your reaction to the medicine is also crucial.

2 Switching

Switching refers to **exchanging a biological medicine with a biosimilar (or vice versa), following your doctor's decision**.

Your doctor should discuss this with you, provide you with all the necessary information and, together with you and the nurse's support, carefully oversee the transition.[8]

Healthcare authorities in your country may decide to automatically substitute your biological medicine with a biosimilar. Your doctor and nurse will be there to discuss it with you and monitor your treatment, as they always do. Don't be afraid to ask for any explanation you may need.

Automatic substitution

Automatic substitution occurs when **one medicine is dispensed instead of another at pharmacy level, without consulting the doctor**.[9]

Until now, this practice is **not recommended** for biological medicines. Currently in the European Union 21 countries forbid automatic substitution at pharmacy level.[10]

3 Indications

As long as a biosimilar has been proven to work as well as the biological medicine, it can be **used for all the indications** listed on the label of the originator, even those it has not been tested for itself (extrapolation).[9]

E.g. biosimilars of the originator trastuzumab, a biological medicine used in breast cancer treatment, can also be used for metastatic and early breast cancer, even if biosimilars have not been clinically tested for these indications. This is because the originator trastuzumab has gone through the whole process of clinical development, and the biosimilar has proven to have the same mechanism of action, safety and efficacy profile as the originator.[10]

Speak to your doctor

Interaction and collaboration between patients, nurses, doctors and other medical staff, are essential elements for the successful use of biosimilars in cancer treatment.

It is your right to be informed about any treatment you receive. If you have any questions or concerns about biosimilars or other treatments, you should ask your doctor.

Frequently used terms you may want to know

Efficacy: Ability of a medicine to produce an effect (e.g. reduce tumor size).[11]

Extrapolation: Extending safety and efficacy data for treatment indications from an originator biological medicine to a biosimilar, where the biosimilar has not undergone comparative clinical testing for this indication (see the section *Indications* above).[9]

Immunogenicity: Ability of a substance (e.g. protein) to cause an immune reaction (see the section *Immune reactions and other side effects* above)[7]

Monoclonal antibodies: Type of proteins made in the laboratory that can bind to substances in your body, including cancer cells. They are being used to treat some types of cancer.[12]

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