INFORMATION FOR PATIENTS 2021
BIOSIMILARS

Biological drugs (biologics) are created in living cells or bacteria and have a complex structure. The development of the drug takes a lot of time and money. For this reason, these reference-drugs (first-mover) receive patent protection of up to 20 years. They are prescribed, for example, for cancer, rheumatism, certain skin diseases, or diseases of the intestines.

A biosimilar is a successor drug to a reference biologic. After the patent expires other manufacturers may also produce this drug. However, they must prove in studies that these are equivalent in terms of efficacy, safety, and quality.

Biosimilars help to ensure that there are no drug shortages and that patients can always be well cared for.

You can only receive a biosimilar after a doctor's prescription.

EQUAL IN EFFICACY AND SAFETY

Biological drugs are produced by living cells or bacteria and are very similar to substances produced by the body. Because of to their complicated structure, natural variations in production are completely normal. This means that biosimilars may differ only minimally from their reference drug, but efficacy and safety must be the same. This also applies to the reference drug, because here too there are minimal, unavoidable differences between each new production process (batch).

HOW WIDESPREAD ARE BIOSIMILARS

In Europe, the first biosimilar was approved in 2006; currently, ~50 biosimilars are available in Austria. These are, for example, blood cell growth factors that are used in the context of chemotherapy or so-called monoclonal antibodies that can be used for cancer or permanently inflammatory diseases, for example of the joints, skin, or intestines. They are usually administered as a pre-filled syringe, a pre-filled pen (with an applicator), or an infusion.

BIOSIMILARS MEET STRINGENT APPROVAL TESTS

Prior to approval by the European Commission, experts from the EMA (European Medicines Agency) examine the efficacy, safety, and quality of a drug very closely in accordance with strict criteria. Carefully conducted studies confirm that the biosimilar is effective and safe. It is only approved if there are no significant differences in a direct comparison with the reference biologic.

Anyone wishing to market a biosimilar must demonstrate in clinical trials that it is just as effective and safe as the original biological drug for a specific disease.

BIOSIMILARS - IMPORTANT FOR PATIENTS, THE MEDICAL PROFESSION, AND THE HEALTHCARE SYSTEM

- Biosimilars provide patients with effective therapy without compromising quality
- More patients can get earlier access to biological therapies
- The Austrian health care system is relieved financially by the considerable savings
- Physicians have more choice of therapy options
- Patients often have access to additional dosage forms of this modern therapy

BIOSIMILARS IN AUSTRIA - ARE THEY SAFE?

Biosimilars have been prescribed in Austria since 2006. They have been shown to behave exactly like the reference drug (benefit/risk ratio). There has not been a single incident in these 15 years that has resulted in a biosimilar having to be withdrawn from the market.

Biosimilarsverband Österreich
Bundesamt für Sicherheit im Gesundheitswesen BASG
ÖSTERREICHISCHE APOTHEKERKAMMER
ÖSTERREICHISCHE ÄRZTEKAMMER

ARE THERE SIDE EFFECTS?

Like any drug, biologics have side effects. The same side effects can occur with a biosimilar as with the reference biologic. That a biosimilar is as safe as its reference drug has been previously tested in clinical trials.

People with certain intolerances or allergies should report them to their healthcare professional so that the other ingredients can also be checked. Inform your medical or pharmacy team of any abnormalities or side effects during the course of treatment and do not discontinue any medication without consulting a doctor.

CAN A PATIENT RECEIVING OR SCHEDULED TO RECEIVE A SPECIFIC BIOLOGIC BE SWITCHED TO OR FROM A BIOSIMILAR?

Yes, a switch is usually safe. There are now many studies showing that there is no impact on efficacy and safety when switching from the reference drug to a biosimilar or immediately switching to the biosimilar. However, it is important that medical professionals closely monitor this treatment.

WHY CAN FOLLOW-ON PRODUCTS BE OFFERED TO HEALTH INSURERS AND HOSPITALS AT A LOWER PRICE THAN THE REFERENCE DRUG?

Biosimilar producers can adopt many scientific findings from the reference drug. This means that not all the clinical studies that the reference drug had to conduct have to be repeated. This makes development for Biosimilars less expensive.
And when they are launched on the market, they have to compete with the reference drug. This healthy competition lowers the price to a reasonable extent.

ARE BIOSIMILARS IMPORTANT FOR THE HEALTHCARE SYSTEM?

Biosimilars are becoming increasingly important to our healthcare system. This is because if a biosimilar is available for an active ingredient, this biosimilar triggers price reductions in the group and this benefits all insured persons. Likewise, if there are multiple suppliers on the market, supply is assured for patients.

CAN BIOSIMILARS IMPROVE QUALITY OF LIFE?

Treatment with a biologic made possible by biosimilars leads to an earlier return to everyday life for many patients and improves their quality of life.

DO YOU STILL HAVE QUESTIONS?

Then write to us at
office@biosimilarsverband.at
or call +43 650 544 92 92.

Austrian Biosimilars Association
C/O Gaisberg Consulting GmbH
Lugeck 4 (entrance Bäckerstraße 1)
1010 Vienna

For more information, please visit
www.biosimilarsverband.at

This patient information is available in different languages. Please scan the QR-Code.

Biosimilarsverband Österreich

Bundesamt für Sicherheit im Gesundheitswesen BASG

ÖSTERREICHISCHE APOTHEKERKAMMER

ÖSTERREICHISCHE ÄRZTEKAMMER

This information for patients was developed in cooperation of the Austrian Biosimilars Association (BiVÖ) with the Austrian Federal Office for Safety in Health Care (BASG), the Austrian Chamber of Pharmacists and the Austrian Medical Association.

Further information: www.biosimilarsverband.at
2021

Sources: Guideline of the Drug Commission of the German Medical Association (AkdÄ); List of Goods, Information for Patients 2020;

10/2021