EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Questions and answers

Questions and answers on biosimilar medicines (similar biological medicinal products)

What is a biological medicine?

A biological medicine is a medicine that contains one or more active substances made by or derived from a biological source. Some of them may be already present in the human body and examples include proteins such as insulin, growth hormone and erythropoietins. The active substances of biological medicines are larger and more complex than those of non-biological medicines. Only living organisms are able to reproduce such complexity. Their complexity as well as the way they are produced may result in a degree of variability in molecules of the same active substance, particularly in different batches of the medicine.

What is a biosimilar medicine?

A biosimilar medicine is a biological medicine that is developed to be similar to an existing biological medicine (the 'reference medicine'). Biosimilars are not the same as generics, which have simpler chemical structures and are considered to be identical to their reference medicines.

The active substance of a biosimilar and its reference medicine is essentially the same biological substance, though there may be minor differences due to their complex nature and production methods. Like the reference medicine, the biosimilar has a degree of natural variability. When approved, its variability and any differences between it and its reference medicine will have been shown not to affect safety or effectiveness.

An authorised biosimilar is generally used at the same dose to treat the same conditions. If there are specific precautions to be considered when taking the reference medicine, the same will generally apply to the biosimilar.

Biosimilars are usually authorised several years after the approval of the reference medicine. This is because the reference medicine benefits from a period of exclusivity, during which biosimilars cannot be authorised.

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A list of all biosimilar medicines authorised centrally in the EU can be found on the EMA website. Information on whether a medicine is a biosimilar medicine can be found in the medicine's summary of product characteristics (SmPC).

How are biosimilar medicines evaluated in the EU?

Because the reference medicine has been authorised in the EU for several years and its clinical benefit is established, some studies carried out with the reference medicine may not need to be reproduced. Since 2003, a new EU pathway for approving biosimilar medicines has been in place. The main part of the evaluation is a comparison of the biosimilar with its reference medicine to show that there are no significant differences between them.

The relevant regulatory authority applies stringent criteria in their evaluation of the studies comparing the quality, safety and effectiveness of the two medicines. The studies on quality include comprehensive comparisons of the structure and biological activity of their active substances, while the studies on safety and effectiveness should show that there are no significant differences in their benefits and risks, including the risk of immune reactions.

Biosimilar medicines are manufactured following the same standards as for other medicines, and regulatory authorities perform periodic inspections of the manufacturing sites.

How is the safety of biosimilar medicines monitored?

As for all medicines, the safety of biosimilar medicines is continuously monitored after authorisation. Each company is required to set up a system to monitor side effects reported with its medicines. Patients can also report suspected side effects themselves. The regulatory authorities evaluate the safety data that is captured as well as the company's safety monitoring system. When signals of a safety concern arise, regulatory authorities investigate and take action as appropriate.

Can a biosimilar medicine and its reference medicine be used interchangeably?

The EMA evaluates biosimilar medicines for authorisation purposes. The Agency's evaluations do not include recommendations on whether a biosimilar should be used interchangeably with its reference medicine. For questions related to switching from one biological medicine to another, patients should speak to their doctor and pharmacist.