



## **Questions and Answers on biosimilar medicines (similar biological medicinal products)**

### **What is a biological medicine?**

A biological medicine is a medicine whose active substance is made by or derived from a living organism. For example, insulin can be produced by a living organism (such as a bacterium or yeast), which has been given the gene that enables it to produce insulin.

### **What is a biosimilar medicine?**

A biosimilar medicine is a medicine which is similar to a biological medicine that has already been authorised (the 'biological reference medicine'). The active substance of a biosimilar medicine is similar to the one of the biological reference medicine. Biosimilar and biological reference medicines are used in general at the same dose to treat the same disease. Since biosimilar and biological reference medicines are similar but not identical, the decision to treat a patient with a reference or a biosimilar medicine should be taken following the opinion of a qualified healthcare professional.

The name, appearance and packaging of a biosimilar medicine differ to those of the biological reference medicine. It may also contain different inactive ingredients. Like for all medicines, where precautions are necessary because of any inactive ingredient, these will be described both on the label and in the package leaflet of the medicine.

### **How is a biosimilar medicine authorised?**

Like all medicines, a biosimilar medicine needs to receive a marketing authorisation before it can be marketed. The marketing authorisation is granted after a regulatory authority, such as the EMA, has conducted a scientific evaluation of the efficacy, safety and quality of the medicine.

Innovative medicines benefit from a period of data protection following the pharmaceutical legislation. After expiry of this period, companies can apply for a marketing authorisation for a biosimilar medicine.

### **How is a biosimilar medicine evaluated?**

As the biological reference medicine has been authorised for several years, there is available information, which does not need to be reproduced. The legislation defines the studies that need to be carried out to show that the biosimilar medicine is similar and as safe and effective as the biological reference medicine.

Due to the complex method of production of biological medicines, the active substance may differ slightly between the biological reference and the biosimilar medicine. Therefore, studies comparing the two medicines have to be carried out. These studies involve a step-by-step process starting with a comparison of the quality and the consistency of the medicinal product and of the manufacturing process. Studies are also conducted to compare the safety and efficacy of the medicines. These studies should demonstrate that there are no meaningful differences between the biosimilar and the biological reference medicines in terms of safety or efficacy. When the biological reference medicine is used to

treat different diseases, the efficacy and safety of the biosimilar medicine may also have to be assessed using specific tests or studies for each disease.

Biosimilar medicines are manufactured following the same quality standards as for all other medicines.

Regulatory authorities also perform periodic inspections of the manufacturing site(s) as for all other medicines.

### **Is the safety of biosimilar medicines monitored?**

The safety of all medicines, including biosimilar medicines, is also monitored after authorisation. Each company marketing a new medicinal product is required to set up a system to monitor the safety of the products that it markets, including any immunological responses to the administration of biological products. The regulatory authorities may also perform an inspection of this system. If there are specific precautions to be considered when taking the reference medicine, the biosimilar medicine will require in general the same safeguards.