

## Biological and biosimilar medicines: What patients should know

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The questions and answers in this document have been edited and approved for NALA's Plain English Mark.



### WHAT IS A BIOLOGICAL MEDICINE?

A **biological medicine** contains an active substance that is produced from a biological source such as living cells. The active substance in a biological medicine is what makes the medicine work. Biological medicines are also called **biologics**.

Here are some biological medicines that you may have heard of:

- The hormone insulin, which is used to treat diabetes;
- Vaccines;
- Monoclonal antibodies, which are a type of protein that can bind to substances in the body. They are used to treat a wide variety of conditions such as cancer or arthritis.

Biological medicines are different to chemical medicines such as paracetamol or aspirin.

Chemical medicines are smaller and less complex than biological medicines. When chemical medicines are made, the active substance is identical in every batch and every brand.

No two batches of biological medicine will be identical, even if they are made by the same manufacturer. There will be some difference between batches due to the biological materials used and the way the medicines are made.

As a result, there are strict limits on how much difference there can be between different batches of the same biological medicine. These limits help manufacturers make sure that the biological medicine is safe and effective.

In Ireland, either the [Health Product Regulatory Authority](#) (HPRA) or the European Commission must approve a new biological medicine before doctors can prescribe it. Medicines approved by the European Commission are first evaluated by the [European Medicines Agency](#) (EMA).

## WHAT IS A BIOSIMILAR MEDICINE?

A **biosimilar medicine** is a biological medicine that is very similar to an original biological medicine. The original biological medicine is called the **reference medicine**. Every new biosimilar medicine must work the same way as the reference medicine.

It is not possible to produce an exact copy of an original biological medicine. The active substance of a biosimilar medicine and its reference medicine is essentially the same biological substance, but there will be small differences between them. This is because the active substance in a biological medicine is complex and varies naturally. Also, every brand of biological medicine is made differently.

Like its reference medicine, the biosimilar medicine will vary slightly from batch to batch. This is carefully controlled and monitored so the biosimilar medicine will be as safe and effective as its reference medicine.

Normally, you will take or be given a biosimilar medicine in the same way as its reference medicine. The dose of the biosimilar medicine will also be the same as the dose of its reference medicine.

In Ireland, either the [HPRA](#) or the European Commission must approve a new biosimilar medicine before doctors can prescribe it. Medicines approved by the European Commission are first evaluated by the [EMA](#).

When a new biological medicine is approved for use, the manufacturer has exclusivity for this medicine. This means that no other manufacturer can make a biosimilar medicine until the period of **exclusivity** ends. In general, exclusivity lasts for at least ten years.

## ARE BIOSIMILAR MEDICINES THE SAME AS GENERIC MEDICINES?

No. A biosimilar medicine is different to a generic medicine.

The term **generic medicine** is used only for chemical medicines such as atorvastatin which is used to lower cholesterol.

The active substance in a generic medicine is an exact copy of the active substance in the original chemical medicine, which is called the **reference medicine**.

The active substance in a biosimilar medicine is a biological molecule made using biological material such as living cells.

It is not possible to make an exact copy of the active substance in a reference biological medicine. This is because the active substance in a biological medicine is complex and varies naturally. Also, every brand of biological medicine is made differently.

### **IS A BIOSIMILAR MEDICINE AS EFFECTIVE AS THE REFERENCE BIOLOGICAL MEDICINE?**

Yes. A biosimilar medicine is tested to make sure it is as effective as the reference biological medicine.

### **IS A BIOSIMILAR MEDICINE AS SAFE AS THE REFERENCE BIOLOGICAL MEDICINE?**

Yes. A biosimilar medicine is tested to make sure it is as safe as the reference biological medicine.

A biosimilar medicine should not have more side effects than its reference medicine.

All medicines can have side effects. If you have any questions about side effects, talk to your doctor, nurse specialist or pharmacist.

### **IS A BIOSIMILAR MEDICINE THE SAME QUALITY AS THE REFERENCE BIOLOGICAL MEDICINE?**

Yes. A biosimilar medicine must meet the same quality standards as the reference medicine.

### **HOW ARE BIOSIMILAR MEDICINES APPROVED FOR USE?**

In Ireland, biosimilar medicines are approved by the [HPRA](#) or the European Commission. Medicines approved by the European Commission are first evaluated by the [EMA](#).

During the approval process, the biosimilar medicine is compared to the reference medicine. This comparison makes sure that there are **no clinically meaningful differences** between the biosimilar medicine and the reference medicine. The

biosimilar medicine must treat the same symptoms in the same way. The biosimilar medicine will have the same possible side effects as the reference medicine.

The HPRA and EMA are very strict when they evaluate studies on biosimilar medicines.

The biosimilar medicine must meet the same high quality standards as the reference medicine. Studies on quality compare the structure and biological activity of the active substances in great detail.

The biosimilar medicine must be as safe and effective as the reference medicine. Studies compare how effective the biosimilar medicine and the reference medicine are when treating specific diseases. The results must show that there are no significant differences in the benefits and risks of the two medicines, including the risk of immune reactions such as allergies.

When a biosimilar medicine is tested, the reference medicine has been in use in the EU for some time, and it has proven to be safe and effective during this time. Some of the information from the original studies on the reference medicine may be used for the biosimilar medicine. This means these studies may not have to be done again, which may mean the biosimilar medicine has a lower price than the reference medicine.

### **HOW DO I KNOW IF I HAVE BEEN PRESCRIBED A BIOSIMILAR MEDICINE?**

A list of biosimilar medicines approved by the European Commission are available on the EMA website. Click on the name of each biosimilar medicine on the [EMA website](#) to learn more.

If you have any questions, talk to your doctor, nurse specialist or pharmacist.

### **ARE THERE BENEFITS TO BEING PRESCRIBED A BIOSIMILAR MEDICINE?**

Yes. Biological medicines have changed and improved the treatment of many serious diseases such as cancer. But biological medicines are usually very expensive.

Biosimilar medicines encourage competition and may reduce the cost of biological medicines. This means that healthcare systems such as the HSE can save money and be more efficient. Reducing the cost of biological medicines can help free up resources for other important areas of healthcare.

## WHO DECIDES WHETHER I RECEIVE THE REFERENCE MEDICINE OR A BIOSIMILAR MEDICINE?

Your doctor will talk to you about what medicine you should take.

If you are getting a medicine for the first time, your doctor may prescribe the reference medicine or a biosimilar medicine if one is available.

After you start treatment for a disease or condition, your doctor might suggest changing your medicine. For example you might change from the reference medicine to a biosimilar one, or you might change from a biosimilar medicine to the reference medicine.

Changing your medicine in this way should not change your treatment results. If you have any questions, talk to your doctor, nurse specialist or pharmacist.

## WHAT DO I NEED TO KNOW ABOUT THE BIOLOGICAL MEDICINE I TAKE?

You need to know the **brand name** of your medicine. This is very important! Biological medicines with different brand names are not identical, even when the name of the active substance is the same. Knowing the brand name means that you can report side effects for the correct medicine. It also means that your medicine will not be changed to a different brand by mistake.

Your medicine comes with a patient information leaflet. You should read this leaflet. It contains important information for you. If you have any questions, talk to your doctor, nurse specialist or pharmacist.

## CAN A PHARMACIST CHANGE THE BRAND OF BIOLOGICAL MEDICINE I TAKE?

No. In Ireland, you must have a prescription from your doctor to change from the reference medicine to a biosimilar medicine. A pharmacist cannot decide to give you a biosimilar medicine instead of the reference medicine unless they agree this with your doctor.

## HOW DO I REPORT A SIDE EFFECT OF A BIOLOGICAL MEDICINE?

If you think you have a side effect from your medicine, report it to your doctor, pharmacist or nurse.

You can also [report side effects directly to the HPRA](#).

When you report a side effect, try to include the brand name and batch number of the medicine, if you know them. The batch number will be on the medicines box. This helps match the report to the correct medicine.

### **WHERE CAN I FIND MORE INFORMATION ABOUT BIOLOGICAL AND BIOSIMILAR MEDICINES?**

The HPRA has published a detailed [Guide to Biosimilars for Healthcare Professionals and Patients](#).

The European Commission has published a [Q&A for patients](#). You can also find more information about the regulation of biosimilar medicines on the [EMA website](#).