PATIENT INFORMATION SHEET

Biological and biosimilar medicines

Biological medicines

Biological medicines are a type of medicines that are made from living organisms, such as a yeast, bacteria or animal cell. Biological medicines are an important part of modern health care. They include familiar products like vaccines and insulin to treat diabetes. Biological medicines are used to treat conditions such as: cancer, arthritis and auto-immune disorders.

What is different about biological medicines?

Biological medicines tend to be large, complex molecules. They cannot be made by a chemical process (like most medicines) but need to be made from a living organism.

Because biological medicines are made from living organisms, they vary naturally. This creates small differences between batches of the same biological medicine.

There are limits set on these differences to make sure they do not change the medicine's safety or effectiveness.

Patients taking biological medicines often require careful monitoring

All medicines have the potential to cause adverse reactions. However, biological medicines are more likely to cause an allergic-type reaction because they are larger molecules.

People on biological medicines need to be monitored carefully for these types of reactions.

Biosimilar medicines

A biosimilar medicine is a very similar version of a biological medicine (usually called the reference medicine). Small differences occur because the molecules in these medicines are large, complex, and from living organisms. These differences are similar to the differences that can occur between batches of a reference biological medicine.

Despite these small differences, biosimilar medicines are expected to be as safe and effective as the reference biological medicine.

Biosimilars are usually made by a different pharmaceutical company and have a different 'brand name' to the reference medicine. A biosimilar medicine can only be marketed once the patent on the reference biological medicine has expired.

How do we know the biosimilar medicine works?

Biosimilar medicines must undergo extensive quality and clinical testing to show they are as safe and effective as the original. However, they don't have to go through quite as many trials as the original.

Biosimilar medicines are manufactured following strict quality requirements, using state-of-the-art methods. Every facility making medicines is audited to ensure it's following Good Manufacturing Practice.

The value of biosimilar medicines

Biosimilar medicines help PHARMAC give patients better access to important treatments. Biosimilars reduce costs for the New Zealand health care system in two main ways:

- They cost less to make than the reference medicine because they don't need as many clinical studies. They build on the existing scientific knowledge of the medicine.
- They compete with the reference medicine. This can help to push down the price of the medicine.

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Medsafe approves biosimilar medicines

Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, approves all medicines used in New Zealand.

To ensure the biosimilar works and is safe, Medsafe examines:

- the information about the quality of the biosimilar
- evidence of how the biosimilar was developed
- how patients have responded to the biosimilar

All data the company provides about safety and effectiveness must meet international standards.

Biosimilar medicines are global

Biosimilar medicines have been widely used overseas since 2006. In New Zealand, biosimilar medicines have been funded by PHARMAC since 2012.

Over this time, both local and international clinical experience has shown that biosimilar medicines are safe and effective.

Who to contact

Your health care team is a great place to ask for information on your medicine. Talk to your doctor, nurse or pharmacist. Check out the Health Navigator website for New Zealand specific information about medicine at **www.healthnavigator.org.nz**

Commonly asked questions

How are biological medicines different to other medicines?

The way a biological medicine is made is different from other medicines. Most medicines are made using a chemical process, whereas a biological medicine is made from a living organism.

When a medicine is made using a chemical process it turns out exactly the same every time, this is because a chemical process can be tightly controlled to produce identical results.

However, since biological medicines are made from living organisms they can vary. This is like leaves on a tree; no two leaves on a tree are exactly the same despite them being produced in the same conditions by the same organism.

Most biological medicines have undergone many manufacturing changes over time, often causing slight variation to the medicine. This means that the biological medicine someone takes today is not identical to the medicine that was used in clinical trials and approved years ago. However, these small differences in the medicine are tightly controlled to ensure they do not change the safety or effectiveness of the medicine.

What is a biosimilar medicine?

A biosimilar medicine is a highly similar version of a reference biological medicine. Biosimilar medicines undergo clinical trials to demonstrate that they have similar safety, quality and efficacy to a reference biological medicine.

They are usually manufactured by a different pharmaceutical company and have a different 'brand name' to the reference biological medicine. A biosimilar medicine can only be marketed once the patent on the reference biological medicine has expired.

Do biosimilar medicines work the same as the original medicine?

Yes. To be approved by regulators such as Medsafe, a biosimilar medicine must have demonstrated comparable quality, safety and efficacy to an approved biological medicine.

Are biosimilar medicines available in New Zealand?

Yes. The first funded biosimilar medicine was introduced in New Zealand in 2012 – biosimilar filgrastim, a medicine used to boost white blood cell counts in patients receiving chemotherapy for cancer. In 2014 PHARMAC also funded a biosimilar somatropin, a human growth hormone.

Why are biosimilar medicines important?

Some biological medicines are very expensive and can cost more than $50,000 per patient per year. In New Zealand, biosimilar medicines increase competition which can reduce costs and improve access for patients to these medicines.

What are the regulatory approval processes biosimilars go through?

In order to be approved by regulators, biosimilar medicines must undergo extensive testing and quality assurance steps. Clinical trials are conducted with all biosimilar medicines to demonstrate that they have comparable safety and effectiveness to an approved biological medicine.

This must be done before they are approved by regulators like Medsafe in New Zealand. One of the purposes of these clinical trials is to rule out any clinically meaningful differences between a biosimilar and the original biological medicine.

Where can I find out more about my biosimilar medicine?

Ask your health care team, your doctor, nurse or pharmacist, if you want more information on your medicine. There are also some great websites providing New Zealand specific information about medicine such as Health Navigator at **www.healthnavigator.org.nz**.