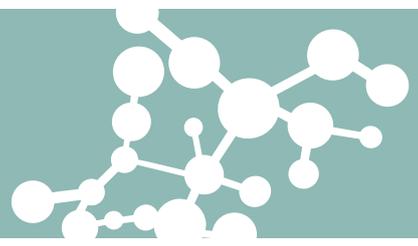


# Biologics and biosimilars



**Biologics are a relatively new form of medicines that are increasingly being used. They include products like vaccines, insulin to treat diabetes, hormones such as human growth hormone, and many modern medicines used to treat cancer, arthritis and other auto-immune disorders.**

Unlike most traditional medicines that are made through chemical processes, biologic products are made of, or from, living things like yeasts, bacteria or animal cells. They usually have a more complex structure than other medicines.

Biologics are being used more and more around the world. While global spending on all medicines grew 24 percent from 2007-2012, spending on biologics grew 367 percent over the same period. Currently approximately US\$170 billion is spent on biologics worldwide, and this is forecast to grow to approximately US\$220 billion by 2017.

In New Zealand, expenditure on biologic medicines has increased 48 percent over the last five years. By comparison total expenditure on other medicines decreased 5 percent over the same period. The class of biologic medicines called 'monoclonal antibodies' accounts for around \$150 million per annum, mostly for treating cancer, arthritis and related disorders. These medicines account for approximately 10 percent of all the spending on medicines in NZ for less than one percent of prescriptions funded.

The rapid growth in spending on biologic medicines is unsustainable. PHARMAC, and health care providers worldwide, must work to reduce these costs in order to maintain existing services and provide new pharmaceuticals to patients.

## Biosimilars

If you want to replicate a traditional chemical medicine you produce a generic – an expert copy made by companies that didn't develop the original medicine themselves. You can't make an exact copy of a biologic medicine because they are made from living things and there is natural variability in all living things, just like two apples are never exactly alike.

The generic equivalents of biologics are called 'biosimilars'. A biosimilar is a highly similar, comparable version of an approved biologic medicine. New biosimilar medicines undergo clinical trials to demonstrate that they work just as well as the approved biologic medicine.

Biologic medicines are often very expensive due to the lack of competition. Biosimilars will help PHARMAC to increase competition which will reduce costs, improve access for patients to these important medicines, and provide access to other medicines.

Biosimilars have been available for many years and are used extensively overseas. Countries with a high acceptance of biosimilars include Austria, Germany, UK and Sweden.

Australia and New Zealand regulators have approved a number of biosimilar medicines. From 2012 PHARMAC funded a biosimilar form of filgrastim, a medicine used to treat low white blood cell count in people going through chemotherapy treatment, and in 2014 PHARMAC funded a biosimilar somatropin, a human growth hormone.

EXPENDITURE ON BIOLOGIC MEDICINES HAS INCREASED **48%** OVER THE LAST FIVE YEARS



# Questions and answers

## How are biologics different to other medicines?

The process of making biologic medicines can be quite complex and involves processes like brewing, extracting proteins from cells and formulating them into medicines.

Because they are made of or from living things biologic medicines are naturally variable. Even small changes in a manufacturing process have the potential to produce differences in the final medicine. There can even be variability between different batches of the same biologic medicine. Most biologic medicines have undergone many manufacturing changes over time meaning that the biologic medicine someone takes today is not identical to the medicine that was used in clinical trials and approved years ago.

## What is a biosimilar?

Because biologic medicines are made in living things like yeasts, bacteria or animal cells which are naturally variability exact copies of biologic medicines cannot be made.

Competitor products of biologic medicines are known as biosimilars, which can be marketed once the patent on the original biologic medicine has expired.

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

## Do biosimilars 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 biologic medicine.

## Are biosimilars available in New Zealand?

Yes, the first funded biosimilar was introduced in New Zealand in 2012 – biosimilar filgrastim (Zarzio, Sandoz), a medicine used to boost white blood cell counts in patients receiving chemotherapy for cancer. In 2014 PHARMAC also funded a biosimilar brand of somatropin, a human growth hormone; and has run commercial processes for other off patent biologics for which biosimilars have been developed including infliximab, a monoclonal antibody medicine to treat auto-immune disorders like rheumatoid arthritis and inflammatory bowel disease.

## Why are biosimilars important?

Some biologic medicines are very expensive, costing \$50,000 per patient per year, or more. In New Zealand, biosimilars offer considerable potential for PHARMAC to increase competition, reduce costs and improve access for patients to these, and other, medicines.

## Do biosimilars go through the same assessment process as other medicines?

Yes. 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 biologic 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 biologic medicine.

Biosimilars are made in facilities that use state of the art technology which undergo stringent auditing and certification processes to ensure products are made to a high, internationally-accepted standard. In fact, many biosimilars are made using the same facilities that are used to manufacture innovator biologic medicines.

## Contacting Us

Call us on 0800 66 00 50  
(between 9am and 5pm, Monday to Friday),

Write to us at:

PHARMAC, PO Box 10 254, Wellington

Email us at [enquiry@pharmac.govt.nz](mailto:enquiry@pharmac.govt.nz)

[www.pharmac.govt.nz](http://www.pharmac.govt.nz)

