# Biosimilars

**This Infosheet explains what biosimilars are, what risks and benefits are associated with them and how they might be used in the treatment of myeloma.**

## What are biosimilars?

Most drugs developed by pharmaceutical companies are made using chemical processes. Chemicals are responsible for making these drugs work. Biological drugs are developed using living cells (bacteria, fungi, plant or animal) and involve a much more complex manufacturing process than chemical drugs. Biological substances, such as proteins, make biological drugs work.

Once the patent – the legal protection preventing others from copying a drug – has expired, that drug can legally be copied and sold by other companies. The process of producing an identical copy of a chemical drug, such as aspirin, is relatively straightforward. These copy drugs are called 'generic' drugs.

For biological drugs, the process is more complex; so much so that it is impossible to produce an identical copy of an original biological drug. Therefore, copies of biological drugs are known as 'biosimilars' rather than generics.

## How does a biosimilar drug differ from a generic drug?

A generic drug contains a chemical or active ingredient identical to the one found in the original (chemical) drug.

Generic drugs therefore work in an identical way to the original drug, producing the same benefits and side-effects. It is fairly easy to produce generic drugs and today there are many generic versions of pharmaceutical drugs available, usually at a much lower cost than the originals.

As generic drugs are relatively simple to manufacture and are 100% identical, they are considered to be interchangeable from the point of view of the regulators and the doctors prescribing them.

Biosimilar drugs are different. Due to the complexity of biological drugs and the fact that they are derived from living organisms, biosimilars cannot be identical to the original biological drug. There may be subtle differences between the biosimilar and original biological drug, which may impact on their comparative effectiveness and safety profiles. These differences may not be fully apparent until their use has been better established.

This difference means that biosimilars are licensed, monitored for safety and approved for use on the NHS in a different way from generic drugs.

## Are biosimilars safe and effective?

All drugs are subject to thorough checks and testing before they are authorised for use. This applies to chemical, generic, biological and biosimilar drugs.

In Europe, for most biosimilars, it is the role of the European Medicines Agency (EMA) to assess the safety and how well it works in patients of each drug before deciding whether it can be licensed for use. In the UK, there may also be additional approvals required from national bodies such as the National Institute for Health and Care Excellence (NICE) before the drug is routinely given to patients on the NHS.

Before a generic drug is approved for use it needs to be shown that it works in exactly the same way as the original pharmaceutical drug. This is a relatively straightforward process, and many of the tests and studies used to assess the original drug do not need to be reproduced for the generic version.

However, due to the complex processes involved in producing biological drugs and the possibility that there are small differences between the original and the biosimilar, biosimilar drugs are subject to a more rigorous and lengthy assessment by the EMA. Most importantly, biosimilar have to demonstrate that they are 'highly similar' in terms of safety and effectiveness to the original biological drug.

The number of clinical trials required before the EMA will consider approving a biosimilar drug varies. Additionally, because biosimilars are not a copy of the original drug, a safety monitoring programme is required to be put in place after the biosimilar drug first becomes available to safeguard patient safety.

The effectiveness and safety of the biosimilar drug will be compared to that of the original drug. It is also sometimes a requirement for effectiveness data to be collected after the drug has been licensed, but the extent of this collection is determined on a case by case basis.

## Are there potential risks to patients in using biosimilar drugs?

Like all newly approved drugs, biosimilars can occasionally produce unpredictable side-effects. It is therefore very important that the safety of all drugs, including biosimilars, continues to be monitored after they have been authorised for use.

Due to the potential for differences between the original biological drug and the biosimilar, the long-term safety of biosimilars is less predictable than for generic drugs.

Importantly, this means that automatic substitution between an original and biosimilar drug without your doctor's knowledge is forbidden. This measure aims to increase patient safety as it means that your doctor is always aware of exactly which drug you are taking to ensure that any potential side-effects are appropriately recorded and properly managed.

## Why are biosimilars considered/ approved for use?

As the research and development of a biosimilar drug is often quicker and less complex than for the original biological drug, they generally cost less to develop. This means that biosimilar drugs are likely to be more competitively priced than the original drug. By bringing competition into the drug market, biosimilar drugs have the potential to offer cost savings to the NHS.

## Which biosimilars are used for myeloma in the UK?

There are five biosimilars licensed for use in myeloma in the UK. These are summarised in Table 1. This means that these drugs have been shown in trials to be safe and effective in treating anaemia and neutropenia in myeloma patients.

## Future directions

Biosimilars are relatively new compared to generics. The first biosimilar drug was only approved for use in Europe in 2006. It is likely that there will be more biosimilar drugs that gain approval for use in Europe and the UK in the future as the patents on other biological drugs expire.

## About this Infosheet

The information in this Infosheet is not meant to replace the advice of your medical team. They are the people to ask if you have questions about your individual situation. All Myeloma UK publications are extensively reviewed by patients and healthcare professionals prior to publication.

**Table 1: Summary of the biosimilar drugs available in the UK for the treatment of myeloma, anaemia and neutropenia**

| Biosimilar drug | Original drug | Active ingredient | What is the drug used for? |
|---|---|---|---|
| **Binocrit®** | Eprex® | Epoetin alpha | Treatment of anaemia |
| **Retacrit®** | Eprex® | Epoetin zeta | Treatment of anaemia |
| ***Eporatio®** | Eprex® | Epoetin theta | Treatment of anaemia |
| **Ratiograstim®** | Neupogen® | Filgrastim | Treatment of neutropenia<br>Mobilisation of peripheral blood progenitor cells for autologous infusion |
| **Zarzio®** | Neupogen® | Filgrastim | Treatment of neutropenia<br>Mobilisation of peripheral blood progenitor cells for autologous infusion |

## Other information available from Myeloma UK

Myeloma UK has a range of Essential Guides, Infoguides and Infosheets available covering many areas of myeloma, its treatment and management.

To order your free copies or to talk to one of our Myeloma Information Specialists about any aspect of myeloma, call the **Myeloma Infoline: 0800 980 3332** or **1800 937 773** from Ireland.

The Myeloma Infoline is open from Monday to Friday, 9am to 5pm and is free to phone from anywhere in the UK and Ireland. From outside the UK and Ireland, call **0131 557 9988** (charged at normal rate).

Information and support about myeloma is also available around the clock at **www.myeloma.org.uk**

# Notes

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