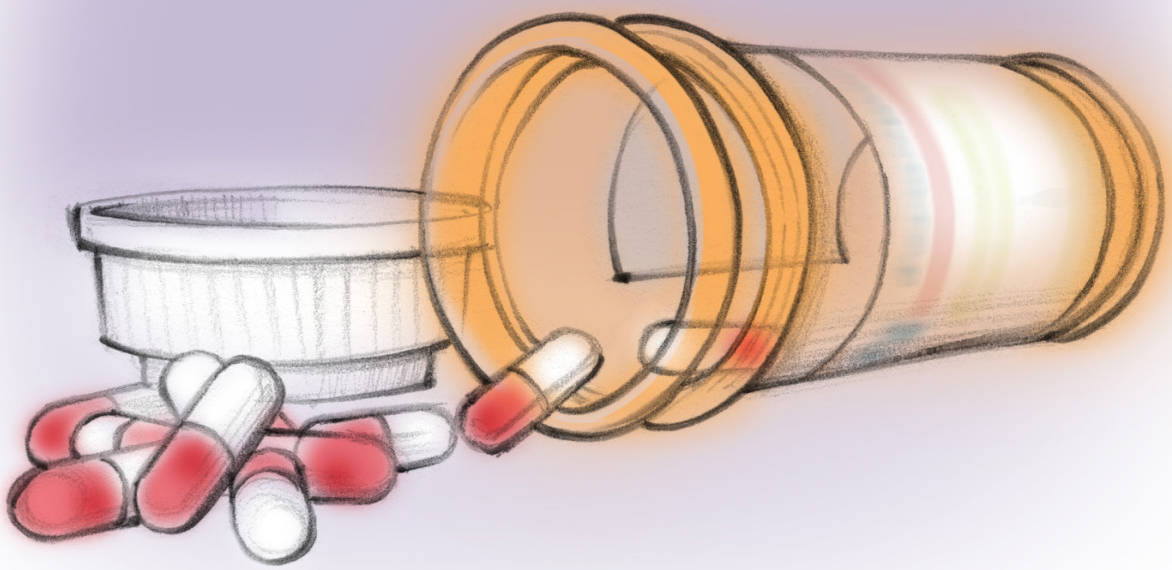
What is a Biosimilar?



Leukaemia Care
YOUR Blood Cancer Charity

What is a biosimilar?

What is a biological medicine?

People often think of medicines as chemicals, but many medicines are made by living organisms, such as cells in a laboratory or from bacteria. Biological medicines are those whose active substance (i.e. the drug) comes from these biological sources.

What is a biosimilar?

When pharmaceutical companies create a new medicine, they obtain a patent, which gives them a period of market exclusivity. This means that only their company can make and market their drug for a set period of time. This allows them to recoup the costs of developing that drug and because companies know their patent will eventually expire, they reinvest some of the profits into developing new treatments.

After the patent expires, biosimilar medicines can be made by other companies.

The European Medicines Agency defines a biosimilar medicine as "a biological medicine highly similar to another already approved biological medicine (the 'reference medicine')". Often several different biosimilars will become available, which usually leads to lower prices for the NHS.

What is the difference between biosimilars and generics?

For those who have read our advocacy toolkit 'Generic Medicines – What are your rights?', this may all seem very familiar.

Biosimilars are the biological medicine equivalent of generics. However, whilst generics require the active substance to be 'identical' to the original drug, biosimilars only require the active substance of molecule to be 'highly similar'. This is because, generics usually involve small molecules and biosimilars involve complex biological molecules from living cells, which make the molecules much harder to reproduce identically.

Biosimilars – similar but not the same?

Because biosimilars only have to be 'similar' to the reference product, there may be small variations between the biosimilar product and the reference medicine. The European

Medicines Agency describes this as "natural variability inherent to all biological medicines". However, this is also the case for different 'batches' of the biologic reference medicine.

One possible way to think of biological medicines is like wine. Whilst they are all made to the same 'recipe', because they involve biological sources, different vintages will be slightly different from each other, within an agreed set of limits.

How are they regulated?

The European Medicines Agency are responsible for evaluating biological medicines, including biosimilars. They require manufacturers to undertake 'comparability studies' to show the biosimilar is comparable to the reference medicine. This ensures they are "highly similar" and there are "no clinically meaningful differences" between them in terms of "safety, quality and efficacy".

Once approved, the biosimilar medicine can be used in all the same indications as the reference medicine. In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) recommends that all biological medicines are prescribed by brand name. This includes biosimilars, so it should be clear to you which version of a drug is being used.

Case Study – rituximab

An example of a biological medicine used to treat leukaemia, is rituximab. Rituximab is marketed by Roche under the brand name Mabthera in the UK.

In February 2017, the EMA approved the first biosimilar version of rituximab for use (Truxima, marketed by Napp). Whilst other biosimilars have been approved over the last few years, this was the first cancer indication approved for a biosimilar in Europe.

It should be clear which version of rituximab is being used. If you're not sure, or have any questions, ask your medical team.

Where can I find out more?

NHS England have produced a 'What is a Biosimilar Medicine?' document:

https://www.england.nhs.uk/wp-content/uploads/2015/09/biosimilar-guide.pdf

The EMA have produced a guide on biosimilar use for patients within the European Union:

http://ec.europa.eu/docsroom/documents/26643

Further questions:

If you have any further questions

about biosimilars then you can contact our Campaigns and Advocacy team.

They are available Monday to Friday from 9:00am – 5:30pm. If you would like to speak to them, you can:

- Call our office line on 01905 755977
- Send them an email at advocacy@leukaemiacare.org.uk

You can also call our helpline, free of charge on 08088 010 444. The team will pass your enquiry onto the Campaigns and Advocacy team.

Please note that our Campaigns and Advocacy team are unable to provide:

- Detailed medical advice or recommendations
- Legal advice
- Advocacy for a course of action which is contrary to the aims and objectives of Leukaemia Care