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Biosimilars for lymphoma

This page is about biosimilars of biological medicines for lymphoma.

On this page

We have separate information about the topics in **bold font**. Please get in touch if you'd like to request copies or if you would like further information about any aspect of lymphoma. Phone 0808 808 5555 or email **information@lymphoma-action.org.uk**.

What is a biosimilar?

Developing medicines is very expensive. When a company **develops a new medicine**, they patent it so that other companies cannot copy it for a certain amount of time. This gives the company a chance to earn back the development cost.

After the patent protection runs out, other companies are allowed to make copies of the original medicine.

Most medicines are made by chemical processes in a laboratory. Drug companies are able to make exact copies of these types of medicine. These copies are called 'generic' medicines. There are generic versions of lots of chemical medicines (for example, ibuprofen).

Biological medicines are more complex medicines that are made using living sources (such as cells). Because manufacturing biological medicines involves

living processes, they are much harder to copy. Even within the original brand of a biological medicine, there are slight differences between batches.

A biosimilar is a medicine that is developed to be highly similar to an existing biological medicine. Biosimilars might vary slightly from the original brand of medicine, but they work in the same way and they are equally as effective.

If your **treatment for lymphoma** includes a biological medicine, such as **rituximab**, you might be treated with the original brand of medicine or you might be treated with a different brand – a biosimilar.

Why are biosimilars important?

Copying a successful medicine is much quicker than developing a new medicine. The original medicine has already been scientifically proven to work, so fewer clinical trials are needed for a biosimilar. As a result, biosimilars are usually less expensive than the original medicine even though the quality of the medicines is the same. The availability of biosimilars also increases competition between drug companies, which should drive costs down further.

How are biosimilars tested and approved?

A biosimilar goes through extensive tests in a laboratory and in small **clinical trials** to compare it with the original medicine. It has to match in quality, safety and efficacy (how well it works).

Then a large clinical trial is carried out in a group of people with a disease that the original medicine is used for. This is to confirm that the safety and efficacy of the biosimilar match the original medicine.

A biosimilar must be proven to match the original medicine, and to work as well as the original in one disease that the original medicine is approved to treat. It does not have to be tested in every disease that the original branded medicine is approved for. Instead, the manufacturer can refer to the evidence already available from the original medicine.

Once testing is complete, the manufacturing company submits the results to the **European Medicines Agency** (EMA). The EMA looks at the evidence and decides whether to recommend that the biosimilar medicine is approved

for use in Europe. If so, it is then approved in the UK by the **Medicines and Healthcare products Regulatory Agency** (MHRA).

During the transition period of the UK's withdrawal from the EU, the UK is following the EMA's approval process. At the time of writing, it is not clear how the approval process will be affected when the transition period ends on 31st December 2020.-

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Are biosimilars available on the NHS?

In most cases, if the original biological medicine is available on the NHS, any biosimilar that is approved by the EMA and MHRA will also be available on the NHS.

Biosimilars used to treat lymphoma

At the time of writing, the only biosimilar medicines approved to treat lymphoma are **rituximab** biosimilars.

Rituximab is a biological medicine that is widely used to treat people with **non-Hodgkin lymphomas** that develop from **B lymphocytes** (B cells). It is used on its own or with other medicines to treat lymphoma. The original brand of rituximab is called MabThera. Rituximab biosimilars include Truxima and Rixathon. Other brands might become available.

Rituximab biosimilars that are given through a drip into a vein (intravenously) have been available in Europe since 2017. Different brands of rituximab have different trade names. They have all been tested to make sure they match the original brand in quality, safety and efficacy.

At the time of writing, only the original brand of **subcutaneous rituximab** (given by injection under the skin) is available.

Frequently asked questions about biosimilars

Talk to your medical team if you have a question about biosimilars that isn't answered here or if you are worried about switching to a biosimilar.

What brand of rituximab will I have?

The brand of rituximab you have depends on which brand your hospital stocks. This in turn depends on what arrangements they have with the

manufacturing companies. They are likely to choose the most cost-effective option.

Brands of rituximab that are available include MabThera (the original brand), Truxima (a biosimilar) and Rixathon (a biosimilar). All brands of rituximab are equally effective at treating lymphoma.

Your medical team can give you more information about your brand of rituximab, including the patient information leaflet.

Will I be switched from the original brand to a biosimilar?

If you are being treated with a biological medicine, your doctor should prescribe you with a named brand. You can't be switched to a different brand (a biosimilar) unless your doctor changes your prescription.

If your doctor plans to switch your brand of medicine, they should discuss this with you. This might happen if, for example, a new biosimilar becomes available, or if your hospital or pharmacy decides to change the brand of biological medicine they stock. Since biosimilars work in the same way as the original biological medicine, you should not notice any difference in the effects the new brand of medicine has on you.

Your medical team should be able to answer any questions you may have about switching brands.

What should I do if I have any problems?

You are monitored in exactly the same way regardless of which brand of medicine you have. If you experience problems with any treatment, report these promptly to your medical team.

Find out about biosimilars (unbranded versions of biological medicines): what they are, how they're tested and why they're used.

Further reading

- **Antibody therapy**
- **Rituximab**
- **Targeted drugs**
- **Drug development**
- **Glossary**

Further information and support

If you would like further information or would like to talk about any aspect of your lymphoma, please contact us.

European Medicines Agency

The European Medicines Agency (EMA) is responsible for monitoring the safety of medicines in the EU.

Medicines and Healthcare Products Regulatory Agency

The Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines in the UK.

References

The full list of references for this page is available on our website. Alternatively, email **publications@lymphoma-action.org.uk** or call 01296 619409 if you would like a copy.

Acknowledgements

- With thanks to Dr Shivir Moosai, Haematology Registrar, West Midlands.
- We would also like to thank the members of our Reader Panel who gave their time to review this information.
- This information was developed in conjunction with the Cancer Vanguard (http://cancervanguard.nhs.uk).

Content last reviewed: July 2020
Next planned review: July 2023
LYMweb0222Biosimilars2020v2

✓	Evidence-based
✓	Approved by experts
✓	Reviewed by users

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