

Biosimilars for lymphoma

This information is about medicines developed to be very similar to existing licensed biological medicines for lymphoma.

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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). This means that 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 medicine 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?

The Medicines and Health products Regulatory Agency (MHRA) is the UK's medicine regulator responsible for the licensing of medicines. There is an extensive testing process before a biosimilar is approved for use.

A detailed head-to-head comparison of the new product with the original medicine is needed to show that there are no clinically significant differences between them. The new product needs to match in terms of quality, safety (including potential side effects) and efficacy (how well it works). If this is shown by the tests, then the MRHA can authorise the new product as a biosimilar. This means that it can be used as an equivalent treatment for all conditions the original medicine is licensed for.

In most cases, if the original biological medicine is available on the NHS, any biosimilar that is approved by the 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 B-cell **non-Hodgkin lymphomas**. The original brand of rituximab is called MabThera®.

Rituximab biosimilars that are given through a drip into a vein (intravenously) have been available since 2017. Rituximab biosimilars that are currently available include Rixathon, Ruxience and Truxima. 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 rituximab (MabThera®) is available to be given by injection under the skin (subcutaneously).

Switching to a biosimilar

The brand of rituximab you have depends on which brand your hospital stocks. This depends on what arrangements they have with the manufacturing companies. They are likely to choose the most cost-effective option.

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.

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.

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.

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