

Resource

## Latest news on Best Value Biologics: Biosimilars

Now that the patents are beginning to expire for the original biological medicines, another generation of biological medicines is becoming available, enabling valuable savings to be made for the NHS.

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### Why you could be asked to switch to a biosimilar medicine

The NHS has introduced many life-saving innovations in its 70-year history. Antibiotics, medicines to control diabetes and heart disease, and specialist treatments for cancer are some of many revolutionary advances.

### Biological medicines

The latest innovation has been biological medicines, available since 2000, and becoming much more widespread. These medicines treat conditions which were previously very difficult to treat – certain cancers, rheumatoid arthritis, Crohn's disease and psoriasis.

They are a new type of medicine – one that acts on the immune system rather than on the body. Until they were developed, almost all medicines were made by mixing chemicals together to produce the final product. Biological medicines are derived from living organisms which means living cells are used to make large, complex, molecule-like proteins, and other substances produced by the body,

that can then be used as medicines. The complex processes needed to make biological medicines often involve the latest DNA technology.

## The benefits

Biological medicines are already making a difference to thousands of people's lives.

"Without access to biologic drugs for the last 18 years, I would be in a wheelchair and unable to work". Ailsa Bosworth, CEO of NRAS and RA patient diagnosed 39 years ago.

## Biosimilar medicines

Now another generation of biological medicines is becoming available, produced when the patent for the originator biological medicine expires, and enabling valuable savings to be made to the NHS while providing drugs which are equally safe and effective as the original biologic.

It is not possible to make an exact copy of an originator biological medicine; because they are made from living cells so there will always be some natural and slight differences between them. Therefore, the new versions are known as biosimilars, which means they are highly similar to the originals, and as safe and effective, but they are not an identical copy.

## Patient safety and biosimilars

Biosimilars are thoroughly tested and analysed in the laboratory and in clinical trials to ensure they are as safe and effective as the originator biological medicine. They have also gained the regulatory approvals from and been licenced by the authorities in the UK and Europe in the same way as all medicines.

Where the [National Institute for Health and Care Excellence](#) (NICE) has recommended the originator biological medicine in its guidance, they have stated that the same guidance will normally apply to a biosimilar version of that medicine.

## Are they really as safe?

Biosimilars are only available on the NHS once the European Medicines Agency has looked at the evidence and decided that they just as safe and effective as the original medicine. Steve Brown, regional pharmacist for NHS England and NHS Improvement, is confident that biosimilars are safe:

"There have been a number of research studies looking at how well biosimilars work and their safety," he says. "There appear to be no significant differences in efficacy between the originator biologicals and the new biosimilars. Where patients switch to a biosimilar we expect them to remain stable, as if they had stayed on the originator biological medicine."

NRAS has been working in the field of biosimilars to provide patient information and support since 2014 and are familiar with the evidence to date which reinforces the fact that they are as safe and effective as the reference products. The vast majority of patients have been switched successfully and we believe are happy to see savings being made which can be reinvested in improving patient care and services. Relatively few patients have been switched back to the originator product.

## What next with biological medicines?

Biosimilar medicines represent very good value for the NHS since they are often much less costly than the originator medicine. Therefore the NHS is asking clinical teams, in discussion with individual patients, to ensure they are using the best value biological medicines – whether that is the originator biological medicine or a new biosimilar medicine – so that the money saved can be reinvested in new medicines and treatments for patients. In 2017-18, the NHS saved a massive £200 million with this approach.

## What does this mean for me?

Any switching to a new medicine should involve a consultation between you and your clinical team and should take into account your needs, preferences and values as well as all the available clinical evidence. Shared decision making between clinical prescribers and patients will be vital if the best value, clinically effective medicines are to be used. In discussion with your clinical team you can agree on the most appropriate medicine. In some cases, it may continue to be the originator biological medicine.

## Adalimumab (Humira®) biosimilars

After its patent expires on 16 October 2018, the NHS is expecting new biosimilar versions of Humira® to become available from January 2019. Adalimumab is used to treat immune-mediated inflammatory conditions such as:

- Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis
- Inflammatory bowel disease
- Psoriasis
- Uveitis

If patients with the support of their clinical teams are switched to the best value biological versions of adalimumab, then the NHS stands to save a further £100 million a year – money that can be reinvested into helping other people access much needed treatments.

Ailsa Bosworth, CEO of National Rheumatoid Arthritis Society said “Today, more than ever with stretched resources, it’s vital that we use NHS resources wisely and carefully and so we should be using best value biologics, wherever possible. When switching patients from an originator biologic to its biosimilar, it’s important that commissioners and health professionals proactively adopt the principles of shared decision making.”

To find out more about what the changes mean for you:

Visit our web area devoted to the subject of biosimilars which can be accessed at [www.nras.org.uk/biosimilars](http://www.nras.org.uk/biosimilars). This includes a video interview with their NRAS Chief Medical Advisor, Prof. Peter Taylor, on all aspects of biosimilar switching and a short animation on biosimilars. NRAS position statement on biosimilars can also be accessed on the website. For further information contact [enquiries@nras.org.uk](mailto:enquiries@nras.org.uk) or ring NRAS freephone helpline on 0800 298 7650

# Medicines in rheumatoid arthritis

We believe it is essential that people living with RA understand why certain medicines are used, when they are used and how they work to manage the condition.

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