**INSERT ORGANISATION LOGO**

**Patient Information Leaflet -**

**Bioequivalent Medicines**

**Approved by Humber and North Yorkshire Area Prescribing Committee – February 2025**

**For local adoption by individual organisations.**

You have been given this leaflet because your doctor wants to prescribe you a medicine that belongs to a group called ‘biologics’. Your specialist team will have thought very carefully about which medicines are the most helpful and appropriate for you and your treatment.

**This leaflet tells you**

• What a biologic medicine is.

• Why we use bioequivalent medicines. • How we choose which product to use.

You may have other questions, which your specialist team will be very happy to answer.

**What is a biologic medicine?**

Biologic medicines have been used in hospitals for many years in the treatment of diseases such as rheumatoid arthritis, psoriasis, ulcerative colitis, Crohn’s disease, some cancers, and diabetes. For example, insulin is a biologic medicine.

These medicines are made from living cells or organisms. They often contain highly complex molecules. The manufacturing systems that produce these medicines are closely controlled to make sure that the products all meet strict quality standards.

Because the molecular structure of biologic medicines is so complex, it is not possible to produce an absolutely identical copy every time.

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There may be differences in the complex structure, even between different batches of the product made in the same manufacturing facility. These differences have to be kept within very strict limits, and they have to be measured as bioequivalent.

**What is a bioequivalent medicine?**

Biologic medicines are sometimes very expensive and time consuming to develop. When a pharmaceutical company first develops a new biologic medicine that is shown to help treat certain patients, they can obtain a time-limited patent so that only they can make and sell that medicine.

Some of these patents have ended so other manufacturers are allowed to make and sell the product. These newer versions of the original brand are called bioequivalents or sometimes you might hear them called ‘biosimilars’.

Bioequivalent medicines meet the same strict quality standards as the original brand. They work in the same way and can be used to treat patients with the same conditions.

**Do they work as well?** Yes.

**Are bioequivalent medicines as safe as the original biologic medicines?**

Bioequivalent medicines have been used by specialist teams for over 15 years and have been fully tested to show they work just as well and are just as safe as the original brand.

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**Why do we use bioequivalents?**

Their big advantage for the NHS is that they are usually much cheaper and this allows us to treat more patients with the best medicines available.

For example, using bioequivalent monoclonal antibody medicines (‘mabs’) means the NHS can now afford to treat more people with early stage rheumatoid arthritis before their symptoms get worse.

**How do we choose which product to use?**

You and your specialist decide together which is the best treatment for you. This is called informed consent.

Once your specialist team have prescribed for you, you can always be sure that we will use medicines that have been through the strict quality standards required in the UK.

**Why do we change your medicine to a different brand?**

• Original biologic brands and their bioequivalents are considered to be equally effective and safe.

• This means that we may change to a different brand of the same medicine over time.

• When you start a biological treatment, your specialist team will explain to you how it works, what to expect, and how to manage any side effects. They will ask for your agreement (consent) before prescribing the medicine for the first time.

• The first time you receive this medicine, you will receive the best value product we have at that time.

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• You may then receive different brands of the same medicine over the course of your treatment. We won’t need to ask you for your agreement each time you are treated.

• We will keep a record of exactly which product you receive. If you wish to know which product we are using when you receive your treatment, please do ask.

**What do I do if I am still worried?**

Talk to your specialist team or the hospital pharmacist about your treatment. They will listen carefully to your concerns and give you more information or help you find the support you might need.

We welcome questions and are here to support you.

**Further information**

• <<insert information of provider pharmacy team or equivalent

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**Questions / Notes**

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