Blood and Lymphatic cancers
Leukaemia CARE
supporting a quality of life

Advocacy Toolkit:
Generic medicines- What are your rights?

What is a generic drug?

A generic medicine is a version of a branded medicine, made by a different company (usually at a cheaper price). For example, Nurofen is the branded version of ibuprofen (the generic) – an anti-inflammatory. Pharmaceutical companies normally patent each new drug that they make which means only they can make and market that drug. In the UK, a patent usually lasts for twenty years. When it runs out, other companies can make a treatment containing the same active ingredient.

Why does the NHS use generic drugs?

Generic medicines are often substantially cheaper than the original branded equivalent which means that savings made by the NHS using generic medicines are significant. In fact, generic medicines save the NHS over £13 billion pounds each year. The money saved by using generic drugs can then be used to pay for other, more expensive treatments and services that patients need.
The use of generic medicines also promotes innovation in drug development. Because manufacturers know that each medicine will eventually become generic (so other companies can use the active ingredient) they focus their research on creating new medicines.

Is there a difference between the branded drug and the generic version?

Generic medicines contain the same active ingredient as the original branded version of the drug and as such, should work in exactly the same way. Generic medicines may contain different non-active ingredients (colourings, sugars, starches, for example) which can change the size, shape and colour of the generic drug. This should not impact on the way the drug works in the patient's body, or how effective it is.

Are generic drugs safe?

Yes, all medicines, branded and generic, must be authorised before they can be produced and distributed to patients in the UK. A generic medicine must be as safe and as effective as the branded version of the drug.
The European Medicines Agency (EMA) authorises all medicines for European use and the Medicines and Healthcare Produces Regulatory Agency (MHRA) is the UK government agency that makes sure that all medicines are safe, effective and of high quality for patients in the UK. The MHRA regularly inspects manufacturers to ensure that their procedures are satisfactory and make sure that medicines are being produced to a high standard. As with all medicines, once a generic drug is sold on the market, it must be monitored by the manufacturer in case there are any significant side effects reported.

Do generic drugs work as well as the branded version?

Yes, for a generic drug to be produced in Europe, it has to be as safe and effective as its branded equivalent. A generic drug must contain the same key ingredient as the original, be identical in strength, dosage form, route of administration, be manufactured under the same strict standards as the brand-name drug and be bioequivalent. Products are bioequivalent if the rate and extent of the active ingredient lies within predefined limits after administration. These limits ensure that the products are comparable in terms of safety and efficacy.

Are generic drugs tested before being issued to patients?

Generic medicines manufacturers research and develop their own version of products, which must be approved under the same EU requirements as the original branded medicines. Because the generic medicines contain the same safe, effective active ingredient as the branded version, clinical trials that have been carried out by the branded drug's manufacturer will not be carried out again. All pharmaceutical companies, however, have to follow strict quality control procedures when producing generic medicines and are inspected regularly.

Will the generic drug look the same as the branded version?

The generic drug will not always look the same as the branded version – they can differ in size, colour and shape and the packaging may look different, but this will not impact on how clinically effective the drug is. It is also possible that there is more than one type of the generic version of the drug, which can change in appearance but they still work in the same way.

Will I be informed if I am switched to a generic drug?

For the majority of medicines, there are no big differences between the branded and generic version of the drug and it should therefore be safe to switch between them as often as is required. However, if you have been taking the branded version, your clinician or pharmacist should advise you that they are switching you to the generic form of the drug.

Will I always be given the same generic drug- or will it keep changing?

Usually, you will be prescribed the same generic brand that your hospital pharmacy use, although it is possible that the type of generic medicine you receive will vary on occasion. This is because manufacturers of generic medicines often produce large batches of a single medicine at a time. So, although pharmacies order the same medicine each time, it is possible that they may receive generic medicines from different manufacturers. As a result, this means that the appearance of the tablet and its packaging can look different. Importantly, the clinical effectiveness of the tablet should not vary.

Case study: Imatinib

At the beginning of this year, imatinib, a tyrosine kinase inhibitor, manufactured and marketed by Novartis in Europe as Glivec, became available as a generic medicine. Throughout the course of 2017, patients will be switched to generic versions of imatinib.
For some patients, changing to a generic medicine can lead to confusion and concern. The packaging or the tablet itself can look different, for instance. If you are prescribed a generic medicine, instead of the branded version, your consultant should tell you that they have made the change, and made it clear that the active ingredient remains the same.
If you are on another type of TKI (dasatinib, bosutinib or nilotinib or ponatinib), you should not be moved to a generic version of imatinib unless your clinician thinks that you will clinically benefit. For example, that you would achieve a better response. These alternative treatments remain available as per existing guidelines.

What do I do if I experience severe or abnormal side effects when taking a generic drug?

It is important that you tell your consultant if you notice any changes in how you feel or experience side effects (that you did not experience when taking Glivec) so that they can monitor your response. You can also report any severe side effects through the Yellow Card Scheme.

Yellow Card Scheme

The Yellow Card Scheme is run by the Medicines and Healthcare products Regulatory Agency (MHRA) to monitor the safety of all healthcare products in the UK. The scheme collects information on side effects from drugs. This helps to ensure that they are safe for patients who use them.

How does it work?
Severe side effects that are reported on the Yellow Card scheme are evaluated, together with clinical trial data, medical literature or data from other medicine regulators to identify safety risks that might be present. All of the reports are examined by medicine safety experts (doctors, pharmacists, researchers) who study the benefits and risks of the drug.

How do I report adverse side effects?
It is important that if you experience substantial side effects from a drug, to report them so that action can be taken by the MRHA to minimise risk and maximise benefit to patients. You can report abnormal side effects here: https://yellowcard.mhra.gov.uk/yellowcards/reportmediator/

What should I include in my Yellow Card report?

1. Drug name – (if it is a generic drug, then it is very important that you include the generic drug's manufacturer).
2. Dose, route of administration and frequency.
3. What the reaction was, its seriousness and the treatment given
4. Patient details, including diagnosis, sex, age, comorbidities, medical history, other medication.

You can find more information on the Yellow Card Scheme here:
https://www.gov.uk/report-problem-medicine-medical-device