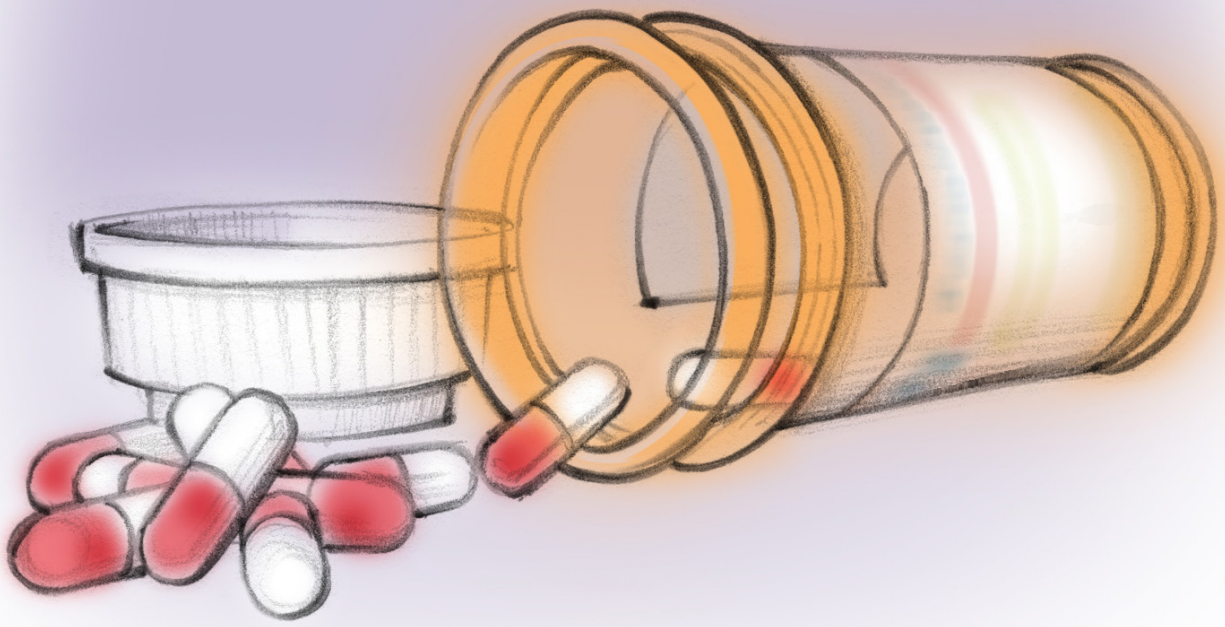
Generic Medicines

What are your rights?



Leukaemia Care

YOUR Blood Cancer Charity

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. On the 31st of July 2018, the NHS released figures saying they had saved £324 million in 2017 by "better value and equally effective" drugs, which include generics, as well as similar medicines called biosimilars. These figures include the use of a generic version of imatinib (see case study below). 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 (for example: colourings, sugars, starches) 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 and be bioequivalent. Drugs release their active ingredient at a certain speed in the body, a bit like how fast a tablet dissolves in water. The active ingredient spreads within the body at a certain rate too. These two properties make up the bioavailability of the drug. Injections are said to be 100% bioavailable because the contents are put directly into your circulation, whereas other ways of taking medicine mean the drug has to cross a barrier, like your intestine wall, before it can be used and not all the

drug gets through. For example, if you swallowed a pain relief tablet, a generic and a branded tablet should dissolve, release the active ingredient and have that ingredient enter your circulation in the same amounts and in the same amount of time. Products are bioequivalent if this rate and extent of the active ingredient lies within predefined limits after administration; i.e. there is a limit to how differently the generic vs. the branded works in the body, they must be similar even if it is hard to make them identical. These limits ensure that the products are comparable in terms of safety and efficacy.

Are generic drugs tested before issued to patients?

Manufacturers of generic medicines 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 and effective active ingredient as the branded version, clinical trials that have been carried out by the manufacturer of the branded version will not be carried out again. All pharmaceutical companies, however, must 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 differ 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 versions 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, explain why and talk through any concerns you may have.

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

In January 2017, imatinib, a tyrosine kinase inhibitor (TKI), manufactured and marketed by Novartis in Europe as Glivec[tm], is due to become available as a "generic medicine". Imatinib is a drug for CML, Philadelphia chromosome positive ALL and a few other blood cancer patients. If you have been diagnosed with one of these conditions since the generic date and prescribed imatinib, you are very likely to have always been taking the generic version. Patients who had been taking Glivec[tm] prior to the generic date will have been moved over to the generic imatinib within a year.

In July 2018, the NHS released figures on savings from generic medicines in the 2017-18 financial year; £66.3 million was saved by using generic imatinib instead of Glivec[tm].

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, nilotinib or ponatinib), you should not be moved to a generic version of imatinib unless your clinician thinks that you will clinically benefit from taking imatinib instead, such as that you would achieve a better response. These alternative treatments remain available as per existing guidelines.

CASE STUDY: Dasatinib

Dasatinib is another TKI also used for CML and Philadelphia chromosome positive ALL. In early 2018, eligible ALL patients will be switched from Sprycel™ (the branded dasatinib) to a generic version, if treated on the NHS. CML patients should continue taking their current drugs as the patent for use of "Sprycel" in CML patients does not expire until 2024. Please speak to your clinician or contact Leukaemia Care if you have any questions about generic dasatinib.

What to 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 (for example, that you did not experience when taking Glivec™ that you do experience when you are on the generic imatinib) so that they can monitor your response. Your care will not change unless your consultant is concerned about anything after the change to a generic version. For example, you will not be monitored more frequently unless your clinician decides you need it. You can also report any severe side effects through the Yellow Card Scheme.

Yellow Card Scheme

What is it?

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?

Drug name – (if it is a generic drug, then it is very important that you include the generic drug's manufacturer).

Dose, route of administration and frequency.

What the reaction was, its seriousness and the treatment given

Patient details, including diagnosis, sex, age, comorbidities, medical history, other medications.

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

If you have any further questions about generic medicine, you can contact our Campaigns and Advocacy team. They are available Monday to Friday from 9:00am – 5:30pm. If you would like to speak to them, you can:

Call our office line on 01905 755977

- Send them an email at advocacy@leukaemiacare.org.uk
- You can also call the help line, free of charge on 08088 010 444. The team will pass your enquiry onto the Campaigns and Advocacy team.

Please note that our Campaigns and Advocacy team are unable to provide:

- Detailed medical advice or recommendations
- Legal advice
- Advocacy for a course of action which is contrary to the aims and objectives of Leukaemia Care

If you have any questions, or for more information, please contact our Campaigns and Advocacy team by emailing advocacy@leukaemiacare.org.uk or speak to our nurse by phoning 08088 010 444