What I tell my patients about **generic medicines**

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Most medicines are called by two or more different names: a generic (or non-proprietary) name, such as paracetamol, and a brand (or trade) name, such as Panadol®. This can be confusing. The generic name is the approved name of the medicine and is often linked to the class of medicines to which it belongs, while the brand name is the name given to the medicine by the manufacturer. The brand name is often easier to spell or pronounce than the generic name, and is intended to be more memorable for marketing purposes.

For many medicines, both the generic and the brand names appear on the packaging. For newer medicines, the brand name may be the most prominent name on the box, but the generic name must also be shown, although sometimes it will be found to be in much smaller text.

How are medicines regulated?

In the UK, the Medicines and Healthcare Products Regulatory Agency (MHRA) is the government agency that ensures that all medicines are safe, effective and of high quality. Before a medicine can be prescribed or sold, the MHRA must assess whether it meets these standards. If it does, then the MHRA issues a marketing authorisation (previously called a product licence) to the manufacturer. A medicine's marketing authorisation number can usually be found on the packaging.

As well as issuing marketing authorisations, the MHRA regularly inspects manufacturers to ensure that their procedures are satisfactory and that medicines are being produced to the correct standards. The MHRA has the power to withdraw a product from the market, suspend production and prosecute a manufacturer if the law is not followed.

Generic medicines

What are generic medicines?

It costs a great deal of money, and takes many years of laboratory and clinical research, to discover and develop a new medicine. Therefore, in order for pharmaceutical companies to recoup their research and development costs, new medicines are patented for a number of years. During that time, the developing manufacturer is able to determine the price of the medicine, and other pharmaceutical companies are not allowed to produce it.

When a medicine's patent expires, any regulated pharmaceutical company can manufacture that medicine, which is referred to as a generic medicine. As the manufacturers of generic medicines have no research and development costs, and marketing of the medicine has already occurred, they are able to charge a much lower price. Some generic medicines also have a brand name, which is different to the original brand name. They are referred to as branded generics.

Advantages of generic medicines

Due to rigorous monitoring by the MHRA, most generic medicines are so similar to the original branded medicine that there are no clinical differences between them. This means that, although the tablets may have different shapes or colours, they have the same effect.

For the NHS, the major advantage of generic medicines is that, due to competition between

manufacturers, the cost of generic medicines is often much lower than that of branded medicines. Because of this, apart from a small number of exceptions where switching products may affect treatment, doctors are encouraged to prescribe all medicines by their generic name, so that the NHS does not pay a premium for the branded medicines. Due to the large amounts spent on medicines each year by the NHS, these savings can have a significant effect on NHS budgets.

Another advantage of generic medicines is that, if for any reason a manufacturer is unable to supply a medicine, patients are still able to obtain their medicines from other manufacturers, and do not need to switch to a different medicine or interrupt treatment.

Disadvantages of generic medicines

While generic medicines have advantages for both patients and the NHS, they also have disadvantages compared with branded medicines. Manufacturers of generic medicines often produce large batches of a single medicine at a time, rather than a steady stream of multiple medicines. This means that, although pharmacies order the same medicine each time, they may receive generic medicines produced by different companies. As a result, the packaging and tablets may look different from month to month, which can be confusing for some patients.

For the vast majority of medicines, there are no big differences between the branded and generic versions, and it is safe to switch between them as often as is needed. However, for some medicines, switching may be more difficult. This is particularly the case for medicines where the level of drug in the blood must be maintained within a narrow range. If the level is below the range, the medicine is ineffective; if it is above the range, the risk of side effects is high. These medicines are said to have a narrow therapeutic window; patients taking such medicines should not be switched between branded and generic versions without monitoring.

Switching between branded and generic medicines

Which medicines should be prescribed by brand?

The MHRA specifies that certain medicines should be prescribed by brand – this may be the original brand or a branded generic if one is available. These medicines include those with a narrow therapeutic window. Patients who are taking them often need regular blood tests to make sure that the correct level of drug is maintained in the blood.

Other types of medicines that should be prescribed by brand are some modified- or controlled-release preparations, certain medicines that need to be administered with devices, such as insulin pens, and medicines with a combination of ingredients, such as multivitamin supplements.

If you are taking a specific brand of medicine that should not be switched to a generic medicine, your doctor or pharmacist should advise you of this when it is first prescribed to you.

Table 1. Examples of immunosuppressant medicines and their brand and generic names

Generic name	Original brand name	Branded generic name
Ciclosporin	• Neoral® • Sandimmune®	• Capimune® • Capsorin®
Mycophenolate mofetil	Cellcept®	• Myfenax® • Arzip®
Mycophenolate sodium	Myfortic®	None currently available
Sirolimus	Rapamune®	None currently available
Tacrolimus	Prograf®	• Adoport® • Capexion® • Perixis® • Tacni® • Vivadex®
Tacrolimus (prolonged-release)	Advagraf®	None currently available

When should a switch to a generic medicine be monitored?

For most renal patients, the medicines that should not be switched without careful monitoring are some of the newer immunosuppressant (antirejection) medicines, as they have a narrow therapeutic window. Examples of immunosuppressants with their generic and brand names are shown in Table 1.

Some issues have arisen in the last few years, as the patents of several widely used immunosuppressants expired and branded generics became available. Initially, GPs often prescribed these medicines by their generic names. This meant that pharmacies dispensed whichever version was in stock at the time, (either the original brand or a branded generic), so the versions of the medicine dispensed to the patient might have changed. As different brands of the same medicine can be absorbed into the bloodstream slightly differently, in some patients, the level of immunosuppressant in the blood was not kept
within the correct range, leading to a few cases of transplant rejection or over-immunosuppression.

Immunosuppressants that have a narrow therapeutic window, and thus should not be switched without careful monitoring, include ciclosporin, sirolimus and tacrolimus. As branded generic versions of tacrolimus and ciclosporin are now available, many transplant units have chosen to switch patients from the original brand to a branded generic medicine

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because of the lower cost. To prevent rejection or over-immunosuppression, this switch must be supervised by a transplant consultant so that the level of medicine in the blood is maintained within range.

Monitoring usually involves a blood test taken between one and two weeks after switching from one version to another. In most cases, no change in dose is needed, but in a small number of patients (around 5%, in my experience), a dose adjustment is required. To confirm that the new dose is correct, another blood test needs to be taken between one and two weeks after the dose adjustment.

Which medicines can be switched to generics without monitoring?

You will find that the patents of many of the medicines that you may be taking, such as omeprazole (a medicine to reduce the amount of acid produced by the stomach), expired many years ago. This means that you may have been switched from the branded to the generic version without noticing any difference. For medicines that have been a common treatment for a long time, such as aspirin, you may never have taken the original branded version.

Mycophenolate mofetil is a very commonly used immunosuppressant, and several generic versions are available. Although the amount of mycophenolate mofetil absorbed into the bloodstream may differ slightly between the original brand and the generic versions, this is not usually clinically relevant. This means that the level of mycophenolate mofetil in the blood is not usually monitored and patients can be switched without additional monitoring. However, if you have been switched between different versions of mycophenolate mofetil, you should inform your renal consultant ■

Declaration of interest
The author declares that there is no conflict of interest.

Key points

- Most generic medicines are so similar to the original branded medicine that there are no clinical differences between them.
- A small number of medicines must be prescribed by brand name, including some transplant immunosuppression medicines such as ciclosporin, sirolimus and tacrolimus.
- When you start taking a new medicine, make sure that you know whether or not it is important that you stick to the same brand.
- If you are taking medicines that need to be prescribed by brand, check that you have been given the brand you usually take each time you receive a new supply, to ensure that you do not accidentally switch to another brand.
- Switching between different versions of a medicine that needs to be prescribed by brand must be done under the supervision of a consultant and with appropriate monitoring.

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SUPPORTING KIDNEY PATIENTS

Despite every effort from the renal community, led by the National Kidney Federation (NKF) and the All Party Parliamentary Kidney Group (APPKG), NKF was recently informed that ministers have decided that, as of 1 April 2015, NHS England will no longer be responsible for renal dialysis, and dialysis services will be commissioned by clinical commissioning groups (CCGs).

At a meeting with the Department of Health (DH) on 18 November 2014, Richard Jeavons, Director of Specialised Services, told stunned participants that ministers had informed him that dialysis was no longer to be an NHS England prescribed service. After a six-week period of consultation from the end of November, led by the DH, legislative changes will be introduced in parliament in February, and the change to CCG commissioning will commence on 1 April 2015.

Participants at that meeting also learnt that co-commissioning was not an option available for dialysis, unless the move to CCG commissioning failed. They were not able to learn from Richard Jeavons any details as to how CCG commissioning would work or what commissioning models would be used.

The renal community, led by NKF, must now consider if there are any further chances to reverse this decision, widely seen as hurried, dangerous and without supporting evidence, or whether we can delay its implementation while a full and proper consultation takes place (not over the Christmas period as planned by the DH).

As a first step, NKF has briefed all its kidney patient associations on the issues and dangers surrounding this change, and asked them to make representations to their MPs. Members of the APPKG raised this matter with the Secretary of State during health service questions in the House of Commons on 25 November 2014 and have been offered a meeting with him. NKF continues to urge all MPs to halt the progress of these ill-considered changes, at least until the renal community has had a chance to respond ■

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