



GENERIC

medicines

Generic medicines are in the main copies of pharmaceutical products that are no longer protected by patent. This makes them attractive to the NHS, because they are generally less expensive than branded products. The prescribing of medicines by their generic name ('*generics*') by doctors continues to increase, yielding major savings in the NHS, yet some commentators have suggested that pharmacists should be free to override the decisions of doctors and dispense generics even where doctors have specifically written a prescription for a branded product. This process, known as *generic substitution*, would have few benefits in practice and many disadvantages. It would undermine doctors' relationships with their patients and could compromise patient health by disrupting the choice of medication selected by their doctor.

WHAT IS A GENERIC MEDICINE?

A generic medicine contains the same active ingredient as a prescription medicine that is no longer protected by patent. Any number of such copies can be placed on the market, all with formulations similar, but not necessarily identical, to the original product. However, they must all go through the same stringent safety and quality requirements demanded of the original product.

WHY GENERIC MEDICINES ARE POPULAR

Generic medicines are popular with bulk purchasers of health care, such as the NHS. This is because they are significantly cheaper than the original products, as their manufacturers do not incur the significant risks and costs associated with the research and development of innovative

medicines – estimated to be on average around £350 million for each new product that reaches the market. Last year, the UK pharmaceutical industry spent £2.2 billion on researching and developing new medicines.

WHAT IS GENERIC PRESCRIBING?

Generic prescribing is when a doctor prescribes a medicine using the generic name of its active ingredient. The name given to a medicine when it is first licensed for use is its trade name, or brand or proprietary name, and this identifies it as the exclusive property of a particular company.

GENERIC PRESCRIBING IN THE UK

The prescribing of generic medicines in Britain is high - far higher than in many other EU countries - and increasing. More than 55 per cent of all prescriptions for NHS patients in England are now written generically. This compares with 35 per cent in the mid-1980s. In some GP surgeries, generic prescribing is more than 90 per cent.

Generic prescribing is likely to continue to increase significantly in the UK over the next few years, not least because information technology allows doctors to prescribe generically at the touch of a button.

LIMITS TO GENERIC PRESCRIBING

Each year, doctors make thousands of decisions about the best way to treat their patients, given a wide variety of factors often unique to the individual, such as their ability or willingness to comply with a particular course of medication.

It is not unusual for doctors to prefer to prescribe branded medicines even when a generic is available, because they are concerned that a change of medication could influence compliance with the course of treatment.

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Patients with certain conditions or particular sensitivities should not deviate from their regular medication, so for safety reasons, there is a limit to the degree to which generic prescribing can take place.

Despite these concerns, some commentators have recommended a policy that would prevent doctors from ensuring that their patients get the medicines they specify on their prescriptions. This policy is known as generic substitution.

WHAT IS GENERIC SUBSTITUTION?

Generic substitution is different to generic prescribing in that the doctor's choice to write a prescription with a generic or a brand name can be overridden by the pharmacist, without consulting either the patient or the doctor. What would happen in practice is that a doctor would write a prescription using the brand name of a product, yet the pharmacist would have the freedom to dispense any generic version of the product instead.

Generic substitution is not permitted by UK law, except in an emergency or under strict hospital control, and the pharmaceutical industry and most health care experts support this position.

THE HAZARDS OF GENERIC SUBSTITUTION

The main problem with generic substitution is that it would mean that doctors' judgements about individual patients would not prevail.

Doctors already freely prescribe generically where they feel that the use of a generic rather than a branded medicine would not present any significant disadvantages to their patients. Generic substitution ignores these judgements, since the doctor's decision is overridden.

While the generic should have the same key clinical characteristics as the branded product, it is often a different shape or colour, or is packaged differently.

This can create problems, especially with older patients who have to take a variety of medicines at different times of the day and for whom a change in medication can lead to confusion and non-compliance, i.e. a failure to adhere to the course of treatment recommended by their doctor.

This can be a major source of waste in the NHS if expensive medicines are left unused and the benefits of courses of treatments undermined, as many are only effective if the medicines are taken consistently as prescribed.

GENERIC SUBSTITUTION AND THE NHS

Prescribing in the NHS has become increasingly rational and cost-effective over the past ten years, as a result a mixture of information technology, financial incentives, practice-level formularies, advice from specialist health authority advisers, and the greater availability of cost and clinical effectiveness data.

These measures encourage, rather than compel, doctors to prescribe rationally, while at the same time enhancing their ability to make clinical judgements.

By overriding doctors' judgements, generic substitution would undermine the doctor-patient relationship and in turn cause potentially major concerns for both patients and doctors.