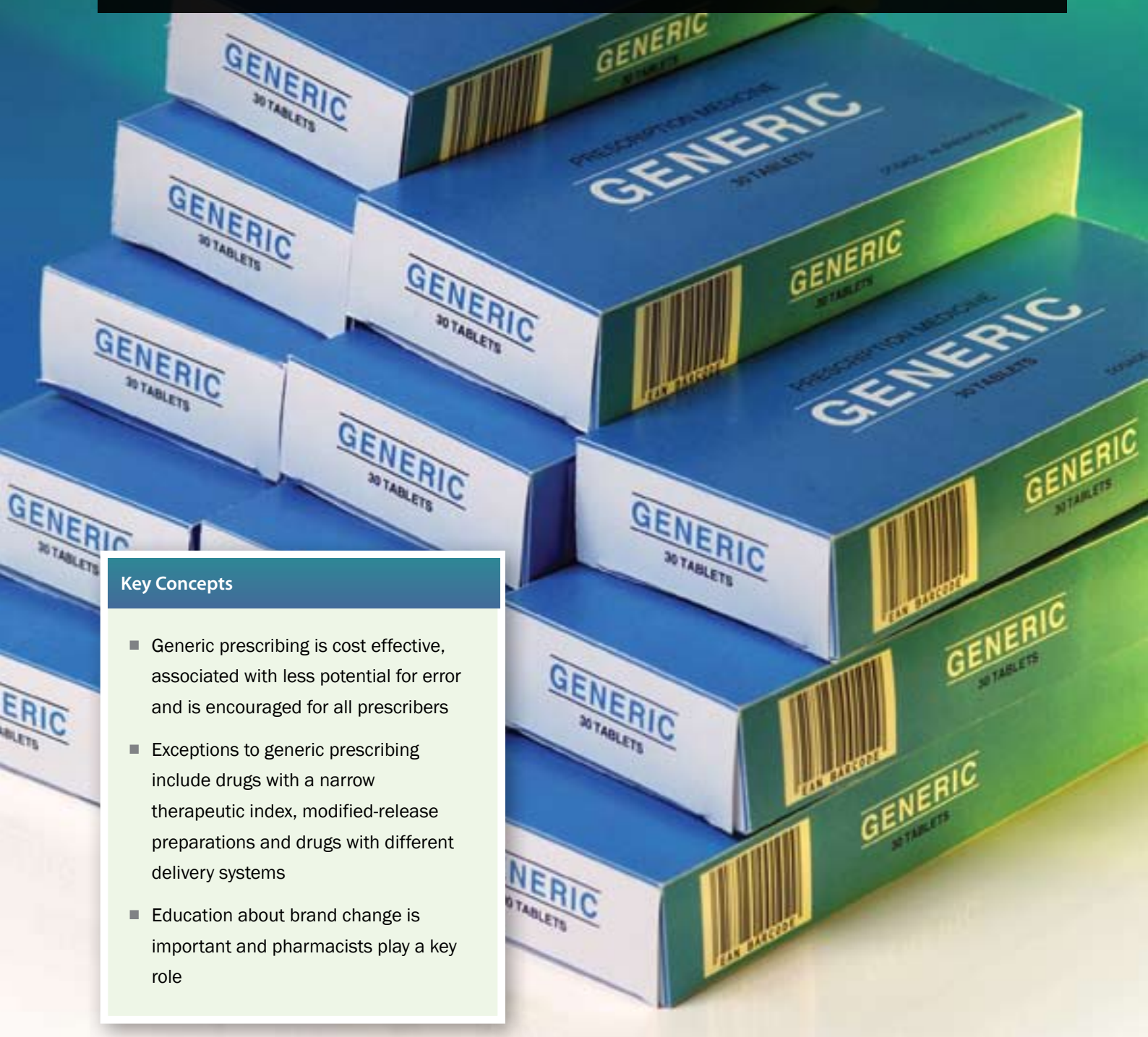
Why you should prescribe GENERICALLY



Key Concepts

- Generic prescribing is cost effective, associated with less potential for error and is encouraged for all prescribers
- Exceptions to generic prescribing include drugs with a narrow therapeutic index, modified-release preparations and drugs with different delivery systems
- Education about brand change is important and pharmacists play a key role

Prescribing a drug generically is an indicator of good prescribing practice

Generic prescribing is promoted in many countries as a way of reducing pharmaceutical costs. In the UK the adoption of generic prescribing is used as a measure to assess performance in primary care[1] and some practices have achieved a generic prescribing rate of 80%.

Prescribers in New Zealand are encouraged to write prescriptions for a medicine, using the generic name of its active ingredient rather than its brand name. While there are exceptions to this rule (see below) and some issues to take into consideration, generic prescribing can be regarded as rational and cost-effective use of medicines.

Six reasons to prescribe medicines using generic rather than brand name

1. You don't have to remember different brand names
2. You don't have to remember which brand is currently subsided
3. There is less potential for confusion and error, especially when brand names are similar
4. Less expensive medication brands can be used more often, allowing other medicines to be funded
5. Pharmacists can dispense the medication in stock without having to consult the prescriber
6. The generic name provides a guide to the drug's pharmacology and chemical class

✓	✗
Omeprazole 20 mg	Losec 20 mg, Omezol 20mg, Dr Reddy's Omeprazole 20 mg

Not all drugs should be prescribed generically

Examples of medicines which should **not** be prescribed generically include:

All anticonvulsants, all antiarrhythmics, theophylline, warfarin, cyclosporin, thyroxine and lithium.*

Some medicines are generally not considered interchangeable when:

The product has a narrow therapeutic range. In medicines where efficacy and/or toxicity are critically dependent on plasma concentration, the allowable differences in bioavailability between the reference and generic product in bioequivalence testing may result in changes in clinical effect between brands, although this is unlikely.

The product is modified release. The composition and pharmacokinetics of modified release medicines are more difficult to standardise compared to standard release formulations. For this reason, substitution of a modified release product may not be advisable once treatment has been initiated.

The delivery systems or dose forms of the products are not pharmaceutically equivalent. The use of transdermal patches (e.g. oestradiol patches), suppositories and systemically acting creams or ointments may be supported by data demonstrating bioequivalence with oral or other dose forms. However because of variability due to pharmaceutical form, these products are not considered interchangeable.

* Lithium tablets and capsules are also not equivalent

Medsafe determines bioequivalence for generic drugs

In New Zealand, Medsafe is responsible for determining that a generic copy of an innovator drug is bioequivalent, before it is released onto the market. Bioequivalence is determined using international regulations and guidelines. It is defined as the absence of a significant difference in the rate and extent of absorption into systemic circulation of two pharmaceutically equivalent medicines, when administered in the same dose under similar conditions.[2]

See BPJ Special Edition March 2007 "What is bioequivalence" for further information on the calculation of bioequivalence and variables in bioequivalence studies.

Patient perception may influence therapeutic effect

Generic prescribing may lead to a patient receiving a different brand of drug than previously used which in turn may give rise to concerns about new side effects and variation in therapeutic effect. Different brands of an equivalent medicine must include identical amounts of the active ingredient in the same dose formulation and route of administration but some excipients (inactive ingredients) are allowed to differ.[2] Some people may have individual sensitivities to excipients, for example lactose intolerance or avoidance of excipients of animal origin.

Worsening in symptom control or intensity of effect may be perceived as therapeutic inequivalence but actually may be due to disease progression[3] or psychological factors. These factors may include patient preference and perceived inferiority of a generic brand and may be more significant when the drug in question is used to treat a serious medical condition or psychological illness.[4]

See BPJ Special Edition, March 2007 "Changing to a generic drug" and BPJ 6, June 2007 "Upfront: Brand change" for further information on patient perceptions.

Education and counselling about brand change is important

The different appearance of medicines when brands change can be troubling to some patients and can lead to confusion and difficulty in complying with medicine regimens. Pharmacists have an important role in helping patients through this change. Many pharmacies place stickers on new brands of medicine to assure patients that they are still receiving the same drug in the same amount, despite the different appearance. Verbal or written information may be required to counsel patients through changes in medicines associated with mental illness and other serious conditions.

Pharmacists can also ensure that patients get the same brand of medication for repeat prescriptions.

See BPJ Special Edition, March 2007 "Counselling patients through a brand change".

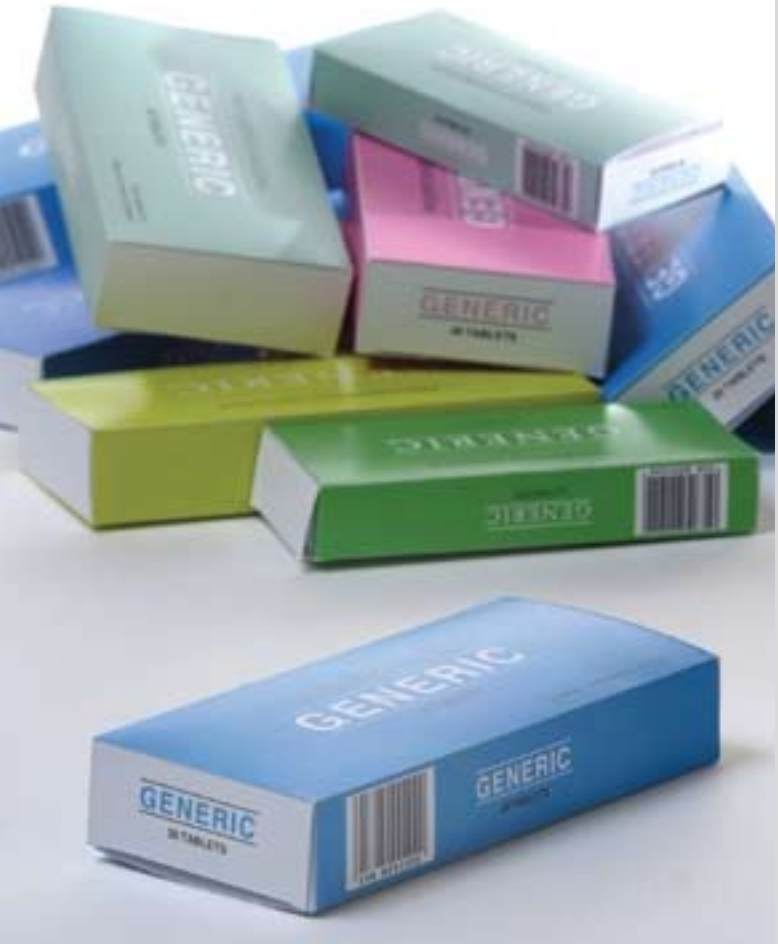
Prescribers should make the best decision for their patient

Despite education, counselling and reassurance, generic prescribing for some patients may compromise their ability or willingness to comply with their medicine regimen. In these situations it may be reasonable for the doctor to prescribe a branded medication.

Brand names should be used when prescribing drugs with a narrow therapeutic index, modified release formulations and drugs with different delivery systems. For all other situations, **generic prescribing is best practice**.

References

1. Walley T, Burrill P. Generic prescribing: time to regulate the market? BMJ 2000;320(7228):131-2.
2. Medsafe. New Zealand regulatory guideline for medicines. Section 15. Bioequivalence testing of oral medicines. 5th ed, 2001.
3. Rheinstein P. Therapeutic inequivalence. Drug Saf 1990;5(Suppl 1):114-9.
4. Mott D, Cline R. Exploring generic drug use behaviour: The role of prescribers and pharmacists in the opportunity for generic drug use and generic substitution. Med Care 2002;40(8):662-74.



Some generic drug names about to change

Submitted by Safe and Quality Use of Medicines Group

The World Health Organisation agreed many years ago that all drugs should have a recommended international non-proprietary name (rINN). Problems arise when this rINN differs from the British Approved Name (BAN) that most of us are familiar with. For many years manufacturers continued to use the BAN or even the US adopted name (USAN), however in 2004, UK manufacturers had to change to rINNs to obey a European directive.

This means that the names of some common drugs could be about to change on the shelves of pharmacies and on patients' bottles – in some cases they have changed already. Patients may worry about suddenly finding their frusemide has turned into furosemide and whether levothyroxine is the same as the thyroxine they had last time.

Some name changes may cause dispensing errors and confusion. Mercaptamine is very similar to mercaptopurine in name but not pharmacologically. Levothyroxine (previously thyroxine) sounds like liothyronine. Methotrimeprazine has started arriving on shelves labelled as levomepromazine. The oestrogens will no longer be spelt with an "o" and acyclovir and cyclosporin become aciclovir and ciclosporin respectively.