

Health care professionals have an important role in helping patients understand that generic medicines are as safe and effective as the innovator medicine.

Patients should be educated about the names of the active ingredient of their medicine to avoid confusion between different brands of the same medicine.

#### Accentuate the positive

The pharmacist is in an ideal position to counsel patients about a change to a generic medicine. A good understanding of the likely reasons behind any objections, and a positive reinforcement of the facts during the first interaction with the patient will ensure greater acceptance of change.

It is important to realise that in both clinical trials and in practice there is a significant placebo effect. This applies to most medical conditions. This means that the actual taking of a 'medicine' whether it contains an active ingredient or not can elicit a measured clinical response. It can therefore be logically argued that even if a generic medicine was identical with respect to active ingredient and the rate of release, a person's actual perception or acceptance of receiving something different may influence therapeutic effect, especially if there is a degree of subjectivity involved.

# Experiences with the paroxetine brand change

In March 2007, bpac<sup>nz</sup> initiated an education programme for pharmacists to coincide with the change of funding to paroxetine brands. The programme was evaluated and the results showed:

- Almost all pharmacists accessed programme resources and rated them useful or extremely useful
- An average of four minutes was spent explaining the brand change to each patient
- Just over half of the pharmacists had a concern with Loxamine, mainly in regards to bioequivalence and ability to split the tablet
- Pharmacists with a previous negative experience with brand change, and those who participated in the education programme were more likely to provide private counseling at the time of change
- Pharmacists who did not actively participate in the programme were more likely to have concerns about bioequivalence
- Almost all pharmacists would like to see similar programmes for future brand changes

## Counselng - three common questions and answers

#### Why the change?

The rationale for change is outlined in both the medicine specific patient information pamphlet produced by PHARMAC, as well as the "My Medicine Looks Different" pamphlet.

Giving this pamphlet to the patient and working through the key points with them should provide the patient with sufficient understanding of the reasons for the change. Although the current leaflet 'My Medicine Looks Different' mentions brand changes, it can be explained that this is the same as changing to a generic.

#### Q Is it the same medicine, and will it do the same job?

A A confident response can be supported with a professional knowledge of the regulatory process and bioequivalence (see page 4) and other information in this journal.

You can explain that the medicine itself is not changing but it is being supplied by a different manufacturer.

"Medsafe, the agency that approves medication for use in New Zealand, approved the generic medicine after carefully considering clinical study data. To gain this approval, the new supplier had to show that the generic delivers the same amount of the same medicine at the same rate as your previous brand. This means you should have the same clinical effect from taking the generic medicine as you did from your previous brand. If you notice any change you should discuss this with your pharmacist or doctor."

## Q Will there be any adverse effects from changing to a generic?

Understanding the potential for 'new' adverse effects is the key to an effective response to this question and will require a considered approach from the pharmacist. Some adverse effects are related to the dose of medicine and may be more apparent if the amount of medicine received is increased, others can occur when the dose of medicine received is suddenly reduced.

At the extremes of compliance with international standards of bioequivalence testing, it is possible that there may be small differences in the amount of the active ingredient compared with the reference product. This may lead to subtle changes if the effect is related to plasma concentrations. However, such effects are unlikely and, in theory, similar differences can also occur between different batches of the same brand.

It is also worth pointing out that generic medicines are not new. They have been available and in use in New Zealand and other countries for many years.

#### **Practice Tips for health professionals**

All health professionals have a role in successfully guiding patients through brand changes and acceptance of generic medicines

- **GPs** Prescribe by generic name
- Pharmacists provide appropriate counseling

### **Avoiding confusion over names**

The best way to avoid confusion over names is to prescribe generically. This allows the medicine to be dispensed with the generic name on the label.

Many generics have a brand name (e.g. Loxamine) and this can lead to confusion. In addition, patients may perceive the generic name as a different medicine to the brand they were formerly taking.

It is useful to encourage patients to know the name of the active ingredient in the medicine they are taking rather than the product brand name.

Pharmacists can assist with this by counseling and appropriate labelling. This will help the patient to understand that the same medicine may be available with different names.

Hospitals may have a different range of innovators and generics to those available in community. This emphasises the need for patients to have a list of their medicines by generic name as they move in and out of hospital.

A further challenge is product appearance and taste and it is not uncommon for patients to associate the tablet or capsule colour with the active ingredient. In order to maintain adherence, it is important for GPs and pharmacists to explain that these changes do not compromise clinical effectiveness.



# Patient Information Programmes make brand changes easier

Health professionals, especially GPs can have a significant influence on patient acceptance of generic medicines. In a consumer survey, 50% indicated they would not use a generic medicine without checking with their GP, despite agreeing that the generic medicine contained the same active ingredients as the branded medicine.<sup>6</sup>

A study based in Spain<sup>4</sup> assessed the acceptance of substitution of innovator medicines for generic medicines for chronic conditions in primary care. Of the patients who received verbal and written information on generic medicines, almost all agreed to receive a generic medicine. The reasons for refusal in the remaining patients included the influence of prescribers other than the general practitioner, patients' satisfaction with the innovator product and concern about adverse effects.

There was no statistically significant difference between patients that agreed and those that didn't agree with substitution based on age, gender or educational level. There were however, significant differences in acceptability rates according to individual primary care centres, suggesting differences in quality of information provided.

It was concluded that an individual educational intervention (that lasted less than five minutes in most cases) in patients with repeat prescriptions resulted in a high rate of generic acceptability. The intervention also helped to stimulate health practitioner's knowledge of generic medicines.<sup>4</sup>

In a study that assessed the impact of introducing generic substitutes to patients in a general practice clinic in Scotland, 70% accepted the generics and were satisfied with the change. Of the remaining patients, 19% were still taking the branded medicine, 4% were on other prescribed treatment, 4% had stopped treatment and 3% were purchasing their own alternative. Patients were either sent an explanatory letter detailing the change or were informed when first collecting their repeat prescription.

Reasons for dissatisfaction were largely due to the quality of information provided to the patient rather than problems with the generic medicine itself. Almost three quarters of patients (73%) could recall being informed of the change in at least one way. Satisfaction with the communication received was closely correlated with satisfaction about the change to the generic medicine itself. After four months, generic prescribing increased from 37% to 58%.<sup>7</sup>

The results of these studies suggest that appropriate care must be taken to inform patients properly. Interviews with patients showed the most common cause for dissatisfaction was a failure of communication. Patients were much more likely to be willing to accept the change if they understood the rationale and could be reassured about safety and effectiveness.

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