

Quality use of generic medicines

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The use of generic drugs has been steadily increasing internationally as a result of economic pressure on drug budgets.¹ Generic drugs provide the opportunity for major savings in healthcare expenditure since they may be substantially lower in price than the innovator brands. Prescribing drugs by their generic name and requesting pharmacists to dispense generic drugs are frequently suggested means for lowering the costs of health care. The practice of generic substitution is strongly supported by health authorities in many countries including Australia.²

Australia's National Medicines Policy aims to 'meet medication and related needs, so that both optimal health outcomes and economic objectives are achieved for Australians'.³ In response to the rising cost of the Pharmaceutical Benefits Scheme (PBS), the Australian Government has introduced policies to encourage

the use of generic drugs. Probably the most significant of these to date have been the Brand Premium Policy (1990) and the Brand Substitution Policy (1994).⁴ Under the Brand Premium Policy, pharmaceutical manufacturers were allowed to set their own prices for the different brands of the same medicine. The PBS subsidy was determined by the lowest priced brand, the so-called 'benchmark brand'. Patients must pay the difference between the price of the dispensed drug and the benchmark brand. The Brand Substitution Policy allows pharmacists to substitute bioequivalent generic medicines without seeking advice from prescribers, unless otherwise indicated on the prescription.

Changes to prescribing software will further encourage the use of generics. Systems must now default to prescriptions allowing brand substitution. Doctors will still be able to select brand name drugs, but they will have to positively select for disallowing brand substitution. The government estimates that the change will save the government-funded PBS A\$111 million over four years.⁵ However, the potential for savings to the government through generic prescribing is limited because the government subsidy is linked to the 'benchmark' price.

The Australian Government has regulations to assure the quality, safety and efficacy of generic medicines. These include compliance with good manufacturing practice and the requirement that generic products must have demonstrated bioequivalence with the innovator brand, or the Australian market leader, before they can be listed on the PBS.⁶

The quality use of medicines is central to the National Medicines Policy. It requires the judicious selection of management options, the appropriate choice of necessary medicines, and their safe and effective use. Unfortunately, the introduction of generic medicines into the Australian marketplace has the potential for some negative effects on the quality use of medicines.

The main area of concern is the many 'generic brands' that are available through the PBS. Pharmaceutical companies are permitted to assign brand names to their products in Australia so there is the possibility for consumers to be confused if they receive different brand names of the same drug. A common example of this is ranitidine tablets where there are currently

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With the Olympics approaching it is timely to revisit the issue of drugs in sport. Peter Fricker therefore guides us through the latest anti-doping code.

While diuretics can cause problems for athletes, they are still an important treatment for hypertension. Fiona Turnbull and Bruce Neal discuss the evidence that these drugs are as effective as ACE inhibitors.

Like hypertension, type 2 diabetes is a common problem in Australia. Almost all patients with type 2 diabetes will eventually require insulin, so Jencia Wong and Dennis Yue have provided practical advice on how to start insulin.

The use of warfarin is also increasing in the community. While there are benefits, Marija Borosak, Shin Choo and Alison Street remind us that these must be weighed against anticoagulation's adverse effects.

Warfarin is one of the drugs which does not have interchangeable brands. Azmi Hassali, Kay Stewart and David Kong discuss some of the other issues surrounding brand substitution and the use of generic drugs.

Fig.1

Some of the brands of ranitidine 150 mg available on the Pharmaceutical Benefits Scheme



Key

- 1 Ranihexal (Hexal)
- 2 Ranitidine BC (Biochemie)
- 3 Rani2 (Alphapharm)
- 4 Ranoxyl (Douglas)
- 5 Ranitidine (GenRx)
- 6 Zantac (GlaxoSmithKline)
- 7 Ausran (Sigma)

nine brands available (Fig.1). In some cases, the appearance of the drugs differs, adding to the problem of different brand names for the same drugs. Confusion could be greatly reduced if generic names of the drugs were required to be more prominent on the label than the 'brand' names.

From the consumers' point of view, the main advantage of generic drugs is that they have the opportunity to choose cheaper brands with savings to themselves as individuals and as taxpayers. This argument is not always as compelling as it may seem, as consumers may have beliefs or experiences that assume higher priority in their decision-making. Some of the quotes we have obtained from our own research into patients' perceptions of generic medicines show that factors other than money alone influence consumer choice.

'Well, I believe in sticking to what you are used to, if it is doing its job ... I know the doctor, I feel safe with my doctor.'

'Well, for a lot of people it is alright ... I've got a sister who is on the generic brand and she doesn't have any side effects but I do, so I can't take them. It doesn't matter if my tablets are a few dollars dearer.'

To achieve optimal outcomes, consumers must not only receive appropriate treatment, but also have the knowledge and skills to use it to best effect. Health professionals have a vital role to play in promoting quality use of medicines through good treatment choices, good communication with consumers, and collaboration with each other. Explaining about low cost brands may help to reduce confusion. While healthcare professionals are ultimately responsible for implementing the best therapeutic options for their patients, consumers should be included in the decision-making so that their beliefs and wishes can be taken into consideration. The following quotes from the consumers in our study clearly illustrate that the consumers are keen to receive information from their healthcare providers about their medicines.

'I wouldn't just swap to a generic medicine without talking. I like to talk to my doctors and my pharmacist about it because I have got very complicated needs in terms of medication.'

'I'm a great believer in consumer participation because I believe that you get as much information (as you can) and get it from the appropriate people ... I mean it is silly to go to a friend rather than my nephrologist. I consider all the information they are giving me and then balance it all to make a decision ... hopefully an informed decision.'

Achievement of optimal health outcomes and economic objectives requires participation, not just regulation.

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