quality and bioequivalence with the Australian innovator or market leader product. This usually requires *in vivo* bioequivalence data but, if satisfactorily justified by the sponsor, may be based on *in vitro* dissolution data for drugs with no known bioavailability problems.

Interchangeable products are marked in the Schedule of Pharmaceutical Benefits by a letter (a or b) and brand substitution by the pharmacist is permitted, unless the prescriber has indicated otherwise on the prescription. A brand premium, paid by the patient, is charged if the pharmacist dispenses a brand which costs more than the base-priced brand.

There has recently been a large proliferation in the number of 'generic' brands available through the PBS. This has resulted from the marketing of brands named according to the pharmacy chain selling them (e.g. Chem mart, GenRx, healthsense, Terry White Chemists). They are, in fact, all exactly the same product made by the same manufacturer and just packed and branded (named) differently. This unnecessary proliferation of brands is unfortunate and has the potential to cause confusion, but cannot be prevented under current legislation. A similar twist applies to some of the oral contraceptive products. Some manufacturers have marketed the innovator product under a different brand name as an interchangeable 'generic'. This allows a premium (of the order of $7–9) to be charged for the original 'innovator' product which is then strongly promoted.

Conclusion

There is no evidence in Australia that generic drugs are dangerous and impair the safety and efficacy of treatment. Our regulatory regime is world standard and conforms to requirements in regions such as Europe and the USA. Indeed, the Australian generic and bioequivalence requirements are 'harmonised' to those in Europe. There is also no evidence of systematic problems occurring because of generic availability and substitution. On the other hand, generics are cost-saving and allow the drug and health budgets to be spread further to enable access to new and expensive treatments where these offer cost-effective health outcomes.

FURTHER READING

Birkett DJ. Pharmacokinetics made easy. 2nd ed. Sydney: McGraw-Hill Australia; 2002.

Professor Birkett is now Executive Director, Research and Development at Johnson & Johnson Research Pty Ltd.

Self-test questions

The following statements are either true or false *(answers on page 95)*

3. In Australia, generic drugs must be bioequivalent to the innovator or market-leading brand of the drug.
4. The two brands of warfarin in Australia are not interchangeable.

Patient support organisations

See article on page 82

Deafness Forum

Deafness Forum represents the interests and viewpoints of the deaf and hearing impaired communities of Australia (including those people who have a chronic disorder of the ear and those who are deaf and blind). The Deafness Forum provides information on supporting organisations in local areas, and a range of links on its web site.

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Australian Hearing

Australian Hearing provides government subsidised hearing care for children and young adults to the age of 21, and pension concession card holders. Subsidised services include hearing assessment, fitting of hearing aids and hearing rehabilitation.

Australian Hearing has over 70 permanent centres. Australian Hearing audiologists also periodically visit community centres, medical centres, local hospitals and other locations. The research arm of Australian Hearing is the National Acoustic Laboratories.

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