

Guidelines for Pharmacists on PBS Brand Substitution

These guidelines represent general advice to support and assist pharmacists. It is expected that professional judgement will be exercised in adapting these guidelines to specific presenting circumstances.

Background

Generic medicines

- 'Generic medicines' refer to products which are equivalent to originator brands or innovator products which are no longer protected by patent. 'Generics' may or may not be less expensive than an equivalent product.
- An application for registration of a generic product in Australia generally includes a bioequivalence study versus the originator brand obtained in Australia. A bioequivalence study has the aim of establishing whether two (or more) formulations of the same drug are equivalent in terms of the rate and extent of absorption of the drug (or active moiety) into the systemic circulation.

Pharmaceutical Benefits Scheme

- In 1994, changes were made to legislation to permit pharmacists to substitute generic products for original brand pharmaceuticals if they are listed in the *Schedule of Pharmaceutical Benefits* (the '*Schedule*') as being bioequivalent and able to be substituted, even where the prescription specifies a particular brand. Under the legislation, substitution must not occur if the prescriber has indicated that substitution is not permitted.
- When writing prescriptions under the Pharmaceutical Benefits Scheme (PBS), approved prescribers should indicate on the prescription where brand substitution is not permitted. PBS prescriptions must not be prepared using a default which would result in all prescriptions being indicated as 'brand substitution not permitted'.
- Pharmacists dispensing PBS prescriptions must be familiar with the definitions that apply to brand equivalence under the *Schedule*. Briefly, brands flagged 'a' are bioequivalent or therapeutically equivalent and may be interchanged without differences in clinical effect. Brands flagged 'b' are also equivalent but indicate that it is not known if there is equivalence between brands marked 'a' and those marked 'b'. Note that even if brands are not 'flagged' it cannot be assumed that they are 'not equivalent' since sponsors can request that an indication of equivalence not be shown. Pharmacists should refer to the current edition of the *Schedule* for further information.

Guidelines

- Pharmacy staff should be trained to assist the pharmacist in informing and educating consumers about brand substitution choices. Pharmacists should have systems in place to ensure that all patients (or their carer) have the opportunity to request a generic equivalent before dispensing occurs and that they have access to relevant information about generic medicines and/or brand substitution.
- Brand substitution may only occur after consultation with and agreement of the patient (or the carer), and if the prescriber has not indicated on the prescription, "no substitution", or equivalent.
- Where substitution is allowed and the patient is offered or enquires about alternate brands, the pharmacist and the patient should discuss the safety and suitability of alternate brands for that patient.
- The patient's health should always be the pharmacist's prime consideration in any brand substitution decision. Decisions to substitute one brand for another should not place patients at risk.
- Pharmacists should endeavour to be consistent in the selection of brands for patients on long-term therapy in order to avoid patient confusion. If this is not possible then the patient should be consulted.
- In some circumstances substitution may be 'unavoidable', for example, due to an inability to source a particular brand which is out of stock at the suppliers. Where substitution is allowed, the pharmacist must provide thorough advice (including for example, differences in product presentation) whenever substitution occurs under such circumstances. If, however, substitution has been disallowed by the prescriber, the pharmacist must discuss the matter with him/her.
- Where the prescriber disallows substitution and the patient requests substitution, pharmacists should either discuss the matter with the prescriber or refer the patient back to the prescriber.
- Pharmacists should encourage (or offer to assist) patients to have their medication regularly reviewed to check for duplication of different brands of the same medicine.
- Pharmacists should discuss brand substitution issues with their local prescribers to maintain and improve professional relationships and minimise the chances of any conflict or misunderstanding.

*Endorsed by National Council July 2004
(v.1 March 1997; v.2 July 2003)*

Resources

1. Commonwealth Department of Health and Ageing. Schedule of Pharmaceutical Benefits — for Approved Pharmacists and Medical Practitioners. *Note: An electronic version can be accessed at <http://www1.health.gov.au/pbs/index.htm>*
2. Pharmaceutical Society of Australia. Essential CPE: Bioequivalence. Dec 2000.
3. Pharmaceutical Society of Australia. Essential CPE Satellite Lecture Series: Generics — the issues, the debate. Jun 2003.
4. Pharmaceutical Society of Australia. Generic medicines. inPHARMation, Jun 2003.
5. Pharmaceutical Society of Australia. Generic medicines. Pharmacy Self Care Fact Card. Jun 2003.
6. Birkett DJ. Generics – equal or not? Aust Prescr 2003; 26: 85–7.