

National Health (Pharmaceutical Benefits) Amendment Regulations 2002 (No. 1) 2002 No. 239

EXPLANATORY STATEMENT

STATUTORY RULES 2002 No. 239

Issued by Authority of the Minister for Health and Ageing

National Health Act 1953

National Health (Pharmaceutical Benefits) Amendment Regulations 2002 (No. 1)

Section 140 of the *National Health Act 1953* ("the Act") provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which by the Act are required or permitted to be prescribed, or which are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Paragraph 105(b) of the Act provides that the regulations may make provision for, or in relation to, the writing of prescriptions.

Under paragraph 103(2)(a) of the Act, it is an offence for a pharmacist, to whom a prescription is presented, to supply anything other than the pharmaceutical benefit as specified in the prescription. However, subsection 103(2A) of the Act provides an exception whereby a pharmacist may substitute a different brand of the pharmaceutical benefit from that prescribed under certain conditions.

One of those conditions, in paragraph 103(2A)(a) of the Act, is that the prescriber of the pharmaceutical benefit did not indicate on the prescription that only that benefit was to be supplied. Prescription forms issued by the Health Insurance Commission to medical practitioners and participating dental practitioners contain a box to be marked by the prescriber if brand substitution is not to be permitted. That is, the prescriber must consider for each individual prescription whether or not to prohibit the substitution of another brand. If the box is not marked, and the other conditions specified in subsection 103(2A) are satisfied, the pharmacist may substitute another brand of the same pharmaceutical benefit. Brand substitution normally occurs to enable the patient to avoid additional cost when the brand prescribed is more expensive than other brands of the same medication.

Regulation 19 of the National Health (Pharmaceutical Benefits) Regulations 1960 governs the writing of prescriptions. It provides that prescriptions may be prepared:

- by handwriting on a prescription form;
- by computer on a prescription form; or
- by another method approved in writing by the Secretary, which includes by computer on paper other than standard prescription forms.

For computer prepared prescriptions, some prescription-writing computer programs allow a default to be set that has the effect of automatically prohibiting brand substitution for all prescriptions.

The purpose of the Regulations is to provide that a computer-prepared prescription must not be prepared using a computer program that permits a default automatically prohibiting brand substitution. This will put computer-prepared prescriptions on the same basis as handwritten

prescriptions, by requiring the prescriber to make a conscious decision in the case of each prescription whether or not to prohibit brand substitution.

Details of the Regulations are in the Attachment.

The Regulations commence on 1 February 2003.

ATTACHMENT

Regulation 1 of the amending regulations provides that the name of the amending regulations is the *National Health (Pharmaceutical Benefits) Amendment Regulations 2002 (No. 1)*.

Regulation 2 of the amending regulations provides that the amending regulations will commence on 1 February 2003.

Regulation 3 of the amending regulations provides that the *National Health (Pharmaceutical Benefits) Regulations 1960* will be amended as set out in Schedule 1.

Item 1 of the Schedule defines "brand" to have the same meaning as in Part VII of the Act, namely, a trade name under which a manufacturer sells a drug or medicinal preparation or the name of the manufacturer who sells a drug or medicinal preparation.

Item 2 of the Schedule inserts new subregulation 19(5) which provides that a prescription must not be prepared using a computer program that enables a default to be set that only the brand of pharmaceutical benefit specified in the prescription is to be supplied.