

EXPLANATORY STATEMENT

STATUTORY RULES 1984 NO. 342

NATIONAL HEALTH (PHARMACEUTICAL BENEFITS)

REGULATIONS (AMENDMENT)

Issued by the Authority of the Minister for Health

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 to be prescribed for carrying out or giving effect to the Act.

Part VII of the Act makes provision for the supply by the Commonwealth of certain drugs and medicinal preparations as pharmaceutical benefits. Section 85 provides that, with such exceptions and additions as are prescribed, namely those noted in Schedule 1 to the National Health (Pharmaceutical Benefits) Regulations ('the Regulations'), the drugs and medicinal preparations which are the subject of monographs in the British Pharmacopoeia shall be available as benefits. That section further provides that prescribed compounds of those drugs and medicinal preparations shall also be available as benefits

(namely those listed in Schedule 2 to the Regulations).

Section 88A of the Act provides that the writing of a prescription for the supply of a prescribed pharmaceutical benefit may be authorised only in circumstances prescribed in relation to that pharmaceutical benefit.

Section 101 of the Act establishes the Pharmaceutical Benefits Advisory Committee, consisting of medical practitioners, pharmacists and a pharmacologist, to recommend to the Minister for Health ('the Minister') the drugs and medicinal preparations which it considers should be made available as pharmaceutical benefits, and to advise the Minister on any matter concerning the operation of Part VII referred to it by the Minister.

The Committee meets three times a year and after each meeting makes recommendations to the Minister in accordance with the Act. In making its recommendations, the Committee carefully considers all relevant facts about each drug or medicinal preparation. Drugs considered for listing would normally be more effective or less toxic than those already listed. A drug may be delisted when a more

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effective or less toxic drug is available or when it has fallen into disuse. Fixed combinations of two or more drugs are rarely acceptable because the Committee considers that more than one drug should not be used when one drug is all that is needed. If the Minister accepts the Committee's recommendations, he agrees to the drafting of Statutory Rules to amend the Regulations to give effect to the recommendations.

The Schedules to the Regulations provide as follows:

Schedule 1 lists those drugs and medicinal preparations that are the subject of monographs in the British Pharmacopoeia but which are not available as pharmaceutical benefits;

Schedule 2 lists those fixed combinations of drugs and medicinal preparations which are available as pharmaceutical benefits;

Schedule 3 lists those drugs and medicinal preparations which are not the subject of monographs in the British Pharmacopoeia but which are available as pharmaceutical benefits;

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Schedule 4 lists the additives that may be used with pharmaceutical benefits;

Schedule 5 lists the pharmaceutical benefits, the prescribing of which is subject to certain conditions and restrictions provided for in the Regulations.

The regulations which came into effect on 1 December 1984 amended Schedules 1, 2, 3 and 5 to the National Health (Pharmaceutical Benefits) Regulations to give effect to the Pharmaceutical Benefits Advisory Committee's recommendations of 14-15 June 1984 to the Minister.

S.R. 334/84