

EXPLANATORY STATEMENT
INSTRUMENT NUMBER PB 29 OF 2012
NATIONAL HEALTH ACT 1953
AMENDMENT DETERMINATION UNDER PARAGRAPH 98C(1)(b)

Summary

This legislative instrument in giving effect to recommendations of the Pharmaceutical Benefits Advisory Committee (PBAC) amends the determination under section 98C(1)(b) made by legislative instrument number PB 119 of 2008 which came into effect on 1 December 2008. The amendments provide for changes to the conditions subject to which payments will be made by the Commonwealth in respect of the supply of pharmaceutical benefits by approved pharmacists and approved medical practitioners. The amendments are set out in the items of Schedule 1 to the instrument.

Purpose and operation

Part VII of the *National Health Act 1953* (the Act) is the legislative basis of the Pharmaceutical Benefits Scheme (PBS) by which the Commonwealth provides reliable, timely, and affordable access to a wide range of medicines for all Australians.

Subsection 85(1) provides that benefits are to be provided by the Commonwealth in accordance with Part VII in respect of pharmaceutical benefits.

Drugs and medicinal preparations to which Part VII applies are (with the exception of some medicinal preparations with additives) declared by the Minister by legislative instrument to be so under subsection 85(2). These are listed drugs as defined in subsection 84(1).

The Minister by legislative instrument can determine the form or forms of a listed drug by reference to strength, type of unit, size of unit or otherwise (subsection 85(3)); the manner of administration of the form of the listed drug so determined (subsection 85(5)); and a brand of the pharmaceutical item (defined in subsection 84(1)) that has the listed drug in that form with that manner of administration (subsection 85(6)). These determinations govern what constitutes the pharmaceutical benefit (defined in subsection 84(1)) under Part VII of the Act. Under section 84AF, the Minister may determine a responsible person for a brand of a pharmaceutical item.

Paragraph 98C(1)(b) of the Act provides that the Minister may, from time to time, determine the conditions subject to which payments will be made by the Commonwealth in respect of the supply of pharmaceutical benefits by approved pharmacists and approved medical practitioners.

The determination under paragraph 98C(1)(b) of the Act sets out the conditions under which payments will be made in respect of the supply of pharmaceutical benefits by approved pharmacists and approved medical practitioners.

This instrument constitutes a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

This instrument commences on 1 May 2012.

Changes to PB 119 of 2008 made by this instrument

This instrument amends Schedule 4 of PB 119 of 2008 by deleting the entry for the listed drug naproxen in the form oral suspension 125 mg per 5 mL, 474 mL and the entry for the listed drug promethazine in the form oral liquid containing promethazine hydrochloride 5 mg per 5 mL, 100 mL.

Consultations

The Department consulted with the Pharmaceutical Benefits Advisory Committee (PBAC) during the regular process of its meetings to consider applications in order to recommend to the Minister which medicines should be subsidised through the Pharmaceutical Benefits Scheme. The Committee is independent of Government and includes members from the following interests or professions: consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and medical specialists. The Committee has received submissions and representations from interested pharmaceutical companies and has recommended the changes to the Minister who has determined the changes to the conditions under paragraph 98C(1)(b) which appear in this Determination.

General

The instrument commences on 1 May 2012.

This instrument is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Amendment determination under paragraph 98C(1)(b)

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The determination under paragraph 98C(1)(b) of the *National Health Act 1953* sets out the conditions under which payments will be made in respect of the supply of pharmaceutical benefits by approved pharmacists and approved medical practitioners.

This legislative instrument amends the *Determination under paragraph 98C(1)(b) of the National Health Act 1953* which came into effect on 1 December 2008. The amendments provide for changes to the conditions subject to which payments will be made by the Commonwealth in respect of the supply of pharmaceutical benefits by approved pharmacists and approved medical practitioners.

This instrument removes 2 pharmaceutical items from schedule 4 of the Determination.

Human rights implications

This legislative instrument engages Article 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The PBS is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

Conclusion

This Legislative Instrument is compatible with human rights because it advances the protection of human rights.

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