

EXPLANATORY STATEMENT
NATIONAL HEALTH ACT 1953
NATIONAL HEALTH DETERMINATION UNDER PARAGRAPH 98C(1)(b)
AMENDMENT 2014 (No. 2)
PB 10 of 2014

Authority

Paragraph 98C(1)(b) of the National Health Act 1953 (the Act) provides that the Minister may 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. *Determination under paragraph 98C(1)(b) of the National Health Act 1953* (PB 119 of 2008) (the Principal Determination) sets out the conditions subject to which these payments will be made.

Purpose

This Amendment Determination amends the Principal Determination to reflect the changes made by the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2014 (No. 2)*, commencing on 1 March 2014. Schedule 4 of the Principal Determination is amended by the addition of bimatoprost in the form eye drops 300 micrograms per mL, single dose units 0.4 mL, 30. Schedule 4 is further amended by removing terbutaline in the form powder for oral inhalation in breath actuated device containing terbutaline sulfate 500 micrograms per dose, 200 doses.

Variation and revocation

Unless there is an express power to revoke or vary PB 119 of 2008 cited in this Instrument and explanatory statement, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary PB 119 of 2008.

Background

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.

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.

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.

This Instrument commences on 1 March 2014.

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

National Health Determination under paragraph 98C(1)(b) Amendment 2014 (No. 2) (PB 10 of 2014)

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* (PB 119 of 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 adds one form of a listed drug to Schedule 4 of the Determination and also removes one form of a listed drug from Schedule 4.

Human rights implications

This legislative instrument engages Articles 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.

**Felicity McNeill
First Assistant Secretary
Pharmaceutical Benefits Division
Department of Health**