

EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (PHARMACEUTICAL BENEFITS – EARLY SUPPLY) AMENDMENT INSTRUMENT 2014 (No.1) – SPECIFICATION UNDER SUBSECTION 84AAA(2)

PB 25 of 2014

Purpose

The purpose of this legislative instrument, made under subsection 84AAA(2) of the *National Health Act 1953* (the Act) is to amend the *National Health (Pharmaceutical Benefits – Early Supply) Instrument 2009 – specification under subsection 84AAA(2)* (PB 30 of 2009) is to add one new pharmaceutical item, delete one form and strength of an existing pharmaceutical item and insert a circumstance to an existing pharmaceutical item.

PB 30 of 2009 specifies the pharmaceutical items that are in pharmaceutical benefits for which Pharmaceutical Benefits Scheme (PBS) Safety Net entitlements will not apply for early supplies.

Authority

Subsection 84AAA(1) of the Act provides that a supply of a pharmaceutical benefit (whether or not the supply is of a kind described in paragraph 84C(4A)(a) of the Act) to a person is an early supply of a specified pharmaceutical benefit if:

- (a) The supply is made within 20 days after the day of a previous supply to the person of:
 - (i) the same pharmaceutical benefit; or
 - (ii) another pharmaceutical benefit that has the same pharmaceutical item as the pharmaceutical benefit; or
 - (iii) another pharmaceutical benefit that is Schedule equivalent to the pharmaceutical benefit;whether or not the previous supply is a supply of a kind described in paragraph 84C(4A)(a) of the Act; and
- (b) The pharmaceutical item in the pharmaceutical benefit is specified in an instrument under subsection 84AAA(2); and
- (c) The supply does not result from a prescription originating from a hospital.

Subsection 84AAA(2) of the Act provides that the Minister may specify, by legislative instrument, pharmaceutical items for the purposes of paragraph 84AAA(1)(b) of the Act.

Subsection 84AAA(3) provides that the instrument may specify a pharmaceutical item by reference to the circumstances in which a pharmaceutical benefit that has the pharmaceutical item is supplied or any other circumstances in relation to a pharmaceutical benefit that has the pharmaceutical item.

Paragraph 84C(4A) of the Act refers to repatriation pharmaceutical benefits supplied under the schemes established under section 91 of the *Veterans' Entitlements Act 1986* or section 18 of the *Australian Participants in British Nuclear Tests (Treatment) Act 2006* or supplied in accordance with a determination made under paragraph 256(1)(c) of the *Military Rehabilitation and Compensation Act 2004*.

Subsection 101(3AA) of the Act requires the Pharmaceutical Benefits Advisory Committee (PBAC) to make recommendations to the Minister about what should be specified in the instrument under subsection 84AAA(2) (currently PB 30 of 2009).

Changes to PB 30 of 2009 made by this instrument

Schedule 1 of the principal instrument (PB 30 of 2009) is amended by the addition of glycopyrronium in the form capsule containing powder for oral inhalation 50 micrograms (as bromide) (for use in Breezhaler), manner of administration inhalation by mouth. The schedule is also amended by removing one form and strength of flutamide in the form tablet 250mg, 30, manner of administration oral. The schedule is further amended by inserting circumstances relating to denosumab.

The 'listed drug', 'form', 'manner of administration', 'maximum quantity or number of units' and 'maximum number of repeats' for a pharmaceutical item are the same as declared and determined under the Act for pharmaceutical benefits that have a pharmaceutical item. These declarations and determinations are made in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012).

Therefore, a supply of a pharmaceutical benefit that has this pharmaceutical item will be an early supply of a specified pharmaceutical benefit providing the requirements of subsection 84AAA(1) are met.

Variation and revocation

Unless there is an express power to revoke or vary PB 30 of 2009 cited in this Instrument and explanatory statement, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary PB 30 of 2009.

Consultation

The Pharmaceutical Benefits Advisory Committee (PBAC) has recommended that the pharmaceutical items referred to in this amendment be included in an instrument under subsection 84AAA(2).

PBAC 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. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC.

This amendment is minor and machinery in nature.

General

This Instrument commences on 1 April 2014.

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

Statement of Compatibility with Human Rights

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

National Health (Pharmaceutical Benefits – Early Supply) Amendment Instrument 2014 (No.1) – specification under subsection 84AAA(2) (PB 25 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 *National Health (Pharmaceutical Benefits – Early Supply) Amendment Instrument 2014 (No.1) – specification under subsection 84AAA(2)* amends the *National Health (Pharmaceutical Benefits – Early Supply) Instrument 2009 – specification under subsection 84AAA(2)* which specifies the pharmaceutical items that are pharmaceutical benefits for which the Pharmaceutical Benefits Scheme (PBS) Safety Net entitlements will not apply for early supplies.

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.

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