

EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH ACT (PHARMACEUTICAL BENEFITS – EARLY SUPPLY) AMENDMENT OCTOBER 2011 – SPECIFICATION UNDER SUBSECTION 84AAA(2)

PB 73 of 2011

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) to insert a new pharmaceutical item and delete 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 *Veteran's 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) 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

This instrument amends the existing pharmaceutical item Degarelix that had the listed form 'Powder for injection 80 mg (as acetate) with solvent, syringe and needles' which has been amended to 'Powder for injection 80 mg (as acetate), injection set'.

The 'listed drug', 'form', 'manner of administration' 'maximum quantity or number of units' and 'maximum number of repeats' for this pharmaceutical item are the same as declared and determined under the Act for pharmaceutical benefits that have this pharmaceutical item. These declarations and determinations are made in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2010*.

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.

Consultation

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

PBAC members are selected from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. 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 October 2011.

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