

EXPLANATORY STATEMENT
NATIONAL HEALTH ACT 1953
NATIONAL HEALTH (PHARMACEUTICAL BENEFITS – EARLY SUPPLY)
AMENDMENT INSTRUMENT 2016 (No. 1)
PB 4 of 2016

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 2015* (PB 120 of 2015) by adding one pharmaceutical item.

PB 120 of 2015 specifies the pharmaceutical items that are in pharmaceutical benefits for which Pharmaceutical Benefits Scheme (PBS) safety net entitlements will not apply for early supplies, and to specify the period following previous supply.

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 286(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 120 of 2015 made by this instrument

Schedule 1 of the Principal Instrument (PB 120 of 2015) is amended by the addition of the listed drug ruxolitinib.

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 120 of 2015 cited in this Instrument and explanatory statement, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary PB 120 of 2015.

Consultation

The PBS Access and Sustainability Package includes measures relating to the Sixth Community Pharmacy Agreement between the Commonwealth of Australia and the Pharmacy Guild of Australia and the Strategic Agreement with the Generic Medicines Industry Association (now known as the Generic and Biosimilar Medicines Association). The measures were negotiated following consultations during the first half of 2015 by the Minister for Health and the Department of Health with stakeholders from the pharmaceutical sector including industry, consumer, medical, pharmacist and wholesaler groups. Organisations represented included Medicines Australia, the Generic Medicines Industry Association, the Consumers Health Forum, NPS MedicineWise, the Australian Medical Association, the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, the Society of Hospital Pharmacists of Australia, and the National Pharmaceutical Services Association.

The involvement of PBAC constitutes a formal and ongoing process of consultation. The PBAC is the independent expert body, established by section 100A of the Act, which makes recommendations to the Minister about which drugs and medicinal preparations should be available as pharmaceutical benefits. 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 Committee, including the option of appointing an industry member. The PBAC has provided advice regarding what should be specified in this Instrument.

This amendment is minor and machinery in nature.

General

This Instrument commences on 1 February 2016.

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 2016 (No. 1) (PB 4 of 2016)

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 2016* (No. 1) amends the *National Health (Pharmaceutical benefits—early supply) Instrument 2015* 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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