EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (PHARMACEUTICAL BENEFITS – EARLY SUPPLY) AMENDMENT INSTRUMENT 2018 (No. 7)

PB 65 of 2018

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) (the Principal Instrument).

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.

The amendments made by this Instrument reflect amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012), which commence on the same day. The *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) is made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the Act.

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).

Changes to PB 120 of 2015 made by this instrument

Schedule 1 to the Principal Instrument is amended by the addition, deletion and alteration of listed pharmaceutical items and associated periods and circumstances. These changes are summarised, by subject matter, in the Attachment.

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 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 to Australians 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. The Committee also includes a pharmaceutical industry nominee. 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. 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 August 2018.

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

ATTACHMENT

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (PHARMACEUTICAL BENEFITS – EARLY SUPPLY) AMENDMENT INSTRUMENT 2018 (No. 7)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Pharmaceutical Benefits – early supply) Amendment Instrument 2018 (No. 7)* and may also be cited as PB 65 of 2018.

Section 2 Commencement

This section provides that the Instrument commences on 1 August 2018.

Section 3 Amendment of *National Health (Pharmaceutical Benefits—early supply) Instrument 2015* (PB 120 of 2015)

This section provides that Schedule 1 amends the *National Health (Pharmaceutical Benefits—early supply) Instrument 2015* (PB 120 of 2015).

Schedule 1 Amendments

The amendments in Schedule 1 involve additions, deletions and changes to pharmaceutical items listed in Schedule 1 of the Principle Instrument and the associated periods (days) and circumstances. These changes are summarised below.

SUMMARY OF CHANGES

Forms Added

Pirfenidone	Tablet 267 mg
Pirfenidone	Tablet 801 mg

Maximum Quantity Added

Ibrutinib	Capsule 140 mg *[Maximum Quantity: 120]*

International Harmonisation of Ingredient Names – form changes

The following forms of listed drugs have been updated to align with the International Harmonisation of Ingredient Names (IHIN) reform being administered by Therapeutic Goods Administration (TGA).

Listed drug	From	To
Levodopa with carbidopa and entacapone	Tablet 100 mg-25 mg-200 mg	Tablet 100 mg-25 mg (as monohydrate)-200 mg
	Tablet 125 mg-31.25 mg-200 mg	Tablet 125 mg-31.25 mg (as monohydrate)-200 mg
	Tablet 150 mg-37.5 mg -200 mg	Tablet 150 mg-37.5 mg (as monohydrate)-200 mg
	Tablet 200 mg-50 mg-200 mg	Tablet 200 mg-50 mg (as monohydrate)-200 mg
	Tablet 50 mg-12.5 mg-200 mg	Tablet 50 mg-12.5 mg (as monohydrate)-200 mg
	Tablet 75 mg-18.75 mg-200 mg	Tablet 75 mg-18.75 mg (as monohydrate)-200 mg
Methyldopa	Tablet 250 mg	Tablet 250 mg (as sesquihydrate)
Pramipexole	Tablet (extended release) containing pramipexole hydrochloride 1.5 mg	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 1.5 mg
	Tablet (extended release) containing pramipexole hydrochloride 2.25 mg	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 2.25 mg
	Tablet (extended release) containing pramipexole hydrochloride 3 mg	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 3 mg
	Tablet (extended release) containing pramipexole hydrochloride 3.75 mg	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 3.75 mg
	Tablet (extended release) containing pramipexole hydrochloride 4.5 mg	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 4.5 mg

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 2018 (No. 7)

(PB 65 of 2018)

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 2018 (No. 7)* 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.

Schedule 1 to the Principal Instrument is amended by the addition, deletion and alteration of listed pharmaceutical items and associated periods and circumstances.

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.

Lisa La Rance
Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division
Department of Health