

## EXPLANATORY STATEMENT

### NATIONAL HEALTH ACT 1953

#### NATIONAL HEALTH (PHARMACEUTICAL BENEFITS – EARLY SUPPLY) AMENDMENT INSTRUMENT 2018 (No. 6)

#### PB 52 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 July 2018.

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

**PROVISION-BY-PROVISION DESCRIPTION OF NATIONAL HEALTH (PHARMACEUTICAL BENEFITS – EARLY SUPPLY) AMENDMENT INSTRUMENT 2018 (No. 6)**

**Section 1 Name of Instrument**

This section provides that the Instrument is the *National Health (Pharmaceutical Benefits – early supply) Amendment Instrument 2018 (No. 6)* and may also be cited as PB 52 of 2018.

**Section 2 Commencement**

This section provides that the Instrument commences on 1 July 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**

**Listed Drugs Added**

Ribociclib	Tablet 200 mg
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**Forms Deleted**

Clopidogrel	Tablet 75 mg
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**Maximum Quantity Deleted**

Balsalazide	Capsule containing balsalazide sodium 750 mg [ <i>Maximum Quantity: 180; Number of Repeats: 5</i> ]
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**International Harmonisation of Ingredient Names – listed drug changes**

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

<b>From</b>	<b>To</b>
Acidinium with eformoterol	Acidinium with formoterol
Benzhexol	Trihexyphenidyl
Esomeprazole and Clarithromycin and Amoxicillin	Esomeprazole and Clarithromycin and Amoxicillin
Oestradiol	Estradiol
Oestradiol and Oestradiol with Dydrogesterone	Estradiol and Estradiol with Dydrogesterone
Oestradiol and Oestradiol with Norethisterone	Estradiol and Estradiol with Norethisterone
Oestradiol with dydrogesterone	Estradiol with dydrogesterone
Oestradiol with Norethisterone	Estradiol with Norethisterone
Frusemide	Furosemide

Levonorgestrel with Ethinylloestradiol  
 Norethisterone with Ethinylloestradiol  
 Phenobarbitone  
 Salcatonin  
 Thyroxine

Levonorgestrel with Ethinylestradiol  
 Norethisterone with Ethinylestradiol  
 Phenobarbital  
 Calcitonin salmon  
 Levothyroxine

### 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).

<b>Listed drug</b>	<b>From</b>	<b>To</b>
<i>Aclidinium with formoterol*</i>	Powder for oral inhalation in breath actuated device containing acclidinium 340 micrograms (as bromide) with eformoterol fumarate dihydrate 12 micrograms per dose, 60 doses	Powder for oral inhalation in breath actuated device containing acclidinium 340 micrograms (as bromide) with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses
<i>Amlodipine</i>	Tablet 5 mg (as besylate) Tablet 10 mg (as besylate)	Tablet 5 mg (as besilate) Tablet 10 mg (as besilate)
<i>Amlodipine with Atorvastatin</i>	Tablet 5 mg amlodipine (as besylate) with 10 mg atorvastatin (as calcium) Tablet 5 mg amlodipine (as besylate) with 20 mg atorvastatin (as calcium) Tablet 5 mg amlodipine (as besylate) with 40 mg atorvastatin (as calcium) Tablet 5 mg amlodipine (as besylate) with 80 mg atorvastatin (as calcium) Tablet 10 mg amlodipine (as besylate) with 10 mg atorvastatin (as calcium) Tablet 10 mg amlodipine (as besylate) with 20 mg atorvastatin (as calcium) Tablet 10 mg amlodipine (as besylate) with 40 mg atorvastatin (as calcium) Tablet 10 mg amlodipine (as besylate) with 80 mg atorvastatin (as calcium)	Tablet 5 mg amlodipine (as besilate) with 10 mg atorvastatin (as calcium) Tablet 5 mg amlodipine (as besilate) with 20 mg atorvastatin (as calcium) Tablet 5 mg amlodipine (as besilate) with 40 mg atorvastatin (as calcium) Tablet 5 mg amlodipine (as besilate) with 80 mg atorvastatin (as calcium) Tablet 10 mg amlodipine (as besilate) with 10 mg atorvastatin (as calcium) Tablet 10 mg amlodipine (as besilate) with 20 mg atorvastatin (as calcium) Tablet 10 mg amlodipine (as besilate) with 40 mg atorvastatin (as calcium) Tablet 10 mg amlodipine (as besilate) with 80 mg atorvastatin (as calcium)
<i>Amlodipine with valsartan</i>	Tablet 5 mg (as besylate)-80 mg  Tablet 5 mg (as besylate)-160 mg Tablet 5 mg (as besylate)-320 mg Tablet 10 mg (as besylate)-160 mg Tablet 10 mg (as besylate)-320 mg	Tablet 5 mg (as besilate)-80 mg  Tablet 5 mg (as besilate)-160 mg Tablet 5 mg (as besilate)-320 mg Tablet 10 mg (as besilate)-160 mg Tablet 10 mg (as besilate)-320 mg
<i>Amlodipine with valsartan and hydrochlorothiazide</i>	Tablet 5 mg (as besylate)-160 mg-12.5 mg  Tablet 5 mg (as besylate)-160 mg-25 mg Tablet 10 mg (as besylate)-160 mg-12.5 mg Tablet 10 mg (as besylate)-160 mg-25 mg Tablet 10 mg (as besylate)-320 mg-25 mg	Tablet 5 mg (as besilate)-160 mg-12.5 mg  Tablet 5 mg (as besilate)-160 mg-25 mg Tablet 10 mg (as besilate)-160 mg-12.5 mg Tablet 10 mg (as besilate)-160 mg-25 mg Tablet 10 mg (as besilate)-320 mg-25 mg
<i>Eprosartan</i>	Tablet 400 mg (as mesylate) Tablet 600 mg (as mesylate)	Tablet 400 mg (as mesilate) Tablet 600 mg (as mesilate)
<i>Eprosartan with Hydrochlorothiazide</i>	Tablet 600 mg eprosartan (as mesylate) with 12.5 mg hydrochlorothiazide	Tablet 600 mg eprosartan (as mesilate) with 12.5 mg hydrochlorothiazide
<i>Esomeprazole and Clarithromycin and</i>	Pack containing 14 tablets (enteric coated) containing esomeprazole 20 mg (as	Pack containing 14 tablets (enteric coated) containing esomeprazole 20 mg (as

<i>Amoxicillin*</i>	<p>magnesium), 14 tablets clarithromycin 500 mg and 28 capsules amoxicillin 500 mg (as trihydrate)</p> <p>Pack containing 14 tablets (enteric coated) containing esomeprazole 20 mg (as magnesium trihydrate), 14 tablets clarithromycin 500 mg and 28 capsules amoxicillin 500 mg (as trihydrate)</p>	<p>magnesium), 14 tablets clarithromycin 500 mg and 28 capsules amoxicillin 500 mg (as trihydrate)</p> <p>Pack containing 14 tablets (enteric coated) containing esomeprazole 20 mg (as magnesium trihydrate), 14 tablets clarithromycin 500 mg and 28 capsules amoxicillin 500 mg (as trihydrate)</p>
<i>Estradiol*</i>	<p>Tablet containing oestradiol valerate 1 mg</p> <p>Tablet containing oestradiol valerate 2 mg</p>	<p>Tablet containing estradiol valerate 1 mg</p> <p>Tablet containing estradiol valerate 2 mg</p>
<i>Estradiol and Estradiol with Dydrogesterone*</i>	<p>Pack containing 14 tablets oestradiol 1 mg and 14 tablets oestradiol 1 mg with dydrogesterone 10 mg</p> <p>Pack containing 14 tablets oestradiol 2 mg and 14 tablets oestradiol 2 mg with dydrogesterone 10 mg</p>	<p>Pack containing 14 tablets estradiol 1 mg and 14 tablets estradiol 1 mg with dydrogesterone 10 mg</p> <p>Pack containing 14 tablets estradiol 2 mg and 14 tablets estradiol 2 mg with dydrogesterone 10 mg</p>
<i>Estradiol and Estradiol with Norethisterone*</i>	<p>Pack containing 4 transdermal patches 780 micrograms oestradiol (as hemihydrate) and 4 transdermal patches 620 micrograms oestradiol (as hemihydrate) with 2.7 mg norethisterone acetate</p> <p>Pack containing 4 transdermal patches 780 micrograms oestradiol (as hemihydrate) and 4 transdermal patches 510 micrograms oestradiol (as hemihydrate) with 4.8 mg norethisterone acetate</p>	<p>Pack containing 4 transdermal patches 780 micrograms estradiol (as hemihydrate) and 4 transdermal patches 620 micrograms estradiol (as hemihydrate) with 2.7 mg norethisterone acetate</p> <p>Pack containing 4 transdermal patches 780 micrograms estradiol (as hemihydrate) and 4 transdermal patches 510 micrograms estradiol (as hemihydrate) with 4.8 mg norethisterone acetate</p>
<i>Estradiol with Norethisterone*</i>	<p>Transdermal patches containing 620 micrograms oestradiol (as hemihydrate) with 2.7 mg norethisterone acetate, 8</p> <p>Transdermal patches containing 510 micrograms oestradiol (as hemihydrate) with 4.8 mg norethisterone acetate, 8</p>	<p>Transdermal patches containing 620 micrograms estradiol (as hemihydrate) with 2.7 mg norethisterone acetate, 8</p> <p>Transdermal patches containing 510 micrograms estradiol (as hemihydrate) with 4.8 mg norethisterone acetate, 8</p>
<i>Levothyroxine*</i>	<p>Tablet containing 50 micrograms anhydrous thyroxine sodium</p> <p>Tablet containing 75 micrograms anhydrous thyroxine sodium</p> <p>Tablet containing 100 micrograms anhydrous thyroxine sodium</p> <p>Tablet containing 200 micrograms anhydrous thyroxine sodium</p>	<p>Tablet containing 50 micrograms anhydrous levothyroxine sodium</p> <p>Tablet containing 75 micrograms anhydrous levothyroxine sodium</p> <p>Tablet containing 100 micrograms anhydrous levothyroxine sodium</p> <p>Tablet containing 200 micrograms anhydrous levothyroxine sodium</p>
<i>Olmesartan with amlodipine</i>	<p>Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besylate)</p> <p>Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besylate)</p> <p>Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besylate)</p>	<p>Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate)</p> <p>Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate)</p> <p>Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate)</p>
<i>Perindopril with amlodipine</i>	<p>Tablet containing 5 mg perindopril arginine with 5 mg amlodipine (as besylate)</p> <p>Tablet containing 5 mg perindopril arginine with 10 mg amlodipine (as besylate)</p> <p>Tablet containing 10 mg perindopril</p>	<p>Tablet containing 5 mg perindopril arginine with 5 mg amlodipine (as besilate)</p> <p>Tablet containing 5 mg perindopril arginine with 10 mg amlodipine (as besilate)</p> <p>Tablet containing 10 mg perindopril</p>

	arginine with 5 mg amlodipine (as besylate)	arginine with 5 mg amlodipine (as besilate)
	Tablet containing 10 mg perindopril arginine with 10 mg amlodipine (as besylate)	Tablet containing 10 mg perindopril arginine with 10 mg amlodipine (as besilate)
<i>Sorafenib</i>	Tablet 200 mg (as tosylate)	Tablet 200 mg (as tosilate)
<i>Telmisartan with amlodipine</i>	Tablet 40 mg 5 mg (as besylate)	Tablet 40 mg 5 mg (as besilate)
	Tablet 40 mg 10 mg (as besylate)	Tablet 40 mg 10 mg (as besilate)
	Tablet 80 mg 5 mg (as besylate)	Tablet 80 mg 10 mg (as besilate)
<i>Trihexyphenidyl*</i>	Tablet containing benzhexol hydrochloride 2 mg	Tablet containing trihexyphenidyl hydrochloride 2 mg
	Tablet containing benzhexol hydrochloride 5 mg	Tablet containing trihexyphenidyl hydrochloride 5 mg

\* New listed drug name (refer to table: *International Harmonisation of Ingredient Names – listed drug changes*)

## **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. 6)*** **(PB 52 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. 6)* 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.

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