**EXPLANATORY STATEMENT**

***NATIONAL HEALTH ACT 1953***

***NATIONAL HEALTH (PHARMACEUTICAL BENEFITS – EARLY SUPPLY) AMENDMENT INSTRUMENT 2023 (No. 7)***

**PB 80 of 2023**

**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:

1. The pharmaceutical item in the pharmaceutical benefit is specified in an instrument under subsection 84AAA(2); and
2. the supply is made within 20 days after the day of a previous supply to the person of:
3. the same pharmaceutical benefit; or
4. another pharmaceutical benefit that has the same pharmaceutical item as the pharmaceutical benefit; or
5. another pharmaceutical benefit that is Schedule equivalent to the pharmaceutical benefit; and
6. 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 and British Commonwealth Occupation Force (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).

**Changes to PB 120 of 2015 made by this instrument**

Schedule 1 to this instrument provides for the addition of listed drugs adapalene with benzoyl peroxide, azacitidine, calcipotriol with betamethasone, chlortalidone, isosorbide dinitrate, pancreatic extract, patiromer, penicillamine, and thiamine, and the addition of forms of the listed drugs calcium, furosemide, and glyceryl trinitrate. It also provides for the addition of maximum quantities and number of repeats for 82 listed drugs, the deletion of the listed drugs losartan and norethisterone with mestranol, and the deletion of a form of the listed drug propranolol from the list of pharmaceutical benefits for which PBS safety net entitlements will not apply for early supplies.

These changes are summarised by subject matter in the Attachment.

**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**

A provision-by-provision description of this Instrument is contained in the Attachment.

This Instrument commences on 1 September 2023.

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 2023 (No. 7)***

**Section 1 Name of Instrument**

This section provides that the Instrument is the *National Health (Pharmaceutical benefits – early supply) Amendment Instrument 2023 (No. 7)* and may also be cited as PB 80 of 2023.

**Section 2 Commencement**

This section provides that the Instrument commences on 1 September 2023.

**Section 3 Authority**

This section states that this Instrument is made under subsection 84AAA(2) of the *National Health Act 1953.*

**Section 4** **Schedules**

Section 4 provides that each instrument that is specified in a Schedule to the Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Instrument has effect according to its terms.

**Schedule 1 Amendments**

The amendments in Schedule 1 involve the addition and deletion of listed drugs, the addition and deletion of forms of listed drugs, and the addition of maximum quantities and number of repeats of listed drugs for the list of pharmaceutical benefits for which PBS safety net entitlements will not apply for early supplies. These changes are summarised below.

**SUMMARY OF CHANGES TO THE *NATIONAL HEALTH (PHARMACEUTICAL BENEFITS—EARLY SUPPLY) INSTRUMENT 2015* MADE BY THIS INSTRUMENT**

**Drugs Added**

|  |
| --- |
| ***Listed Drug*** |
| Adapalene with benzoyl peroxide |
| Azacitidine |
| Calcipotriol with betamethasone |
| Chlortalidone |
| Isosorbide dinitrate |
| Pancreatic extract |
| Patiromer |
| Penicillamine |
| Thiamine |

**Drugs Deleted**

|  |
| --- |
| ***Listed Drug*** |
| Losartan |
| Norethisterone with mestranol |

**Forms Added**

|  |  |
| --- | --- |
| ***Listed Drug*** | ***Form*** |
| Calcium | Tablet, chewable, 500 mg (as carbonate) |
| Furosemide | Oral solution 10 mg per mL, 30 mL |
| Tablet 500 mg |
| Glyceryl trinitrate | Sublingual spray (pump pack) 400 micrograms per dose, 200 doses |

**Form Deleted**

|  |  |
| --- | --- |
| ***Listed Drug*** | ***Form*** |
| Propranolol | Tablet containing propranolol hydrochloride 160 mg |

**Addition of Maximum Quantity and Number of Repeats**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Listed Drug*** | ***Form*** | ***Maximum Quantity*** | ***Number of Repeats*** |
| Alendronic acid | Tablet 70 mg (as alendronate sodium) | 8 | 5 |
| Allopurinol | Tablet 100 mg | 400 | 2 |
| Tablet 300 mg | 120 | 2 |
| Amlodipine | Tablet 5 mg (as besilate) | 60 | 5 |
| Tablet 10 mg (as besilate) | 60 | 5 |
| Amlodipine with atorvastatin | Tablet 5 mg amlodipine (as besilate) with 10 mg atorvastatin (as calcium) | 60 | 5 |
| Tablet 5 mg amlodipine (as besilate) with 20 mg atorvastatin (as calcium) | 60 | 5 |
| Tablet 5 mg amlodipine (as besilate) with 40 mg atorvastatin (as calcium) | 60 | 5 |
| Tablet 5 mg amlodipine (as besilate) with 80 mg atorvastatin (as calcium) | 60 | 5 |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Tablet 10 mg amlodipine (as besilate) with 10 mg atorvastatin (as calcium) | 60 | 5 |
| Tablet 10 mg amlodipine (as besilate) with 20 mg atorvastatin (as calcium) | 60 | 5 |
| Tablet 10 mg amlodipine (as besilate) with 40 mg atorvastatin (as calcium) | 60 | 5 |
| Amlodipine with valsartan | Tablet 5 mg (as besilate)‑80 mg | 56 | 5 |
| Tablet 5 mg (as besilate)‑160 mg | 56 | 5 |
| Tablet 5 mg (as besilate)‑320 mg | 56 | 5 |
| Tablet 10 mg (as besilate)‑160 mg | 56 | 5 |
| Tablet 10 mg (as besilate)‑320 mg | 56 | 5 |
| Amlodipine with valsartan and hydrochlorothiazide | Tablet 5 mg (as besilate)‑160 mg‑12.5 mg | 56 | 5 |
| Tablet 5 mg (as besilate)‑160 mg‑25 mg | 56 | 5 |
| Tablet 10 mg (as besilate)‑160 mg‑12.5 mg | 56 | 5 |
| Tablet 10 mg (as besilate)‑160 mg‑25 mg | 56 | 5 |
| Tablet 10 mg (as besilate)‑320 mg‑25 mg | 56 | 5 |
| Apixaban | Tablet 2.5 mg | 120 | 5 |
| Tablet 5 mg | 120 | 5 |
| Atenolol | Oral solution 50 mg in 10 mL, 300 mL | 2 | 5 |
| Tablet 50 mg | 60 | 5 |
| Atorvastatin | Tablet 10 mg (as calcium) | 60 | 5 |
| Tablet 20 mg (as calcium) | 60 | 5 |
| Tablet 40 mg (as calcium) | 60 | 5 |
| Tablet 80 mg (as calcium) | 60 | 5 |
| Baclofen | Tablet 10 mg | 200 | 5 |
| Tablet 25 mg | 200 | 5 |
| Balsalazide | Capsule containing balsalazide sodium 750 mg | 560 | 5 |
| Bisoprolol | Tablet containing bisoprolol fumarate 2.5 mg | 56 | 5 |
| Tablet containing bisoprolol fumarate 5 mg | 56 | 5 |
| Tablet containing bisoprolol fumarate 10 mg | 56 | 5 |
| Calcitriol | Capsule 0.25 microgram | 200 | 3 |
| Calcium | Tablet 600 mg (as carbonate) | 480 | 1 |
| Candesartan | Tablet containing candesartan cilexetil 4 mg | 60 | 5 |
| Tablet containing candesartan cilexetil 8 mg | 60 | 5 |
| Tablet containing candesartan cilexetil 16 mg | 60 | 5 |
| Tablet containing candesartan cilexetil 32 mg | 60 | 5 |
| Candesartan with hydrochlorothiazide | Tablet containing candesartan cilexetil 16 mg with hydrochlorothiazide 12.5 mg | 60 | 5 |
| Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 mg | 60 | 5 |
| Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg | 60 | 5 |
| Carvedilol | Tablet 6.25 mg | 120 | 5 |
| Tablet 12.5 mg | 120 | 5 |
| Tablet 25 mg | 120 | 5 |
| Clonidine | Tablet containing clonidine hydrochloride 100 micrograms | 200 | 5 |
| Tablet containing clonidine hydrochloride 150 micrograms | 200 | 5 |
| Clopidogrel | Tablet 75 mg (as besilate) | 56 | 5 |
| Tablet 75 mg (as hydrogen sulfate) | 56 | 5 |
| Clopidogrel with aspirin | Tablet 75 mg (as hydrogen sulfate)‑100 mg | 60 | 5 |
| Dabigatran etexilate | Capsule 110 mg (as mesilate) | 120 | 5 |
| Capsule 150 mg (as mesilate) | 120 | 5 |
| Enalapril | Tablet containing enalapril maleate 5 mg | 60 | 5 |
| Tablet containing enalapril maleate 10 mg | 60 | 5 |
| Tablet containing enalapril maleate 20 mg | 60 | 5 |
| Enalapril with hydrochlorothiazide | Tablet containing enalapril maleate 20 mg with hydrochlorothiazide 6 mg | 60 | 5 |
| Eplerenone | Tablet 25 mg | 60 | 5 |
| Tablet 50 mg | 60 | 5 |
| Ezetimibe | Tablet 10 mg | 60 | 5 |
| Ezetimibe and rosuvastatin | Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 5 mg (as calcium) | 2 | 5 |
| Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 10 mg (as calcium) | 2 | 5 |
| Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 20 mg (as calcium) | 2 | 5 |
| Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 40 mg (as calcium) | 2 | 5 |
| Ezetimibe with atorvastatin | Tablet 10 mg‑10 mg | 60 | 5 |
| Tablet 10 mg‑20 mg | 60 | 5 |
| Tablet 10 mg‑40 mg | 60 | 5 |
| Tablet 10 mg‑80 mg | 60 | 5 |
| Ezetimibe with simvastatin | Tablet 10 mg‑10 mg | 60 | 5 |
| Tablet 10 mg‑20 mg | 60 | 5 |
| Tablet 10 mg‑40 mg | 60 | 5 |
| Tablet 10 mg‑80 mg | 60 | 5 |
| Febuxostat | Tablet 80 mg | 56 | 5 |
| Felodipine | Tablet 2.5 mg (extended release) | 60 | 5 |
| Tablet 5 mg (extended release) | 60 | 5 |
| Tablet 10 mg (extended release) | 60 | 5 |
| Fenofibrate | Tablet 48 mg | 120 | 5 |
| Tablet 145 mg | 60 | 5 |
| Fluvastatin | Tablet (prolonged release) 80 mg (as sodium) | 56 | 5 |
| Furosemide | Tablet 20 mg | 200 | 1 |
| Tablet 40 mg | 200 | 1 |
| Gemfibrozil | Tablet 600 mg | 120 | 5 |
| Glyceryl trinitrate | Transdermal patch 25 mg | 60 | 5 |
| Transdermal patch 50 mg | 60 | 5 |
| Hydrochlorothiazide | Tablet 25 mg | 200 | 1 |
| Hydrochlorothiazide with amiloride | Tablet containing hydrochlorothiazide 50 mg with amiloride hydrochloride 5 mg | 200 | 1 |
| Indapamide | Tablet containing indapamide hemihydrate 1.5 mg (sustained release) | 180 | 1 |
| Tablet containing indapamide hemihydrate 2.5 mg | 180 | 1 |
| Irbesartan | Tablet 75 mg | 60 | 5 |
| Tablet 150 mg | 60 | 5 |
| Tablet 300 mg | 60 | 5 |
| Irbesartan with hydrochlorothiazide | Tablet 150 mg‑12.5 mg | 60 | 5 |
| Tablet 300 mg‑12.5 mg | 60 | 5 |
| Tablet 300 mg‑25 mg | 60 | 5 |
| Isosorbide mononitrate | Tablet 60 mg (sustained release) | 60 | 5 |
| Tablet 120 mg (sustained release) | 60 | 5 |
| Lercanidipine | Tablet containing lercanidipine hydrochloride 10 mg | 56 | 5 |
| Tablet containing lercanidipine hydrochloride 20 mg | 56 | 5 |
| Lercanidipine with enalapril | Tablet containing lercanidipine hydrochloride 10 mg with enalapril maleate 10 mg | 56 | 5 |
| Tablet containing lercanidipine hydrochloride 10 mg with enalapril maleate 20 mg | 56 | 5 |
| Lisinopril | Tablet 5 mg | 60 | 5 |
| Tablet 10 mg | 60 | 5 |
| Tablet 20 mg | 60 | 5 |
| Mesalazine | Sachet containing granules, 500 mg per sachet | 400 | 5 |
| Sachet containing granules, 1 g per sachet | 200 | 5 |
| Sachet containing granules, 1.5 g per sachet | 120 | 5 |
| Sachet containing granules, 3 g per sachet | 60 | 5 |
| Sachet containing prolonged release granules, 1 g per sachet | 200 | 5 |
| Sachet containing prolonged release granules, 2 g per sachet | 120 | 5 |
| Sachet containing prolonged release granules, 4 g per sachet | 60 | 5 |
| Tablet 250 mg (enteric coated) | 200 | 5 |
| Tablet 500 mg (enteric coated) | 400 | 5 |
| Tablet 500 mg (prolonged release) | 400 | 5 |
| Tablet 800 mg (enteric coated) | 180 | 5 |
| Tablet 1 g (enteric coated) | 240 | 5 |
| Tablet 1 g (prolonged release) | 240 | 5 |
| Tablet 1.2 g (prolonged release) | 240 | 5 |
| Tablet 1.6 g (enteric coated) | 240 | 4 |
| Metoprolol | Tablet containing metoprolol tartrate 50 mg | 200 | 5 |
| Tablet containing metoprolol tartrate 100 mg | 120 | 5 |
| Metoprolol succinate | Tablet 47.5 mg (controlled release) | 60 | 5 |
| Tablet 95 mg (controlled release) | 60 | 5 |
| Tablet 190 mg (controlled release) | 60 | 5 |
| Moxonidine | Tablet 200 micrograms | 60 | 5 |
| Tablet 400 micrograms | 60 | 5 |
| Nebivolol | Tablet 1.25 mg (as hydrochloride) | 112 | 5 |
| Tablet 5 mg (as hydrochloride) | 56 | 5 |
| Tablet 10 mg (as hydrochloride) | 56 | 5 |
| Nicorandil | Tablets 10 mg, 60 | 2 | 5 |
| Tablets 20 mg, 60 | 2 | 5 |
| Nifedipine | Tablet 30 mg (controlled release) | 60 | 5 |
| Tablet 60 mg (controlled release) | 60 | 5 |
| Olmesartan | Tablet containing olmesartan medoxomil 20 mg | 60 | 5 |
| Tablet containing olmesartan medoxomil 40 mg | 60 | 5 |
| Olmesartan with amlodipine | Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate) | 60 | 5 |
| Olmesartan with amlodipine and hydrochlorothiazide | Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg | 60 | 5 |
| Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg | 60 | 5 |
| Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 25 mg | 60 | 5 |
| Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 12.5 mg | 60 | 5 |
| Olmesartan with hydrochlorothiazide | Tablet containing olmesartan medoxomil 20 mg with hydrochlorothiazide 12.5 mg | 60 | 5 |
| Tablet containing olmesartan medoxomil 40 mg with hydrochlorothiazide 12.5 mg | 60 | 5 |
| Tablet containing olmesartan medoxomil 40 mg with hydrochlorothiazide 25 mg | 60 | 5 |
| Perindopril | Tablet containing perindopril arginine 2.5 mg | 60 | 5 |
| Tablet containing perindopril arginine 5 mg | 60 | 5 |
| Tablet containing perindopril arginine 10 mg | 60 | 5 |
| Tablet containing perindopril erbumine 2 mg | 60 | 5 |
| Tablet containing perindopril erbumine 4 mg | 60 | 5 |
| Tablet containing perindopril erbumine 8 mg | 60 | 5 |
| Perindopril with amlodipine | Tablet containing 5 mg perindopril arginine with 5 mg amlodipine (as besilate) | 60 | 5 |
| Tablet containing 5 mg perindopril arginine with 10 mg amlodipine (as besilate) | 60 | 5 |
| Tablet containing 10 mg perindopril arginine with 5 mg amlodipine (as besilate) | 60 | 5 |
| Tablet containing 10 mg perindopril arginine with 10 mg amlodipine (as besilate) | 60 | 5 |
| Perindopril with indapamide | Tablet containing perindopril arginine 2.5 mg with indapamide hemihydrate 0.625 mg | 60 | 5 |
| Tablet containing perindopril arginine 5 mg with indapamide hemihydrate 1.25 mg | 60 | 5 |
| Tablet containing perindopril erbumine 4 mg with indapamide hemihydrate 1.25 mg | 60 | 5 |
| Potassium chloride | Tablet 600 mg (sustained release) | 400 | 1 |
| Potassium chloride with potassium bicarbonate | Tablet, effervescent, 14 mmol potassium and 8 mmol chloride | 120 | 1 |
| Pravastatin | Tablet containing pravastatin sodium 10 mg | 60 | 5 |
| Tablet containing pravastatin sodium 20 mg | 60 | 5 |
| Tablet containing pravastatin sodium 40 mg | 60 | 5 |
| Tablet containing pravastatin sodium 80 mg | 60 | 5 |
| Prazosin | Tablet 1 mg (as hydrochloride) | 200 | 5 |
| Tablet 2 mg (as hydrochloride) | 200 | 5 |
| Tablet 5 mg (as hydrochloride) | 200 | 5 |
| Propranolol | Tablet containing propranolol hydrochloride 10 mg | 200 | 5 |
| Tablet containing propranolol hydrochloride 40 mg | 200 | 5 |
| Raloxifene | Tablet containing raloxifene hydrochloride 60 mg | 56 | 5 |
| Ramipril | Capsule 1.25 mg | 60 | 5 |
| Capsule 2.5 mg | 60 | 5 |
| Capsule 5 mg | 60 | 5 |
| Capsule 10 mg | 60 | 5 |
| Tablet 1.25 mg | 60 | 5 |
| Tablet 2.5 mg | 60 | 5 |
| Tablet 5 mg | 60 | 5 |
| Tablet 10 mg | 60 | 5 |
| Ramipril with felodipine | Tablet 2.5 mg‑2.5 mg (modified release) | 60 | 5 |
| Tablet 5 mg‑5 mg (modified release) | 60 | 5 |
| Risedronic acid | Tablet containing risedronate sodium 5 mg | 56 | 5 |
| Tablet containing risedronate sodium 35 mg | 8 | 5 |
| Tablet containing risedronate sodium 150 mg | 2 | 5 |
| Tablet (enteric coated) containing risedronate sodium 35 mg | 8 | 5 |
| Rivaroxaban | Tablet 2.5 mg | 120 | 5 |
| Tablet 10 mg | 60 | 5 |
| Tablet 15 mg | 56 | 5 |
| Tablet 20 mg | 56 | 5 |
| Rosuvastatin | Tablet 5 mg (as calcium) | 60 | 5 |
| Tablet 10 mg (as calcium) | 60 | 5 |
| Tablet 20 mg (as calcium) | 60 | 5 |
| Tablet 40 mg (as calcium) | 60 | 5 |
| Sacubitril with valsartan | Tablet containing sacubitril 24.3 mg with valsartan 25.7 mg | 112 | 5 |
| Tablet containing sacubitril 48.6 mg with valsartan 51.4 mg | 112 | 5 |
| Tablet containing sacubitril 97.2 mg with valsartan 102.8 mg | 112 | 5 |
| Simvastatin | Tablet 5 mg | 60 | 5 |
| Tablet 10 mg | 60 | 5 |
| Tablet 20 mg | 60 | 5 |
| Tablet 40 mg | 60 | 5 |
| Tablet 80 mg | 60 | 5 |
| Spironolactone | Tablet 25 mg | 200 | 5 |
| Sulfasalazine | Tablet 500 mg | 400 | 5 |
| Tablet 500 mg (enteric coated) | 400 | 5 |
| Telmisartan | Tablet 40 mg | 56 | 5 |
| Tablet 80 mg | 56 | 5 |
| Telmisartan with amlodipine | Tablet 40 mg‑5 mg (as besilate) | 56 | 5 |
| Tablet 40 mg‑10 mg (as besilate) | 56 | 5 |
| Tablet 80 mg‑5 mg (as besilate) | 56 | 5 |
| Tablet 80 mg‑10 mg (as besilate) | 56 | 5 |
| Telmisartan with hydrochlorothiazide | Tablet 40 mg‑12.5 mg | 56 | 5 |
| Tablet 80 mg‑12.5 mg | 56 | 5 |
| Tablet 80 mg‑25 mg | 56 | 5 |
| Ticagrelor | Tablet 90 mg | 112 | 5 |
| Trandolapril | Capsule 500 micrograms | 56 | 5 |
| Capsule 1 mg | 56 | 5 |
| Capsule 2 mg | 56 | 5 |
| Capsule 4 mg | 56 | 5 |
| Trandolapril with verapamil | Tablet containing trandolapril 2 mg with verapamil hydrochloride 180 mg (sustained release) | 56 | 5 |
| Tablet containing trandolapril 4 mg with verapamil hydrochloride 240 mg (sustained release) | 56 | 5 |
| Valsartan | Tablet 80 mg | 56 | 5 |
| Tablet 160 mg | 56 | 5 |
| Tablet 320 mg | 56 | 5 |
| Valsartan with hydrochlorothiazide | Tablet 80 mg‑12.5 mg | 56 | 5 |
| Tablet 160 mg‑12.5 mg | 56 | 5 |
| Tablet 160 mg‑25 mg | 56 | 5 |
| Tablet 320 mg‑12.5 mg | 56 | 5 |
| Tablet 320 mg‑25 mg | 56 | 5 |
| Verapamil | Tablet containing verapamil hydrochloride 80 mg | 200 | 5 |
| Tablet containing verapamil hydrochloride 180 mg (sustained release) | 60 | 5 |
| Tablet containing verapamil hydrochloride 240 mg (sustained release) | 60 | 5 |

**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 2023 (No. 7)***

**(PB 80 of 2023)**

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 2023 (No. 7)* (the Instrument) amends the *National Health (Pharmaceutical benefits—early supply) Instrument 2015* (PB 120 of 2015) (the Principal Instrument), which specifies the pharmaceutical items that are pharmaceutical benefits, and the respective benefits’ “early supply” periods (days elapsed since previous supply), for which Pharmaceutical Benefits Scheme (PBS) Safety Net entitlements will not apply for early supplies.

The effect of a pharmaceutical benefit being an early supply is that the patient payment for that prescription does not count towards the PBS safety net threshold, and, if the PBS safety net threshold has been reached and the operation of the PBS safety net would normally allow a concessional or nil contribution for the prescription, the patient payment and the amount paid by the Commonwealth to the pharmacy or other approved supplier revert to pre-PBS safety net amounts.

**Human rights implications**

This Instrument engages Articles 9 and 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), specifically the rights to health and social security.

*The Right to Social Security*

The right to social security is contained in Article 9 of the International Covenant on Economic Social and Cultural Rights (ICESCR). It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The UN Committee on Economic Social and Cultural Rights (the Committee) reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

*The Right to Health*

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The Committee has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the ‘highest attainable standard of health’ takes into account the country’s available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

**Analysis**

This Instrument engages the right to health and the right to social security because drugs listed in this Instrument mean that safety net benefits will not apply for resupplies of these medicines when they are obtained earlier than 20 days from the previous supply. This limitation is reasonable, necessary and proportionate, as early supply arrangements support the quality use of medicines and responsible use of PBS entitlements as well as discouraging waste and reducing the quantity of unused medicines in the community. The listing of new and innovative medicines relies on using PBS funding responsibly and keeping the PBS sustainable.

The PBS is a benefit scheme which assists with advancement of these human rights by providing patients subsidised access 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.

This Instrument reflects amendments made to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* to advance the right to health and the right to social security by providing new increased maximum dispensed quantities (MDQs) of 82 existing listed PBS drugs for patients with chronic stable medical conditions (eligible patients) equivalent to two months’ supply. Currently, under the PBS prescribers can only write a prescription for eligible patients directing one month’s supply of these drugs to be dispensed on the one occasion. This will increase the amount of these drugs that eligible patients can receive for a single co-payment, which allows for greater patient access to these drugs, convenience and financial savings.

This instrument also provides for the addition of listed drugs adapalene with benzoyl peroxide, azacitidine, calcipotriol with betamethasone, chlortalidone, isosorbide dinitrate, pancreatic extract, patiromer, penicillamine, and thiamine, the addition of forms of the listed drugs calcium, furosemide, and glyceryl trinitrate, the deletion of the listed drugs losartan and norethisterone with mestranol, and the deletion of a form of the listed drug propranolol for the list of pharmaceutical benefits for which PBS safety net entitlements will not apply for early supplies.

When a sponsor submits a request to delist a drug from the PBS, subsection 101(4AAB) of the *National Health Act 1953* requires that the Minister or their delegate obtain advice from the Pharmaceutical Benefits Advisory Committee (PBAC), an independent and expert advisory body, before varying or revoking declarations under subsection 85(2) so as to delist the drug. In these instances, one of the matters which the PBAC provides advice on is whether the delisting of a drug will result in an unmet clinical need for patients. The PBAC also considers whether the delisting of a form of a drug will result in an unmet clinical need for patients.

The drug losartan in the forms tablet containing losartan potassium 25 mg, and tablet containing losartan potassium 50 mg was requested to be delisted from the PBS by the sponsor. The PBAC noted the low number of services in the last financial year and that there are several alternatives on the PBS. The PBAC advised the delisting of these products would not result in an unmet clinical need. These items were available on the Schedule under Supply Only arrangements for a period of up to 12 months, allowing patients with a pre‑existing valid prescription to access this item pending transition to an alternative treatment option.

The drug norethisterone with mestranol in the form pack containing 21 tablets 1 mg-50 micrograms and 7 inert tablets (Norinyl-1/28) was requested to be delisted from the PBS by the sponsor. The PBAC noted the product was being discontinued by the sponsor and that there were available clinical alternatives. The PBAC advised the delisting of this product would not result in an unmet clinical need. This item was available on the Schedule under Supply Only arrangements for a period of up to 12 months, allowing patients with a pre‑existing valid prescription to access this item pending transition to an alternative treatment option.

The drug propranolol in the form tablet containing propranolol hydrochloride 160 mg was requested to be delisted from the PBS by the sponsor. The PBAC noted the low number of services and the availability of multiple alternatives on the PBS, including the 10 mg and 40 mg tablet forms of propranolol. The PBAC advised the delisting of this product would not result in an unmet clinical need. This item was available on the Schedule under Supply Only arrangements for a period of up to 12 months, allowing patients with a pre‑existing valid prescription to access this item pending transition to an alternative treatment option.

**Conclusion**

This Instrument is compatible with human rights because it advances the protection of human rights.

**Nikolai Tsyganov**

**Assistant Secretary**

**Pricing and PBS Policy Branch**

**Technology Assessment and Access Division**

**Department of Health and Aged Care**