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:

(a) The pharmaceutical item in the pharmaceutical benefit is specified in an instrument under subsection 84AAA(2); and

(b) 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; 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 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.

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