

EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT (MARCH UPDATE) INSTRUMENT 2025

PB 13 of 2025

Purpose

The purpose of this legislative instrument, made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953* (the Act), is to amend the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (PB 26 of 2024) to make changes to the pharmaceutical benefits listed for the purposes of the Pharmaceutical Benefits Scheme (PBS), and related matters.

The *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* determines the pharmaceutical benefits that are on the Schedule of Pharmaceutical Benefits (the PBS Schedule) through declarations of drugs and medicinal preparations, and for ready-prepared benefits: determinations of forms, manners of administration and brands. It also provides for related matters (equivalent brands, responsible persons, prescribing circumstances, maximum quantities, number of repeats, determined quantity and pack quantity, section 100 only status and prescriber bag only status).

Authority

This Instrument exercises various powers in Part VII of the Act, as set out below:

Pharmaceutical benefits listed on the PBS

Subsection 85(2) provides that the Minister may declare drugs and medicinal preparations to which Part VII applies. A drug or medicinal preparation for which there is a declaration in force under subsection 85(2) is a ‘listed drug’ (subsection 84(1)). Subsections 85(3) and 85(5) respectively provide that the Minister may determine the form or forms of a listed drug and the manner of administration of a form of a listed drug. A listed drug in a determined form with a determined manner of administration for that form is a pharmaceutical item (section 84AB). Subsection 85(6) provides that the Minister may determine a brand of a pharmaceutical item.

The Minister may also determine the responsible person for a brand of a pharmaceutical item (subsection 84AF(1)). Under the provisions of section 84AK the Minister may determine the determined quantity and pack quantity for a brand of a pharmaceutical item.

Prescribing pharmaceutical benefits

Paragraph 85A(2)(a) allows the Minister to determine the maximum quantity or number of units of the pharmaceutical item in a pharmaceutical benefit (or of the pharmaceutical benefit where there is no pharmaceutical item) that may, in one prescription, be directed to be supplied on one occasion. Paragraph 85A(2)(b) also allows the Minister to determine the maximum number of occasions on which the supply of the pharmaceutical benefit may, in one prescription, be directed to be repeated. The maximum quantities and repeats may be determined for all purposes or for particular purposes.

Subsection 85(7) provides that the Minister may determine the circumstances in which a prescription may be written for the supply of a pharmaceutical benefit.

Section 88 provides that the Minister may determine the pharmaceutical benefits that may be prescribed by different classes of prescribers, including medical practitioners (subsection 88(1)), participating dental practitioners (subsection 88(1A)), authorised optometrists (subsection 88(1C)), authorised midwives (subsection 88(1D)) and authorised nurse practitioners (subsection 88(1E)).

Paragraph 88(1EB) provides that the Minister can list pharmaceutical benefits without determining any authorised prescribers for the benefit allowing the benefit to be supplied only.

This legislative instrument is made pursuant to section 88 and subsection 100(2) of the Act.

Supplying pharmaceutical benefits

Subsection 85(2A) provides that the Minister must declare that a particular listed drug can only be provided under a special arrangement under section 100 if the Pharmaceutical Benefits Advisory Committee (PBAC) has recommended under subsection 101(4AAD) that the drug be made available only under special arrangements under section 100.

Subsection 85(2AA) provides that the Minister must declare that a particular listed drug can only be provided under one or more of the prescriber bag provisions if the PBAC has recommended under subsection 101(4AACA) that the drug be made available only under one or more of the prescriber bag provisions.

Subsection 85(6A) provides that the Minister may also determine for the purposes of paragraph 103(2A)(b) that a brand of a pharmaceutical item determined under subsection 85(6) is to be treated as equivalent to one or more other brands of pharmaceutical items.

Paragraph 85(7A) provides that the Minister may determine that a particular pharmaceutical benefit may only be supplied under one or more of the prescriber bag provisions.

Paragraph 85(8)(a) provides that the Minister may determine that a particular pharmaceutical benefit may only be supplied under special arrangements under section 100.

Paragraph 85(8)(b) provides that the Minister may determine that a particular pharmaceutical benefit may only be supplied under special arrangements under section 100 for one or more of the circumstances determined for that pharmaceutical benefit under subsection 85(7).

Variation and revocation

Unless there is an express power to revoke or vary PB 26 of 2024 cited in this Instrument and explanatory statement, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary PB 26 of 2024.

Subsection 101(4AAA) allows the Minister to, by legislative instrument, revoke or vary a subsection 85(2) declaration in relation to a drug or medicinal preparation. Advice from the PBAC is required if the effect of the legislative instrument would be that a drug or medicinal preparation would cease to be a listed drug (subsection 101(4AAB)).

Changes to PB 26 of 2024 made by this Instrument

Schedule 1 to this Instrument provides for the addition to the PBS Schedule of the drugs drospirenone with ethinylestradiol, osilodrostat, and progesterone and estradiol, and forms of the listed drugs acarbose, estradiol, estradiol with norethisterone, progesterone, and ursodeoxycholic acid. It also provides for the deletion of a form of the listed drugs amoxicillin with clavulanic acid, azithromycin, sumatriptan, tenecteplase, and timolol, and the alteration of circumstances in which prescriptions may be written for the supply of the listed drugs blinatumomab, faricimab, and risankizumab.

Schedule 1 to this Instrument also provides for the following changes:

- the addition of 17 brands of existing pharmaceutical items
- the deletion of 16 brands of existing pharmaceutical items
- the alteration of an existing brand of pharmaceutical item
- the alteration of authorised prescribers for 20 existing pharmaceutical items
- the addition of maximum quantities and number of repeats for 11 brands of existing pharmaceutical items
- the alteration of responsible person codes for 6 brands of existing pharmaceutical items
- the addition of a responsible person to the list of responsible persons
- the deletion of a responsible person from the list of responsible persons
- the supply only period ending for 2 pharmaceutical items covered under Supply Only arrangements.

These changes are summarised, by subject matter, in the Attachment.

Consultation

The involvement of interested parties through the membership of the PBAC constitutes a formal and ongoing process of consultation. The PBAC is an 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. The PBAC members are appointed following nomination by prescribed

organisations and associations 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 PBAC. In addition, an industry nominee has been appointed to the PBAC membership under the PBS Access and Sustainability Package of reforms announced in May 2015. When recommending the listing of a medicine on the PBS, PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

Pharmaceutical companies are consulted throughout the process of the listing of their medicines on the PBS and in relation to changes to those listings. This includes the company submission to the PBAC and involvement throughout the PBAC process, negotiations or consultation on price, guarantee of supply and agreement to final listing details.

It was considered that further consultation for this Instrument was unnecessary due to the nature of the consultation that had already taken place.

General

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

This Instrument commences on 1 March 2025.

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

PROVISION-BY-PROVISION DESCRIPTION OF NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT (MARCH UPDATE) INSTRUMENT 2025

Section 1 Name of Instrument

This section provides that the name of the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment (March Update) Instrument 2025* and may also be cited as PB 13 of 2025.

Section 2 Commencement

Subsection 2(1) provides for commencement dates of each of the provisions specified in Column 1 of the table, in accordance with Column 2 of the table. In accordance with Column 2 of the table, Schedule 1 to the Instrument commences on 1 March 2025.

Section 3 Authority

This section specifies that sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953* provide the authority for the making of this Instrument.

Section 4 Schedules

This section 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 of drugs, the addition and deletion of forms of listed drugs, the addition and deletion of brands, the alteration of a brand for an existing pharmaceutical item, the alteration of authorised prescribers for existing pharmaceutical items, the addition of maximum quantities and number of repeats for brands of existing pharmaceutical benefits, the alteration of responsible person codes for brands of existing pharmaceutical items, the addition and deletion of responsible persons for the list of responsible persons, the supply only period ending for pharmaceutical items covered under Supply Only arrangements, and the alteration of circumstances for prescribing various pharmaceutical benefits available on the Pharmaceutical Benefits Scheme. These changes are summarised below.

***SUMMARY OF CHANGES TO THE PHARMACEUTICAL BENEFITS SCHEME
MADE BY SCHEDULE 1 OF THIS INSTRUMENT***

Drug Addition

Listed Drug

Drospirenone with ethinylestradiol

Osilodrostat

Progesterone and estradiol

Form Addition

Listed Drug

Form

Acarbose	Tablet 50 mg (S19A)
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	Tablet 100 mg (S19A)
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Estradiol	Transdermal gel (pump pack) 750 micrograms (as hemihydrate) per 1.25 g dose, 64 doses
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	Transdermal patches 1.56 mg, 24 (Sandoz) (S19A)
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Estradiol with norethisterone	Transdermal patches containing 510 micrograms estradiol (as hemihydrate) with 4.8 mg norethisterone acetate, 8 (S19A)
	Transdermal patches containing 620 micrograms estradiol (as hemihydrate) with 2.7 mg norethisterone acetate, 8 (S19A)
Progesterone	Capsule 100 mg
Ursodeoxycholic acid	Capsule 500 mg

Form Deletion

<i>Listed Drug</i>	<i>Form</i>
Amoxicillin with clavulanic acid	Powder for oral suspension containing 125 mg amoxicillin (as trihydrate) with 31.25 mg clavulanic acid (as potassium clavulanate) per 5 mL, 100 mL (S19A)
Azithromycin	Powder for oral suspension 200 mg (as dihydrate) per 5 mL, 15 mL (S19A)
Sumatriptan	Nasal spray 20 mg in 0.1 mL single dose unit
Tenecteplase	Powder for injection 40 mg with solvent
Timolol	Eye drops (gellan gum solution) 5 mg (as maleate) per mL, 2.5 mL (S19A)

Brand Addition

<i>Listed Drug</i>	<i>Form and Brand</i>
Adalimumab	Injection 80 mg in 0.8 mL pre-filled pen (<i>Hyrimoz</i>)
Dutasteride with tamsulosin	Capsule containing dutasteride 500 micrograms with tamsulosin hydrochloride 400 micrograms (<i>Dutasteride/Tamsulosin Sandoz 500/400</i>)
Enoxaparin	Injection containing enoxaparin sodium 20 mg (2,000 I.U. anti-Xa) in 0.2 mL pre-filled syringe (<i>Exarane Safety-Lock</i>)
	Injection containing enoxaparin sodium 40 mg (4,000 I.U. anti-Xa) in 0.4 mL pre-filled syringe (<i>Exarane Safety-Lock</i>)
	Injection containing enoxaparin sodium 60 mg (6,000 I.U. anti-Xa) in 0.6 mL pre-filled syringe (<i>Exarane Safety-Lock</i>)
	Injection containing enoxaparin sodium 80 mg (8,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe (<i>Exarane Safety-Lock</i>)
	Injection containing enoxaparin sodium 100 mg (10,000 I.U. anti-Xa) in 1 mL pre-filled syringe (<i>Exarane Safety-Lock</i>)
	Injection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe (<i>Exarane Forte Safety-Lock</i>)
	Injection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL pre-filled syringe (<i>Exarane Forte Safety-Lock</i>)
Erlotinib	Tablet 100 mg (as hydrochloride) (<i>ERLOTINIB ARX</i>)
Ezetimibe and rosuvastatin	Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 10 mg (as calcium) (<i>Ezetimibe - Rosuvastatin Sandoz 10 mg/10 mg</i>)

	Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 20 mg (as calcium) (<i>Ezetimibe - Rosuvastatin Sandoz 10 mg/20 mg</i>)
	Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 40 mg (as calcium) (<i>Ezetimibe - Rosuvastatin Sandoz 10 mg/40 mg</i>)
	Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 5 mg (as calcium) (<i>Ezetimibe - Rosuvastatin Sandoz 10 mg/5 mg</i>)
Lenalidomide	Capsule 20 mg (<i>Lenalidomide Sandoz</i>)
Metformin	Tablet (extended release) containing metformin hydrochloride 500 mg (<i>Metformin Sandoz XR</i>)
	Tablet (extended release) containing metformin hydrochloride 1 g (<i>Metformin Sandoz XR</i>)

Brand Deletion

Listed Drug	Form and Brand
Betaxolol	Eye drops, solution, 5 mg (as hydrochloride) per mL, 5 mL (<i>BetoQuin</i>)
Entecavir	Tablet 1 mg (as monohydrate) (<i>Entecavir Mylan</i>)
Estradiol	Transdermal patches 1.17 mg, 8 (<i>Estradiol Transdermal System (Sandoz, USA)</i>)
Insulin isophane	Injections (human), cartridges, 100 units per mL, 3 mL, 5 (<i>Protaphane InnoLet</i>)
Irbesartan	Tablet 75 mg (<i>Irbesartan GH</i>)
	Tablet 150 mg (<i>Irbesartan GH</i>)
	Tablet 300 mg (<i>Irbesartan GH</i>)
Modafinil	Tablet 100 mg (<i>Modafinil Mylan</i>)
Olanzapine	Tablet 10 mg (orally disintegrating) (<i>Olanzapine ODT generichealth 10</i>)
Pregabalin	Capsule 150 mg (<i>Cipla Pregabalin</i>)
Quetiapine	Tablet 100 mg (as fumarate) (<i>Quetiapine APOTEX</i>)
Quinapril	Tablet 5 mg (as hydrochloride) (<i>Accupril</i>)
Ramipril	Tablet 1.25 mg (<i>Tryzan Tabs 1.25</i>)
	Tablet 2.5 mg (<i>Tryzan Tabs 2.5</i>)
	Tablet 5 mg (<i>Tryzan Tabs 5</i>)
	Tablet 10 mg (<i>Tryzan Tabs 10</i>)

Brand Alteration

Listed Drug	Form	Brand
Ethosuximide	Capsule 250 mg	From: Zarontin To: ZARONTIN

Authorised Prescriber Alteration

<i>Listed Drug</i>	<i>Form</i>	<i>Authorised Prescriber</i>	
Cladribine	Tablet 10 mg	<i>From:</i> MP	<i>To:</i> MP NP
Dimethyl fumarate	Capsule (modified release) 120 mg	<i>From:</i> MP	<i>To:</i> MP NP
	Capsule (modified release) 240 mg	<i>From:</i> MP	<i>To:</i> MP NP
Diroximel fumarate	Capsule (enteric) 231 mg	<i>From:</i> MP	<i>To:</i> MP NP
Evolocumab	Injection 140 mg in 1 mL single use pre-filled pen	<i>From:</i> MP	<i>To:</i> MP NP
Fingolimod	Capsule 250 micrograms (as hydrochloride)	<i>From:</i> MP	<i>To:</i> MP NP
	Capsule 500 micrograms (as hydrochloride)	<i>From:</i> MP	<i>To:</i> MP NP
Glatiramer	Injection containing glatiramer acetate 40 mg in 1 mL single dose pre-filled pen	<i>From:</i> MP	<i>To:</i> MP NP
	Injection containing glatiramer acetate 40 mg in 1 mL single dose pre-filled syringe	<i>From:</i> MP	<i>To:</i> MP NP
Inclisiran	Injection 284 mg in 1.5 mL single use pre-filled syringe	<i>From:</i> MP	<i>To:</i> MP NP
Interferon beta-1b	Injection set including 1 vial powder for injection 8,000,000 I.U. (250 micrograms) and solvent	<i>From:</i> MP	<i>To:</i> MP NP
Ofatumumab	Solution for injection 20 mg in 0.4 mL pre-filled pen	<i>From:</i> MP	<i>To:</i> MP NP
Ozanimod	Capsule 920 micrograms	<i>From:</i> MP	<i>To:</i> MP NP
	Pack containing 4 capsules 230 micrograms and 3 capsules 460 micrograms	<i>From:</i> MP	<i>To:</i> MP NP
Peginterferon beta-1a	Pack containing single use injection pens containing 63 micrograms in 0.5 mL and 94 micrograms in 0.5 mL	<i>From:</i> MP	<i>To:</i> MP NP
	Single use injection pen containing 125 micrograms in 0.5 mL	<i>From:</i> MP	<i>To:</i> MP NP
Siponimod	Tablet 250 micrograms (as hemifumarate)	<i>From:</i> MP	<i>To:</i> MP NP
	Tablet 1 mg (as hemifumarate)	<i>From:</i> MP	<i>To:</i> MP NP
	Tablet 2 mg (as hemifumarate)	<i>From:</i> MP	<i>To:</i> MP NP
Teriflunomide	Tablet 14 mg	<i>From:</i> MP	<i>To:</i> MP NP

Maximum Quantity and Number of Repeats Addition

<i>Listed Drug</i>	<i>Form and Brand</i>	<i>Maximum Quantity</i>	<i>Number of Repeats</i>
Duloxetine	Capsule 60 mg (as hydrochloride) (APO-Duloxetine; Duloxecor; Duloxetine Sandoz; Duloxetine Sandoz 60; DYTREX 60; Tixel 60)	56	2

Fluoxetine	Tablet, dispersible, 20 mg (as hydrochloride) (<i>Zactin Tablet</i>)	56	2
Gliclazide	Tablet 30 mg (modified release) (<i>APO-Gliclazide MR; Gliclazide MR Viatris; Glyade MR; Pharmacor Gliclazide MR</i>)	200	5

Responsible Person Code Alteration

<i>Listed Drug</i>	<i>Form</i>	<i>Brand Name</i>	<i>Responsible Person</i>	<i>Responsible Person</i>
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	<i>Hadlima</i>	From: OQ	To: RF
	Injection 40 mg in 0.4 mL pre-filled syringe	<i>Hadlima</i>	From: OQ	To: RF
Nicotine	Transdermal patch 17.5 mg	<i>Nicotinell Step 3</i>	From: ON	To: UI
	Transdermal patch 35 mg	<i>Nicotinell Step 2</i>	From: ON	To: UI
	Transdermal patch 52.5 mg	<i>Nicotinell Step 1</i>	From: ON	To: UI
Permethrin	Cream 50 mg per g, 30 g	<i>Lyclear</i>	From: ON	To: UI

Responsible Person Addition

Responsible Person

PERRIGO AUSTRALIA PTY LIMITED (*UI*)

Responsible Person Deletion

Responsible Person

Novo Nordisk Pharmaceuticals Pty. Limited (*NI*)

Supply Only – Period Ending

<i>Listed Drug</i>	<i>Form</i>
Budesonide with formoterol	Pressurised inhalation containing budesonide 50 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses
Triglycerides, long chain with glucose polymer	Oral liquid 250 mL, 18 (ProZero)

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug

Blinatumomab

Faricimab

Risankizumab

Documents Incorporated by Reference

<i>Listed Drug</i>	<i>Document Incorporated</i>	<i>Document access</i>
Blinatumomab Cladribine Evolocumab Inclisiran Risankizumab	<p>Approved Product Information/Australian Product Information/TGA-approved Product Information.</p> <p>The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the <i>Legislation Act 2003</i>.</p> <p>This document provides health professionals with a summary of the scientific information relevant to the safe and effective use of a prescription medicine.</p>	<p>TGA-approved Product Information is available for download for free from the TGA website: https://www.tga.gov.au/product-information-0</p>
Evolocumab Inclisiran	<p>Dutch Lipid Clinic Network Score (DLCNS)</p> <p>The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the <i>Legislation Act 2003</i>.</p> <p>The DLCNS is a validated set of criteria used to categorise the likelihood of a patient having Familial Hypercholesterolaemia, by evaluating family history of premature cardiovascular disease (CVD) in first degree relatives, the patient's own CVD history, their untreated lipid levels and physical signs such as the presence of tendon xanthomata or arcus cornealis prior to the age of 45.</p>	<p>The DLCNS is available for download for free from the Royal Australian College of General Practitioners website https://www.racgp.org.au/FSDEDEV/media/documents/Clinical%20Resources/Guidelines/Red%20Book/Appendix-2B.pdf</p>
Evolocumab Inclisiran	<p>Thrombolysis in Myocardial Infarction (TIMI) risk score</p> <p>The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the <i>Legislation Act 2003</i>.</p> <p>The TIMI score quantifies the risk of having or dying from a heart-related event in the next 14 days</p>	<p>The TIMI risk score is available for download for free from the Journal of the American Medical Association website https://jamanetwork.com/journals/jama/fullarticle/192996</p>
Blinatumomab	<p>World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status/Performance Status Score.</p> <p>The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the <i>Legislation Act 2003</i>.</p> <p>The WHO/ECOG performance status is a standard medical diagnostic tool used to measure how cancer impacts a patient's daily living abilities, by evaluating a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.).</p>	<p>The WHO/ECOG Performance Status is available for download for free from the ECOG-ACRIN Cancer Research Group website: https://ecog-acrin.org/resources/ecog-performance-status</p>

Diagnostic tools referenced in the Instrument

The following standard medical diagnostic tools are referenced in the Instrument but are not intended to incorporate a document by reference.

Listed Drug	Diagnostic tool	Purpose and use in the Instrument	Reason this reference does not serve to incorporate a document
Faricimab	Early treatment diabetic retinopathy study chart (ETDRSC) and Snellen chart	The ETDRSC and Snellen chart are eye charts that are routinely used in clinical practice to measure visual acuity. Measurement results must be reported on as part of the authority application for a number of PBS listed drugs.	Measurement of visual acuity using the ETDRSC and/or Snellen chart is a process for obtaining physiological measurements and does not constitute a written record of information that must be referred to in order to determine whether statutory conditions have been met. It is part of the standard diagnostic work-up for macular oedema.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health (Listing of Pharmaceutical Benefits) Amendment (March Update) Instrument 2025

(PB 13 of 2025)

This 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 Instrument

The *National Health (Listing of Pharmaceutical Benefits) Amendment (March Update) Instrument 2025* (the Instrument) amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (PB 26 of 2024) (the Principal Instrument) which determines the pharmaceutical benefits that are listed on the Schedule of Pharmaceutical Benefits (the Schedule) through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. It also provides for related matters (responsible persons, prescribing circumstances, schedule equivalence, maximum quantities, number of repeats, determined quantities, pack quantities, section 100 only status and prescriber bag only status).

Human rights implications

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

The Right to Social Security

The right to social security is contained in Article 9 of the 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 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

The Instrument advances the right to health and the right to social security by providing new drugs, new forms and brands of existing listed drugs, and ensuring the deletion of forms and brands of listed drugs does not affect access to subsidised medicines. The Pharmaceutical Benefits Scheme (PBS) is a benefit scheme which assists with advancement of these human rights 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 Schedule are evidence-based. The Instrument includes the addition of 3 new drugs, the addition of 8 new forms of existing drugs, and the addition of 17 new brands across 17 existing forms, which allows for greater patient access to these drugs.

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.

Written advice from the PBAC is tabled with the monthly amendments to the Principal Instrument. An unmet clinical need would arise when a currently treated patient population would be left without treatment options once a delisting occurs. Alternative treatment options could include using a different: form, strength or drug. The PBAC considered the delisting of forms of drugs in the abovementioned instruments would not result in an unmet clinical need, except where indicated for a particular form of drug below. Where the PBAC has identified an unmet clinical need, a Supply Only period has been/will be instituted as outlined below to allow opportunity for patients to transition to an alternative treatment option. The delisting of these items will not affect access to the drugs (or an alternative treatment if required), as affected patients will be able to access alternative medicines through the PBS, and the delisting is unlikely to have an effect on the amount patients pay for those drugs, as co-payment amounts are capped, ensuring their rights to social security are maintained. From 1 January 2024, these amounts are \$31.60 for general patients and \$7.70 for concession card holders.

Where there are many brands of a listed drug and form, then the delisting of one brand will not adversely affect members of the public as they will be able to obtain any of the other equivalent brands. The delisting of brands in this Instrument will not affect access to the drugs, as affected patients will be able to access equivalent brands, at the same cost. Consequently, the brand delistings in this instrument do not result in an unmet clinical need. Note that delisting of maximum quantities, number of repeats, and pack sizes are equivalent to brand delistings.

The drug amoxicillin with clavulanic acid in the form powder for oral suspension containing 125 mg amoxicillin (as trihydrate) with 31.25 mg clavulanic acid (as potassium clavulanate) per 5 mL, 100 mL (S19A) (CLAVULIN-125F (GlaxoSmithKline, Canada)) was requested to be delisted from the PBS Schedule by the sponsor. This item was listed under section 19A of the *Therapeutic Goods Act 1989* to address the shortage of amoxicillin with clavulanic acid in the form powder for oral suspension containing 125 mg amoxicillin (as trihydrate) with 31.25 mg clavulanic acid (as potassium clavulanate) per 5 mL, 75 mL. The temporary approval granted in respect of this drug for importation and supply of a medicine not on the Australian Register of Therapeutic Goods lapsed on 31 October 2024. Patient access has not been affected as the approved form of the drug is now available and remains PBS subsidised and accessible for patients.

The drug azithromycin in the form powder for oral suspension 200 mg (as dihydrate) per 5 mL, 15 mL (S19A) (Azithromycin (Zydus, USA)) was requested to be delisted from the PBS Schedule by the sponsor. This item was listed under section 19A of the *Therapeutic Goods Act 1989* to address the shortage of azithromycin in the form powder for oral suspension 200 mg (as dihydrate) per 5 mL, 15 mL. The temporary approval granted in respect of this drug for importation and supply of a medicine not on the Australian Register of Therapeutic Goods lapsed on 31 October 2024. Patient access has not been affected as the approved form of the drug is now available and remains PBS subsidised and accessible for patients.

The drug budesonide with formoterol in the form pressurised inhalation containing budesonide 50 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses (Symbicort Rapihaler 50/3) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted that there are multiple alternatives on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need. This item was available on the PBS Schedule under Supply Only arrangements for a period of 6 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment.

The drug sumatriptan in the form nasal spray 20 mg in 0.1 mL single dose unit (Imigran) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted that this product is being discontinued and considered that the fast-disintegrating tablet form of sumatriptan would be a reasonable alternative. The PBAC advised the delisting of this product would not result in an unmet clinical need.

The drug tenecteplase in the form powder for injection 40 mg with solvent (Metalyse) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the last financial year. The PBAC advised the delisting of this product would not result in an unmet clinical need.

The drug timolol in the form eye drops (gellan gum solution) 5 mg (as maleate) per mL, 2.5 mL (S19A) (Timoptol XE 0.50% (South Africa)) was requested to be delisted from the PBS Schedule by the sponsor. This item was listed under section 19A of the *Therapeutic Goods Act 1989* to address the shortage of timolol in the form eye drops (gellan gum solution) 5 mg (as maleate) per mL, 2.5 mL. Although the temporary approval granted in respect of this drug for importation and supply of a medicine not on the Australian Register of Therapeutic Goods will not lapse until 30 June 2025, the sponsor is no longer able to supply this product. Patient access has not been affected as the same sponsor currently has another form of timolol (eye drops (gellan gum solution) 5 mg (as maleate) per mL, 2.5 mL - (Timoptol-LA) (S19A)) with temporary approval for importation and supply of a medicine not on the Australian Register of Therapeutic Goods that is available and remains PBS subsidised and accessible for patients.

The drug triglycerides, long chain with glucose polymer in the form oral liquid 250 mL, 18 (ProZero) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted that there are alternatives on the PBS, however the alternatives may not be suitable for all patients. The PBAC advised the delisting of these products may result in an unmet clinical need. This item was available on the PBS Schedule under Supply Only arrangements for a period of 6 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment.

Conclusion

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

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