EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

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

PB 40 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 amivantamab, drospirenone, edaravone, epcoritamab, esketamine, fenfluramine, macitentan with tadalafil, prasugrel, relugolix with estradiol and with norethisterone, and vutrisiran, and forms of the listed drugs amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides, aripiprazole, clobetasol, faricimab, glycomacropeptide and essential amino acids with vitamins and minerals, and prazosin. It also provides for the deletion of the listed drugs adefovir, cefotaxime, gentamicin, and praziquantel, the deletion of forms of the listed drugs methylprednisolone, morphine, tenecteplase, and tobramycin, and the alteration of circumstances in which prescriptions may be written for the supply of the listed drugs adalimumab, afatinib, asciminib, dabrafenib, dostarlimab, erlotinib, faricimab, gefitinib, mavacamten, osimertinib, and somatropin.

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

- the addition of 13 brands of existing pharmaceutical items
- the deletion of 10 brands of existing pharmaceutical items
- the deletion of a maximum quantity and number of repeats for a brand of an existing pharmaceutical item
- the alteration of responsible person code for 4 brands of existing pharmaceutical items
- the deletion of 2 responsible persons from the list of responsible persons
- the supply only period commencing 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 May 2025.

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

ATTACHMENT

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT (MAY 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 (May Update) Instrument 2025* and may also be cited as PB 40 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 May 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 and deletion of drugs, the addition and deletion of forms of listed drugs, the addition and deletion of brands, the deletion of a maximum quantity and number of repeats for a brand of an existing pharmaceutical benefit, the alteration of responsible person codes for brands of existing pharmaceutical items, the deletion of responsible persons from the list of responsible persons, the supply only period commencing 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
Amivantamab
Drospirenone
Edaravone
Epcoritamab
Esketamine
Fenfluramine
Macitentan with tadalafil
Prasugrel
Relugolix with estradiol and with norethisterone
Vutrisiran

Drug Deletion

Listed Drug
Adefovir
Cefotaxime
Gentamicin
Praziquantel

Form Addition

Listed Drug	*Form*
Amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides	Oral powder 400 g (Essential Care Jr)
Aripiprazole	I.M. injection (modified release) 720 mg (as monohydrate) in 2.4 mL pre-filled syringe
	I.M. injection (modified release) 960 mg (as monohydrate) in 3.2 mL pre-filled syringe
Clobetasol	Cream containing clobetasol propionate 500 micrograms per g, 30 g
	Ointment containing clobetasol propionate 500 micrograms per g, 30 g
Faricimab	Solution for intravitreal injection 21 mg in 0.175 mL (120 mg per mL) pre-filled syringe
Glycomacropeptide and essential amino acids with vitamins and minerals	Sachets containing oral powder 15 g, 30 (PKU Build 10)
Prazosin	Capsule 1 mg (as hydrochloride) (S19A)

Form Deletion

Listed Drug	*Form*
Methylprednisolone	Powder for injection 40 mg (as sodium succinate) with diluent
Morphine	Oral solution containing morphine hydrochloride trihydrate 5 mg per mL, 1 mL (S19A)
Tenecteplase	Powder for injection 50 mg with solvent (s19A)
Tobramycin	Eye drops 3 mg per mL, 5 mL
	Eye ointment 3 mg per g, 3.5 g

Brand Addition

Listed Drug	*Form and Brand*
Azacitidine	Powder for injection 100 mg *(Azacitidine SXP)*

Bosentan	Tablet 125 mg (as monohydrate) *(Bosentan Viatris)*
Ezetimibe	Tablet 10 mg *(ARX-EZETIMIBE)*
Ganirelix	Injection 250 micrograms (as acetate) in 0.5 mL pre-filled syringe *(Ganirelix Lupin)*
Levodopa with carbidopa	Tablet 100 mg-25 mg (as monohydrate) *(ORIDOPA 100/25)*
Nebivolol	Tablet 5 mg (as hydrochloride) *(Nebaloc)*
	Tablet 10 mg (as hydrochloride) *(Nebaloc)*
Paracetamol	Tablet 665 mg (modified release) *(Chemists' Own Osteo Relief Paracetamol)*
Rivaroxaban	Tablet 10 mg *(RIVAXIB)*
	Tablet 15 mg *(RIVAXIB)*
	Tablet 20 mg *(RIVAXIB)*
Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg *(TENOFOVIR/EMTRICITABINE 300/200 APX)*
Tranexamic acid	Tablet 500 mg *(Tranexamic Acid Waymade)*

Brand Deletion

Listed Drug	*Form and Brand*
Capecitabine	Tablet 500 mg *(Capecitabine Alphapharm)*
Follitropin beta	Solution for injection 300 I.U. in 0.36 mL multi-dose cartridge *(Recagon)*
	Solution for injection 900 I.U. in 1.08 mL multi-dose cartridge *(Recagon)*
Lercanidipine	Tablet containing lercanidipine hydrochloride 20 mg *(Lercanidipine APOTEX)*
Methylprednisolone	Powder for injection 1 g (as sodium succinate) *(Methylpred)*
Perindopril	Tablet containing perindopril erbumine 2 mg *(Indosyl Mono 2)*
	Tablet containing perindopril erbumine 4 mg *(Indosyl Mono 4)*
	Tablet containing perindopril erbumine 8 mg *(Indosyl Mono 8)*
Perindopril with indapamide	Tablet containing perindopril erbumine 4 mg with indapamide hemihydrate 1.25 mg *(Indosyl Combi 4/1.25)*
Polyethylene glycol 400 with propylene glycol	Eye drops 4 mg-3 mg per mL, 15 mL *(Optix)*

Maximum Quantity and Number of Repeats Deletion

Listed Drug	*Form and Brand*	*Maximum Quantity*	*Number of Repeats*
Siponimod	Tablet 250 micrograms (as hemifumarate) *(Mayzent)*	120	5

Responsible Person Code Alteration

Listed Drug	*Form*	*Brand*	*Responsible Person*	
Calcipotriol with betamethasone	Foam containing calcipotriol 50 micrograms with betamethasone 500 micrograms (as dipropionate) per g, 60 g	*Klarvanta*	***From:*** LG	***To:*** XT
Galantamine	Capsule (prolonged release) 8 mg (as hydrobromide)	*Reminyl*	***From:*** JC	***To:*** IX
	Capsule (prolonged release) 16 mg (as hydrobromide)	*Reminyl*	***From:*** JC	***To:*** IX
	Capsule (prolonged release) 24 mg (as hydrobromide)	*Reminyl*	***From:*** JC	***To:*** IX

Responsible Person Deletion

Responsible Person
Leo Pharma Pty Ltd *(LG)*
Organon Pharma Pty Ltd *(OV)*

Supply Only – Period Commencing

Listed Drug	*Form*
Amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides	Oral powder 800 g (Essential Care Jr)
Glycomacropeptide and essential amino acids with vitamins and minerals	Sachets containing oral powder 16 g, 60 (PKU Build 10)

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug	
Adalimumab	Faricimab
Afatinib	Gefitinib
Asciminib	Mavacamten
Dabrafenib	Osimertinib
Dostarlimab	Somatropin
Erlotinib	

Documents Incorporated by Reference

Listed Drug	*Document Incorporated*	*Document access*
Mavacamten Prasugrel	**Approved Product Information/Australian Product Information/TGA-approved Product Information.** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003.* This document provides health professionals with a summary of the scientific information relevant to the safe and effective use of a prescription medicine.	TGA-approved Product Information is available for download for free from the TGA website: https://www.tga.gov.au/product-information-0
Dabrafenib	**Karnofsky Performance Score.** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003.* Karnofsky Performance Score is a way to measure a patient's general well-being and their functional status of daily activities. It is used for patients aged 16 years and older and subjectively assessed by clinicians. The grading runs from 0 to 100 with grade 0 representing 'Dead' and 100 representing 'Normal/No complaints/No evidence of disease'.	The Karnofsky Performance Score is available for download for free from the following websites: https://oncologypro.esmo.org/oncology-in-practice/practice-tools/performance-scales www.mdcalc.com/calc/3168/karnofsky-performance-status-scale Schag, C. C., Heinrich, R. L., & Ganz, P. A. (1984). Karnofsky performance status revisited: reliability, validity, and guidelines. Journal of clinical oncology: official journal of the American Society of Clinical Oncology, 2(3), 187–193.
Dabrafenib	**Lansky Performance Score.** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003.* Lansky Performance Score is a way to measure a patient's general well-being and their functional status of daily activities. It measures the child's usual play activity as the index of performance. This scale is rated by the parent for children under 16 years. The grading runs from 0 to 100 with grade 0 representing 'Unresponsive' and 100 representing 'Fully active/Normal'.	The Lansky Performance Score is available for download for free from the following websites: https://doi.org/10.1002/1097-0142(19871001)60:7<1651::AID-CNCR2820600738>3.0.CO;2-J https://acsjournals.onlinelibrary.wiley.com/doi/10.1002/1097-0142(19871001)60:7%3C1651::AID-CNCR2820600738%3E3.0.CO;2-J
Dabrafenib	**Response Assessment in Neuro-Oncology criteria 2017 (RANO).** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003.* RANO criteria for high-grade gliomas and low-grade gliomas were developed to improve reliability of response assessment in glioma trials.	The Response Assessment in Neuro-Oncology criteria 2017 (RANO) is available for download for free from the following websites: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5516482/ https://ascopubs.org/doi/10.1200/JCO.2017.72.7511
Edaravone	**The ALS Functional Rating Scale – Revised (ALSFRS-R) score.** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003.* The ALSFRS-R questionnaire is routinely administered to patients with ALS by neurologists at every clinic visit, typically 3 monthly. It is not proprietary and can be accessed online, being reproduced on multiple medical websites (e.g.	An ALSFRS-R calculator is available via the MiNDAUS ALS registry https://www.mindaus.org/wp-content/uploads/2023/09/22094546/DataDictionaryPROMMindausHansenJuly2023V01.1.pdf

	https://www.mdcalc.com/calc/10166/revised-amyotrophic-lateral-sclerosis-functional-rating-scale-alsfrs-r). There are also websites that allow the neurologist to input a patient's ratings to obtain a printable or digital copy of their score (https://neurotoolkit.com/alsfrs-r/).	
Afatinib Amivantamab Dabrafenib Epcoritamab Erlotinib Gefitinib Osimertinib	**World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status/Performance Status Score.** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003.* 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 themself, daily activity, and physical ability (walking, working, etc.).	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

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.
Faricimab	Fluorescein angiography	Fluorescein angiography is an eye test that uses a special dye and camera to look at blood flow in the retina and choroid.	Fluorescein angiography are physiological images and the medical equipment/machine used to produce the Fluorescein angiography scan(s) does not constitute a written record of information that must be referred to in order to determine whether statutory conditions have been met.
Faricimab	Optical coherence tomography	Optical Coherence Tomography (OCT) is a non-invasive diagnostic technique that renders an in vivo cross-sectional view of the retina.	OCT scan(s) are physiological images and the medical equipment/machine used to produce the OCT scan(s) does not constitute a written record of information that must be referred to in order to determine whether statutory conditions have been met.

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 (May Update) Instrument 2025

(PB 40 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 (May 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 drugs, 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 10 new drugs, the addition of 8 new forms of existing drugs, and the addition of 13 new brands across 13 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 drugs and 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 adefovir in the form tablet containing adefovir dipivoxil 10 mg (S19A) (Adefovir Dipivoxil Tablets 10 mg (SigmaPharm Laboratories)) 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 adefovir in the form tablet containing adefovir dipivoxil 10 mg. 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 January 2025. Patient access has not been affected as the approved form of the drug is 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. When reviewing the request to delist adefovir in the form tablet containing adefovir dipivoxil 10 mg (APO-Adefovir), the PBAC noted the low number of services in the last financial year and that there are alternatives on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need.

The drug amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides in the form oral powder 800 g (Essential Care Jr) 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 and that the sponsor intends to replace this product with a new pack size and formulation of Essential Care Jr. The PBAC advised the delisting of this product would not result in an unmet clinical need provided the new formulation is listed on the PBS. This item will be 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 cefotaxime in the form powder for injection 1 g (as sodium) (DBL Cefotaxime) 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 noted concerns about the delisting of antibiotics from the PBS and the impacts this can have for clinical choice and antimicrobial resistance. The PBAC advised the delisting of this product may result in an unmet clinical need and requested that the Department seek to retain this product.

The drug gentamicin in the form injection 80 mg (as sulfate) in 2 mL) (Pfizer Australia Pty Ltd) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the moderate number of services in the last financial year and that there is a lack of appropriate alternatives on the PBS. The PBAC advised the delisting of this product may result in an unmet clinical and requested that the Department seek to retain this product,

however, the sponsor decided to proceed with the delisting due to commercial reasons and stated that the form would be available on the private market.

The drug glycomacropeptide and essential amino acids with vitamins and minerals in the form sachets containing oral powder 16 g, 60 (PKU Build 10) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the previous financial year and the sponsor intends to replace this product with a new pack size formulation of PKU Build 10. The PBAC advised the delisting of this product would not result in an unmet clinical need provided the new pack size formulation is listed on the PBS. This item will be available on the PBS Schedule under Supply Only arrangements for a period of 3 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment.

The drug methylprednisolone in the form powder for injection 40 mg (as sodium succinate) with diluent (Solu-Medrol) 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 and that corticosteroids have differences in mineralocorticoid activity. The PBAC advised the delisting of this product may result in an unmet clinical need and requested that the Department seek to retain this product if possible, however, the sponsor decided to proceed with the delisting due to commercial reasons and stated that the form would be available on the private market.

The drug morphine in the form oral solution containing morphine hydrochloride trihydrate 5 mg per mL, 1 mL (S19A) (RA-Morph (NZ)) 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 morphine in the form oral solution containing morphine hydrochloride trihydrate 5 mg per mL, 1 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 January 2025. 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 praziquantel in the form tablet 600 mg (Biltricide) 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 and that there are no suitable alternatives on the PBS. The PBAC noted the low number of services in the last financial year and that there are no suitable alternatives on the PBS. The PBAC advised the delisting of this product may result in an unmet clinical need and requested that the Department seek to retain this product, however, the sponsor decided to proceed with the delisting as the form is being discontinued due to manufacturing reasons.

The drug tenecteplase in the form powder for injection 50 mg with solvent (s19A) (TNKase (Canada) and TNKase (Canada) Medsurge Healthcare Pty Ltd) 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 tenecteplase in the form powder for injection 50 mg with solvent. 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 January 2025. 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 tobramycin in the forms eye drops 3 mg per mL, 5 mL (Tobrex) and Eye ointment 3 mg per g, 3.5 g (Tobrex) were requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted that there are no suitable alternatives on the PBS. The PBAC advised the delisting of these products may result in an unmet clinical need and requested that the Department seek to retain these products if possible, however, the sponsor decided to proceed with the delisting due to commercial reasons and stated that the form would be available on the private market.

Conclusion

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

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