EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT (MAY UPDATE) INSTRUMENT 2024

PB 39 of 2024

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* (2024 Listing Instrument) 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 difelikefalin, dostarlimab, mavacamten, and tafamidis, and forms of the listed drugs amino acid formula with vitamins and minerals without methionine and supplemented with arachidonic acid and docosahexaenoic acid, amino acid formula with vitamins and minerals, without phenylalanine, tyrosine and supplemented with arachidonic acid and docosahexaenoic acid, amino acid formula with vitamins and minerals without valine, leucine, isoleucine and supplemented with arachidonic acid and docosahexaenoic acid, colestyramine, prochlorperazine, and risankizumab. It also provides for the deletion of the listed drug procaine benzylpenicillin, and forms of the listed drugs amino acid formula with vitamins and minerals without lysine and low in tryptophan, cefalexin, cefuroxime, glucagon, and minoxidil, and for the alteration of circumstances in which prescriptions may be written for the supply of the listed drugs abemaciclib, alirocumab, cemiplimab, daratumumab, evolocumab, faricimab, niraparib, ondansetron, palbociclib, ribociclib, tepotinib, upadacitinib, and vericiguat.

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

- the addition of 13 brands of existing pharmaceutical items
- the deletion of 11 brands of existing pharmaceutical items
- the addition of a number of repeats for an existing pharmaceutical item
- the alteration of number of repeats for 2 existing pharmaceutical items
- the alteration of responsible person codes for 4 brands of existing pharmaceutical items
- the deletion of 2 responsible persons from the list of responsible persons

- the addition of 5 pharmaceutical items covered under Supply Only arrangements
- the deletion of 7 pharmaceutical item 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 2024.

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 2024*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment (May Update) Instrument 2024* and may also be cited as PB 39 of 2024.

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 2024.

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 addition and alteration of numbers of repeats for brands of pharmaceutical benefits, the alteration of responsible person codes for existing pharmaceutical items, the deletion of responsible persons from the list of responsible persons, the addition and deletion of pharmaceutical benefits 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

Drugs Added

Listed Drug

Difelikefalin

Dostarlimab

Mavacamten

Tafamidis

Drug Deleted

Listed Drug

Procaine benzylpenicillin

Forms Added

Listed Drug	*Form*
Amino acid formula with vitamins and minerals without methionine and supplemented with arachidonic acid and docosahexaenoic acid	Sachets containing oral powder 12.5 g, 30 (HCU explore5)
Amino acid formula with vitamins and minerals, without phenylalanine, tyrosine and supplemented with arachidonic acid and docosahexaenoic acid	Sachets containing oral powder 12.5 g, 30 (TYR explore5)
Amino acid formula with vitamins and minerals without valine, leucine, isoleucine and supplemented with arachidonic acid and docosahexaenoic acid	Sachets containing oral powder 12.5 g, 30 (MSUD Explore5)
Colestyramine	Powder for oral suspension 4 g (S19A)
Prochlorperazine	Tablet containing prochlorperazine maleate 5 mg (S19A)
Risankizumab	Injection 150 mg in 1 mL pre-filled pen

Forms Deleted

Listed Drug	*Form*
Amino acid formula with vitamins and minerals without lysine and low in tryptophan	Sachets containing oral powder 25 g, 30 (GA express 15)
Cefalexin	Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL (s19A)
Cefuroxime	Powder for oral suspension 125 mg (as axetil) per 5 mL, 100 mL
Glucagon	Injection set containing glucagon hydrochloride 1 mg (1 I.U.) and 1 mL solvent in disposable syringe (s19A)
Minoxidil	Tablet 10 mg (s19A)

Brands Added

Listed Drug	*Form and Brand*
Dabigatran etexilate	Capsule 75 mg (as mesilate) *(PHARMACOR DABIGATRAN)*
	Capsule 110 mg (as mesilate) *(PHARMACOR DABIGATRAN)*
	Capsule 150 mg (as mesilate) *(PHARMACOR DABIGATRAN)*
Lercanidipine	Tablet containing lercanidipine hydrochloride 20 mg *(ARX-LERCANIDIPINE)*

Methotrexate	Tablet 10 mg *(Chexate)*
Sumatriptan	Tablet 50 mg (as succinate) *(Sumagraine Migraine Relief)*
Tacrolimus	Capsule 0.5 mg (once daily prolonged release) *(Tacrolimus XR Sandoz)*
	Capsule 1 mg (once daily prolonged release) *(Tacrolimus XR Sandoz)*
	Capsule 3 mg (once daily prolonged release) *(Tacrolimus XR Sandoz)*
	Capsule 5 mg (once daily prolonged release) *(Tacrolimus XR Sandoz)*
Teriparatide	Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pen *(Teriparatide Lupin)*
Valproic acid	Tablet (enteric coated) containing sodium valproate 200 mg *(APO-Sodium Valproate)*
	Tablet (enteric coated) containing sodium valproate 500 mg *(APO-Sodium Valproate)*

Brands Deleted

Listed Drug	***Form and Brand***
Amlodipine	Tablet 5 mg (as besilate*) (Norvapine)*
	Tablet 10 mg (as besilate*) (Norvapine)*
Amoxicillin with clavulanic acid	Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) (s19A) *(Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo – Pro Pharmaceuticals); Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs))*
Risperidone	Tablet 4 mg *(Risperidone generichealth)*
Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg *(Tenofovir Disoproxil Emtricitabine Mylan 300/200)*
Topiramate	Tablet 25 mg *(Topamax)*
	Tablet 50 mg *(Topamax)*
	Tablet 100 mg *(Topamax)*
	Tablet 200 mg *(Topamax)*
Trimethoprim	Tablet 300 mg *(Trimethoprim Mylan)*

Addition of Number of Repeats

Listed Drug	*Form*	*Brand*	*Maximum Quantity*	*Number of Repeats*
Inclisiran	Injection 284 mg in 1.5 mL single use pre-filled syringe	*Leqvio*	1	0

Alteration of Number of Repeats

Listed Drug	*Form*	*Brand*	*Maximum Quantity*	*Number of Repeats*
Perampanel	Tablet 4 mg (as hemisesquihydrate)	*Fycompa*	56	***From:*** 2 ***To:*** 5
	Tablet 6 mg (as hemisesquihydrate)	*Fycompa*	56	***From:*** 2 ***To:*** 5

Alteration of Responsible Person Code

Listed Drug	*Form*	*Brand Name*	*Responsible Person*
Cemiplimab	Solution concentrate for I.V. infusion 350 mg in 7 mL	*Libtayo*	***From:*** SW ***To:*** WM
Morphine	Oral solution containing morphine hydrochloride trihydrate 2 mg per mL, 1 mL	*Ordine 2*	***From:*** MF ***To:*** XT
	Oral solution containing morphine hydrochloride trihydrate 5 mg per mL, 1 mL	*Ordine 5*	***From:*** MF ***To:*** XT
	Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 1 mL	*Ordine 10*	***From:*** MF ***To:*** XT

Deletion of Responsible Person

Responsible Person and Code

Amneal Pharmaceuticals Pty Ltd *(ED)*

Pro Pharmaceuticals Group Pty. Ltd. *(QZ)*

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug

Abemaciclib

Alirocumab

Cemiplimab

Daratumumab

Evolocumab

Faricimab

Niraparib

Ondansetron

Palbociclib

Ribociclib

Tepotinib

Upadacitinib

Vericiguat

Supply Only – Additions

Listed Drug	*Form*
Capecitabine	Tablet 150 mg *(Capecitabine-DRLA)*
Carbomer 974	Ocular lubricating gel 3 mg per g, single dose units 0.5 g, 30 *(Poly Gel)*
Fluorometholone	Eye drops containing fluorometholone acetate 1 mg per mL, 5 mL *(Flarex)*
Hypromellose with dextran	Eye drops containing 3 mg hypromellose 2900 with 1 mg dextran 70 per mL, single dose units 0.4 mL, 28 *(Bion Tears)*
Risankizumab	Injection 75 mg in 0.83 mL pre-filled syringe *(Skyrizi)*

Supply Only – Deletions

Listed Drug	*Form*
Amino acid formula with vitamins and minerals without methionine	Oral liquid 87 mL, 30 (HCU cooler 10) *(HCU cooler 10)* Oral liquid 130 mL, 30 (HCU cooler 15) *(HCU cooler 15)*
Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine	Sachets containing oral powder 24 g, 30 (MMA/PA gel) *(MMA/PA gel)*
Amino acid formula with vitamins and minerals without phenylalanine and tyrosine	Oral liquid 87 mL, 30 (TYR cooler 10) *(TYR cooler 10)* Oral liquid 130 mL, 30 (TYR cooler 15) *(TYR cooler 15)* Sachets containing oral powder 25 g, 30 (TYR express 15) *(TYR express 15)*
Amino acid formula with vitamins and minerals without valine, leucine and isoleucine	Oral liquid 87 mL, 30 (MSUD cooler 10) *(MSUD cooler 10)*

Documents Incorporated by Reference

Listed Drug	*Document incorporated*	*Document access*
Mavacamten Risankizumab	**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

Niraparib	**Gynaecologic Cancer InterGroup (GCIG) guidelines/GCIG CA-125 response criteria.** 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 GCIG guidelines/GCIG CA-125 response criteria are a set of criteria for defining response and progression of ovarian cancer.	The GCIG guidelines/GCIG CA-125 response criteria are available for download for free in references from the Oxford University Press website: https://academic.oup.com/jnci/article/96/6/487/2606756
Tafamidis	**List of amyloid expert centres** 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 Australian Amyloid Network provides a list of clinic centres that manage amyloidosis and which are considered to be experts on amyloidosis. The list is provided on its website under the 'Contact Us' page. It also provides a list of Australian anatomical pathology laboratories to be contacted for tissue review and immunohistochemistry for amyloid typing.	The Australian Amyloid Network URL for its website homepage is: https://aan.org.au/ The URL for the 'Contact Us' page that lists the expert amyloid treatment centres is: https://aan.org.au/contact-us/
Mavacamten Tafamidis	**New York Heart Association (NYHA) classification** 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 NYHA classification system is used to define the degree of heart failure.	The NYHA classification system is available for download for free from the Heart Foundation website (contained within the heart failure clinical guidelines): https://www.heartfoundation.org.au/Conditions/Heart-failure-clinical-guidelines
Abemaciclib	**Nottingham grading system.** 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 Nottingham grading system is the histologic grading system developed by Elston and Ellis as a modification of the Scarff-Bloom-Richardson grading system. It is used to grade breast cancer cells by describing how different a cancer cell's appearance and growth patterns are from normal, health breast cells.	Elston, CW, Ellis, IO. Pathological prognostic factors in breast cancer. The value of histological grade in breast cancer: experience from a large study with long-term follow-up. Histopathology. 1991 Nov;19(5):403-10. https://pubmed.ncbi.nlm.nih.gov/1757079/
Risankizumab	**Psoriasis Area Severity Index (PASI).** 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 PASI is a widely used tool that enables measurement of the severity and extent of baseline and response of therapy in psoriasis.	The PASI calculation form is available for download for free from the Services Australia website: https://www.servicesaustralia.gov.au/ and forms part of the SA authority application process.
Niraparib	**The Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.**	The RECIST guidelines are available for download for free from the

	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 RECIST guidelines are a tool used widely for defining when tumours in cancer patients respond, stabilise and/or progress during treatment.	RECIST Working Group website: https://recist.eortc.org/
Abemaciclib Dostarlimab Palbociclib Ribociclib	**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

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 2024
(PB 39 of 2024)

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 2024* (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, 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 this human right by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the Schedule are evidence-based. The Instrument includes the addition of 4 new drugs, 6 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 drug or 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 amino acid formula with vitamins and minerals without lysine and low in tryptophan in the form sachets containing oral powder 25 g, 30 (GA express 15) 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. The PBAC noted specialist advice which considered that potential alternatives on the PBS may not be suitable for a subset of patients, who once stabilised on this product, may face challenges in tolerating an alternative product. The PBAC advised the delisting of this product may result in an unmet clinical need. The Department sought to retain the product in line with this advice, however the sponsor indicated retention is unviable due to financial reasons and wished to proceed with the delisting.

The drug amino acid formula with vitamins and minerals without methionine in the form oral liquid 87 mL, 30 (HCU cooler 10) was requested to be delisted from the PBS by the sponsor. The PBAC noted that there were 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 these drugs on the PBS. The sponsor was approached however requested to proceed with its delist request citing commercial reasons. This item was available on the Schedule under Supply Only arrangements for a period of up to 3 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug amino acid formula with vitamins and minerals without methionine in the form oral liquid 130 mL, 30 (HCU cooler 15) was requested to be delisted from the PBS by the sponsor. The PBAC noted that there were 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 these drugs on the PBS. The sponsor was approached however requested to proceed with its delist request citing commercial reasons. This item was available on the Schedule under Supply Only arrangements for a period of up to 3 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine in the form sachets containing oral powder 24 g, 30 (MMA/PA gel) 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 were 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 these drugs on the PBS. The sponsor was approached however requested to proceed with its delist request citing commercial reasons. This item was available on the Schedule under Supply Only arrangements for a period of up to 3 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug amino acid formula with vitamins and minerals without phenylalanine and tyrosine in the form oral liquid 87 mL, 30 (TYR cooler 10) 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 were 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 these drugs on the PBS. The sponsor was approached however requested to proceed with its delist request citing commercial reasons. This item was available on the Schedule under Supply Only arrangements for a period of up to 3 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug amino acid formula with vitamins and minerals without phenylalanine and tyrosine in the form oral liquid 130 mL, 30 (TYR cooler 15) 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 were 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 these drugs on the PBS. The sponsor was approached however requested to proceed with its delist request citing commercial reasons. This item was available on the Schedule under Supply Only arrangements for a period of up to 3 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug amino acid formula with vitamins and minerals without phenylalanine and tyrosine in the form sachets containing oral powder 25 g, 30 (TYR express 15) 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 were 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 these drugs on the PBS. The sponsor was approached however requested to proceed with its delist request citing commercial reasons. This item was available on the Schedule under Supply Only arrangements for a period of up to 3 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug amino acid formula with vitamins and minerals without valine, leucine and isoleucine in the form oral liquid 87 mL, 30 (MSUD cooler 10) 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 were 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 these drugs on the PBS. The sponsor was approached however requested to proceed with its delist request citing commercial reasons. This item was available on the Schedule under Supply Only arrangements for a period of up to 3 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug capecitabine in the form tablet 150 mg (Capecitabine-DRLA) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted a 500 mg strength of capecitabine, which had a greater number of services will remain on the PBS. However, the PBAC noted that delisting of the 150 mg product would have a substantial impact for a small group of patients with cancer requiring the lower dose. The PBAC advised the delisting of this product may result in an unmet clinical need. The Department sought to retain the product in line with this advice, however the sponsor indicated retention is unviable due to financial reasons and wished to proceed with the delisting.This item will be available on the PBS Schedule under Supply Only arrangements for a period of up to 3 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug carbomer 974 (Poly Gel) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the relatively low number of services in the last financial year and 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 will be available on the PBS Schedule under Supply Only arrangements for a period of up to 6 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug cefalexin in the form granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL (s19A) (Keforal) 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 cefalexin in the form granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL. The shortage has been resolved and temporary approval for importation and supply of a medicine not on the Australian Register of Therapeutic Goods has lapsed. 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 cefuroxime in the form powder for oral suspension 125 mg (as axetil) per 5 mL, 100 mL (Zinnat) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the small number of services in the last financial year and that cefuroxime 250 mg tablets are also listed on the PBS. The PBAC noted this is the only liquid formulation of cefuroxime on the PBS with a broad spectrum of activity. The PBAC advised the delisting of this product may result in an unmet clinical need. The Department sought to retain the product in line with this advice, however the sponsor indicated retention is unviable due to manufacturing issues and wished to proceed with the delisting.

The drug fluorometholone in the form eye drops containing fluorometholone acetate 1 mg per mL, 5 mL (Flarex) 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 are multiple alternatives on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need. This item will be available on the PBS Schedule under Supply Only arrangements for a period of up to 4 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug glucagon in the form injection set containing glucagon hydrochloride 1 mg (1 I.U.) and 1 mL solvent in disposable syringe (s19A) (GlucaGen Hypokit (Germany)) 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 glucagon in the form injection set containing glucagon hydrochloride 1 mg (1 I.U.) and 1 mL solvent in disposable syringe. The shortage has been resolved and temporary approval for importation and supply of a medicine not on the Australian Register of Therapeutic Goods has lapsed. 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 hypromellose with dextran in the form eye drops containing 3 mg hypromellose 2900 with 1 mg dextran 70 per mL, single dose units 0.4 mL, 28 (Bion Tears) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the sponsor indicated that the manufacture and supply of this product was being discontinued globally and that there are suitable alternatives on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need. This item will be available on the PBS Schedule under Supply Only arrangements for a period of up to 6 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug minoxidil in the form tablet 10 mg (s19A) (Minoxidil 10 mg (Roma Pharmaceuticals)) 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 minoxidil in the form tablet 10 mg. The shortage has been resolved and temporary approval for importation and supply of a medicine not on the Australian Register of Therapeutic Goods has lapsed. 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 procaine benzylpenicillin (Cilicaine) 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 considered that,

while there are alternatives available on the PBS for the treatment of non-syphilis indications, there are no suitable alternatives for the treatment of syphilis. The PBAC advised the delisting of this product may result in an unmet clinical need. The Department sought to retain the product in line with this advice, however the sponsor indicated retention was unviable due to technical manufacturing problems and wished to proceed with the delisting.

The drug risankizumab in the form injection 75 mg in 0.83 mL pre-filled syringe (Skyrizi) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC advised the delisting of this product would not result in an unmet clinical need. This item will be available on the PBS Schedule under Supply Only arrangements for a period of up to 6 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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