EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

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

PB 76 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 patisiran and selumetinib, and forms of the listed drugs amino acid formula with vitamins and minerals without phenylalanine, atezolizumab, elexacaftor with tezacaftor and with ivacaftor, and ivacaftor, midazolam, permethrin, and timolol. It also provides for deletion of the listed drugs oxprenolol and tafluprost, the deletion of forms of the listed drugs cefazolin, folinic acid, and mitozantrone, and for the alteration of circumstances in which prescriptions may be written for the supply of the listed drugs adalimumab, avelumab, beclometasone with formoterol, cabozantinib, durvalumab, gilteritinib, larotrectinib, lenvatinib, and nivolumab.

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

- the addition of 22 brands of existing pharmaceutical items
- the deletion of 18 brands of existing pharmaceutical items
- the alteration of a brand name for an existing pharmaceutical item
- the addition of number of repeats for 5 existing pharmaceutical items
- the deletion of a pack quantity for an existing pharmaceutical item
- the alteration of a pack quantity for an existing pharmaceutical item
- the alteration of responsible person codes for 6 brands of existing pharmaceutical items
- the alteration of authorised prescriber for an existing pharmaceutical item

- the alteration of section 100 only status for 3 existing pharmaceutical items
- the deletion of a responsible person from the list of responsible persons
- the addition of 8 pharmaceutical items covered under Supply Only arrangements
- the deletion of a 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 August 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 (AUGUST UPDATE) INSTRUMENT 2024*

Section 1 Name of Instrument

This section provides that the name of the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment (August Update) Instrument 2024* and may also be cited as PB 76 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 August 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 listed drugs, the addition and deletion of forms of listed drugs, the addition and deletion of brands, the alteration of a brand name for an existing pharmaceutical item, the addition of numbers of repeats for brands of pharmaceutical benefits, the deletion and alteration of pack quantities for brands of pharmaceutical benefits, the alteration of responsible person codes for brands of existing pharmaceutical items, the alteration of authorised prescriber for an existing pharmaceutical item, the alteration of section 100 only statuses for existing pharmaceutical items, the deletion of a responsible person 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

Patisiran

Selumetinib

Drugs Deleted

Listed Drug

Oxprenolol

Tafluprost

Forms Added

Listed Drug	*Form*
Amino acid formula with vitamins and minerals without phenylalanine	Oral liquid 125 mL, 30 (PKU Lophlex Select LQ)
Atezolizumab	Solution for subcutaneous injection 1875 mg in 15 mL
Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor	Pack containing 28 sachets containing granules elexacaftor 80 mg with tezacaftor 40 mg and with ivacaftor 60 mg and 28 sachets containing granules ivacaftor 59.5 mg
	Pack containing 28 sachets containing granules elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 sachets containing granules ivacaftor 75 mg
Midazolam	Oromucosal solution (as maleate) 5 mg in 0.5 mL single use pre-filled oral syringe
	Oromucosal solution (as maleate) 7.5 mg in 0.75 mL single use pre-filled oral syringe
	Oromucosal solution (as maleate) 10 mg in 1 mL single use pre-filled oral syringe
Permethrin	Cream 50 mg per g, 60 g (S19A)
Timolol	Eye drops (gellan gum solution) 5 mg (as maleate) per mL, 2.5 mL (S19A)

Forms Deleted

Listed Drug	*Form*
Cefazolin	Powder for injection 500 mg (as sodium)
Folinic acid	Injection containing calcium folinate equivalent to 100 mg folinic acid in 10 mL
Mitozantrone	Injection 25 mg (as hydrochloride) in 12.5 mL

Brands Added

Listed Drug	*Form and Brand*
Aciclovir	Tablet 800 mg *(ARX-ACICLOVIR)*
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe *(Abrilada)*
	Injection 40 mg in 0.8 mL pre-filled pen *(Abrilada)*
	Injection 40 mg in 0.8 mL pre-filled syringe *(Abrilada)*
Allopurinol	Tablet 100 mg *(APO-ALLOPURINOL)*
Amoxicillin with clavulanic acid	Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *(Alphaclav Duo Viatris)*
Dasatinib	Tablet 20 mg *(Dasatinib Viatris)*
	Tablet 50 mg *(Dasatinib Viatris)*

	Tablet 70 mg *(Dasatinib Viatris)*
	Tablet 100 mg *(Dasatinib Viatris)*
Metoclopramide	Injection containing 10 mg metoclopramide hydrochloride (as monohydrate) in 2 mL *(Metoclopramide HCI Medsurge)*
Montelukast	Tablet, chewable, 4 mg (as sodium) *(Montelukast Viatris)*
Oxycodone	Capsule containing oxycodone hydrochloride 5 mg *(Oxycodone BNM)*
	Capsule containing oxycodone hydrochloride 10 mg *(Oxycodone BNM)*
	Capsule containing oxycodone hydrochloride 20 mg *(Oxycodone BNM)*
Ramipril	Tablet 10 mg *(Ramipril Viatris)*
Sertraline	Tablet 50 mg (as hydrochloride) *(Blooms The Chemist Sertraline)*
	Tablet 100 mg (as hydrochloride) *(Blooms The Chemist Sertraline)*
Tadalafil	Tablet 20 mg *(Tadalis 20)*
Tenofovir	Tablet containing tenofovir disoproxil fumarate 300 mg *(TENOFOVIR ARX)*
Testosterone	I.M. injection containing testosterone undecanoate 1,000 mg in 4 mL *(Gonadron; REJUNON 1000)*

Brands Deleted

Listed Drug	***Form and Brand***
Acamprosate	Tablet (enteric coated) containing acamprosate calcium 333 mg *(Acamprosate Mylan)*
Acarbose	Tablet 50 mg *(Acarbose Mylan)*
Bosentan	Tablet 125 mg (as monohydrate) *(Bosentan Cipla)*
Cefazolin	Powder for injection 2 g (as sodium) *(Cephazolin Alphapharm)*
Cinacalcet	Tablet 90 mg (as hydrochloride) *(Cinacalcet Mylan)*
Dabigatran etexilate	Capsule 75 mg (as mesilate) *(PHARMACOR DABIGATRAN)*
Ezetimibe	Tablet 10 mg *(Blooms The Chemist Ezetimibe)*
Insulin neutral with insulin isophane	Injections (human), cartridges, 30 units-70 units per mL, 3 mL, 5 *(Mixtard 30/70 InnoLet)*
Ipratropium	Nebuliser solution containing ipratropium bromide 250 micrograms (as monohydrate) in 1 mL single dose units, 30 *(Aeron 250)*
	Nebuliser solution containing ipratropium bromide 500 micrograms (as monohydrate) in 1 mL single dose units, 30 *(Aeron 500)*
Metformin	Tablet (extended release) containing metformin hydrochloride 500 mg *(Blooms the Chemist Metformin XR 500)*

	Tablet (extended release) containing metformin hydrochloride 1 g *(Blooms the Chemist Metformin XR 1000)*
Mycophenolic acid	Capsule containing mycophenolate mofetil 250 mg *(CellCept)*
	Tablet containing mycophenolate mofetil 500 mg *(CellCept)*
Pregabalin	Capsule 25 mg *(Cipla Pregabalin)*
	Capsule 75 mg *(Cipla Pregabalin)*
	Capsule 300 mg *(Cipla Pregabalin)*
Valganciclovir	Tablet 450 mg (as hydrochloride) *(VALGANCICLOVIR HETERO)*

Alteration of Brand Name

Listed Drug	***Form***	***Brand Name***
Larotrectinib	Oral solution 20 mg per mL (as sulfate), 50 mL, 2	***From:*** *VITRAKVI*

Addition of Number of Repeats

Listed Drug	***Form***	***Brand***	***Maximum Quantity***	***Number of Repeats***
Adalimumab	Injection 20 mg in 0.2 mL pre-filled syringe	*Humira*	2	6
	Injection 40 mg in 0.4 mL pre-filled pen	*Adalicip*	2	6
		Humira	2	6
		Yuflyma	2	6
	Injection 40 mg in 0.8 mL pre-filled pen	*Amgevita*	2	6
		Hadlima	2	6
		Hyrimoz	2	6
		Idacio	2	6
	Injection 40 mg in 0.8 mL pre-filled syringe	*Amgevita*	2	6
		Hadlima	2	6
		Hyrimoz	2	6
		Idacio	2	6
Zoledronic acid	Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL	*DEZTRON*	1	0

Deletion of Pack Quantity

Listed Drug	*Form*	*Brand*	*Pack Quantity*
Ceftriaxone	Powder for injection 1 g (as sodium)	*Ceftriaxone Viatris*	5

Alteration of Pack Quantity

Listed Drug	*Form*	*Brand*	*Pack Quantity*
Amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine	Oral powder 400 g (PKU Start)	*PKU Start*	***From:*** 1 ***To:*** 4

Alteration of Responsible Person Code

Listed Drug	*Form*	*Brand Name*	*Responsible Person*
Felodipine	Tablet 2.5 mg (extended release)	*Felodur ER 2.5 mg*	***From:*** TX ***To:*** IY
		Plendil ER	***From:*** GX ***To:*** IX
	Tablet 5 mg (extended release)	*Felodur ER 5 mg*	***From:*** TX ***To:*** IY
		Plendil ER	***From:*** GX ***To:*** IX
	Tablet 10 mg (extended release)	*Felodur ER 10 mg*	***From:*** TX ***To:*** IY
		Plendil ER	***From:*** GX ***To:*** IX

Alteration of Authorised Prescriber

Listed Drug	*Form*	*Circumstances*	*Authorised Prescriber*
Calcium	Tablet, chewable, 500 mg (as carbonate)	C14228	***From:*** MP ***To:*** MP, NP

Alteration of Section 100 only status

Listed Drug	*Form*	*Brand Name*	*Section 100 only*
Atezolizumab	Solution concentrate for I.V. infusion 840 mg in 14 mL	*Tecentriq*	***From:*** D(100) ***To:*** PB(100)
	Solution concentrate for I.V. infusion 1200 mg in 20 mL	*Tecentriq*	***From:*** D(100) ***To:*** PB(100)
Midazolam	Injection 5 mg (as hydrochloride) in 1 mL	*Pfizer Australia Pty Ltd*	***From:*** D(MP) D(NP) ***To:*** PB(MP) PB(NP)

Deletion of Responsible Person

Responsible Person and Code

Gem Pharma Pty Ltd *(GG)*

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug

Adalimumab	Gilteritinib
Avelumab	Larotrectinib
Beclometasone with formoterol	Lenvatinib
Cabozantinib	Nivolumab
Durvalumab	

Supply Only – Additions

Listed Drug	***Form***
Alirocumab	Injection 75 mg in 1 mL single use pre-filled pen
	Injection 150 mg in 1 mL single use pre-filled pen
Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides	Oral powder 400 g (Alfamino)
Fluorometholone	Eye drops 1 mg per mL, 5 mL
Glucose indicator-urine	Test strips, 50 (Diastix)
Mepolizumab	Powder for injection 100 mg
Niraparib	Capsule 100 mg (as tosilate monohydrate)
Protein hydrolysate formula with medium chain triglycerides	Oral powder 400 g (Alfaré)

Supply Only – Deletion

Listed Drug	***Form***
Fluorometholone	Eye drops containing fluorometholone acetate 1 mg per mL, 5 mL

Documents Incorporated by Reference

Listed Drug	***Document incorporated***	***Document access***
Nivolumab Selumetinib	**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

Selumetinib	**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 Karnofsky D, Burchenal J, The clinical evaluation of chemotherapeutic agents in cancer. In: MacLeod C, ed. Evaluation of Chemotherapeutic Agents. New York, NY: Columbia University Press; 1949:191–205. 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.
Selumetinib	**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 website: www.mdcalc.com/calc/3176/lansky-play-performace-scale-pediatric-functional-status Lansky, S. B., List, M. A., Lansky, L. L., Ritter-Sterr, C., & Miller, D. R. (1987). The measurement of performance in childhood cancer patients. Cancer, 60(7), 1651–1656.
Cabozantinib	**Response Evaluation Criteria in Solid Tumours (RECIST) guidelines** 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.	The RECIST guidelines are available for download for free from the RECIST Working Group website: https://recist.eortc.org/

Atezolizumab Avelumab Cabozantinib Durvalumab Gilteritinib Lenvatinib Nivolumab	**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***
Adalimumab	ETDRS Chart	The ETDRS is a test used to measure the visual acuity of patients who suffer from low vision, that is to say, with vision below the desired level. In this instance it is used to assess whether patients have vision threatening disease in order to qualify for Adalimumab.	The ETDRS is standard measurement conducted by ophthalmologists or specialist physicians and is subjective on the performance of a patient's eye condition.
Adalimumab	Standardisation of Uveitis Nomenclature (SUN) criteria	The SUN criteria is a standardised classification for uveitis. In this setting, it is used to determine a patient's baseline and whether they respond to treatment with adalimumab.	The PBS restriction requires a patient to have demonstrated an adequate response to treatment. Such measures are not limited to this particular instrument. Therefore the reference does not serve to incorporate a document.

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 (August Update) Instrument 2024
(PB 76 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 (August 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, and forms and brands of existing listed drugs, and ensuring the deletion of drugs, and 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 2 new drugs, the addition of 9 new forms of existing drugs, and the addition of 22 new brands across 21 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 alirocumab in the forms injection 75 mg in 1 mL single use pre-filled pen, and injection 150 mg in 1 mL single use pre-filled pen (Praluent) 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 suitable alternatives on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need. These items 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 amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides in the form oral powder 400 g (Alfamino) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted that a new formulation of Alfamino was listed on the PBS to replace the old formulation. 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 cefazolin in the form powder for injection 500 mg (as sodium) (Cefazolin-AFT) 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 fluorometholone in the form eye drops 1 mg per mL, 5 mL (FML Liquifilm) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the high number of services in the last financial year and that it has potential clinical benefits compared to alternatives. The PBAC advised the delisting of this product may result in an unmet clinical need. 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 option.

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 was 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 folinic acid in the form injection containing calcium folinate equivalent to 100 mg folinic acid in 10 mL (Leucovorin Calcium (Pfizer Australia Pty Ltd)) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted that this product is an essential medicine and that the alternative product is currently in short supply. The PBAC advised the delisting of this product may result in an unmet clinical need if a stable supply of the alternative product was not available.

The drug glucose indicator-urine in the form test strips, 50 (Diastix) 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 is an alternative 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 6 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment.

The drug mepolizumab in the form powder for injection 100 mg (Nucala) 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 alternatives available 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 3 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment.

The drug mitozantrone in the form injection 25 mg (as hydrochloride) in 12.5 mL (Onkotrone) 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 niraparib in the form capsule 100 mg (as tosilate monohydrate) (Zejula) was requested to be delisted from the PBS Schedule by the sponsor. There are other substitutable forms of niraparib available on the PBS and the delisting of this product will not result in an unmet clinical need. 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 oxprenolol (Corbeton 40) 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 protein hydrolysate formula with medium chain triglycerides in the form oral powder 400 g (Alfaré) 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 advised the delisting of this product may result in an unmet clinical need. This item will be available on the PBS Schedule under Supply Only arrangements for a period of 12 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug tafluprost (Saflutan) 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 available on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need.

Conclusion

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

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