EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

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

PB 111 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 chlormethine, dapagliflozin with sitagliptin, glycomacropeptide formula with amino acids and low phenylalanine, and glycomacropeptide formula with amino acids, vitamins, minerals, trace elements, carbohydrate, fat and low phenylalanine, and forms of the listed drugs choriogonadotropin alfa, estradiol, morphine, and timolol. It also provides for deletion of the listed drug ribavirin, and a form of the listed drug naloxone, and the alteration of circumstances in which prescriptions may be written for the supply of the listed drugs amiodarone, anastrozole, apixaban, auranofin, avelumab, buprenorphine, buprenorphine with naloxone, cefazolin, cefepime, cefotaxime, ceftriaxone, chlorpromazine, dabigatran etexilate, digoxin, disopyramide, eptinezumab, exemestane, ezetimibe, ezetimibe and rosuvastatin, ezetimibe with atorvastatin, ezetimibe with simvastatin, fentanyl, flecainide, fluconazole, flutamide, fremanezumab, galcanezumab, isoniazid, itraconazole, lanreotide, letrozole, lidocaine, methadone, olanzapine, penicillamine, perhexiline, periciazine, posaconazole, quetiapine, rifampicin, risperidone, rivaroxaban, romosozumab, sevelamer, sotalol, tamoxifen, tirofiban, voriconazole, and zuclopenthixol decanoate.

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

- the addition of 13 brands of existing pharmaceutical items
- the deletion of 40 brands of existing pharmaceutical items
- the alteration of a brand name for an existing pharmaceutical item
- the addition of a maximum quantity and number of repeats for an existing pharmaceutical item
- the alteration of responsible person codes for 26 brands of existing pharmaceutical items
- the deletion of a responsible person from the list of responsible persons
- the deletion of 4 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 November 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 (NOVEMBER 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 (November Update) Instrument 2024* and may also be cited as PB 111 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 November 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 brand name for an existing pharmaceutical item, the addition of a maximum quantity and number of repeats for a brand of pharmaceutical benefit, the alteration of responsible person codes for brands of existing pharmaceutical items, the deletion of a responsible person from the list of responsible persons, the 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

Chlormethine

Dapagliflozin with sitagliptin

Glycomacropeptide formula with amino acids and low phenylalanine

Glycomacropeptide formula with amino acids, vitamins, minerals, trace elements, carbohydrate, fat and low phenylalanine

Drug Deleted

Listed Drug

Ribavirin

Forms Added

Listed Drug	*Form*
Choriogonadotropin alfa	Solution for injection 250 micrograms in 0.5 mL pre-filled syringe (S19A)
Estradiol	Transdermal gel 500 micrograms in 0.5 g sachet, 28
	Transdermal patches 585 micrograms, 24 (S19A)
	Transdermal patches 780 micrograms, 24 (S19A)
	Transdermal patches 1.17 mg, 24 (S19A)
	Transdermal patches 1.56 mg, 24 (S19A)
Morphine	Tablet containing morphine sulfate pentahydrate 30 mg
Timolol	Eye drops 5 mg (as maleate) per mL, 5 mL (S19A)

Form Deleted

Listed Drug	*Form*
Naloxone	Nasal spray 1.8 mg (as hydrochloride dihydrate) in 0.1 mL single dose unit, 2 (s19A)

Brands Added

Listed Drug	*Form and Brand*
Atropine	Injection containing atropine sulfate monohydrate 600 micrograms in 1 mL *(Atropine Injection (Bridgewest))*
Citalopram	Tablet 10 mg (as hydrobromide) *(CITALOPRAM-WGR)*
	Tablet 20 mg (as hydrobromide) *(CITALOPRAM-WGR)*
	Tablet 40 mg (as hydrobromide) *(CITALOPRAM-WGR)*
Fluconazole	Capsule 200 mg *(FLUCONAZOLE-WGR)*
Fulvestrant	Injection 250 mg in 5 mL pre-filled syringe *(FULVESTRANT-AFT)*
Imatinib	Capsule 400 mg (as mesilate) *(ARX-IMATINIB)*
Pantoprazole	Tablet (enteric coated) 20 mg (as sodium sesquihydrate) *(APX-PANTOPRAZOLE)*
Pioglitazone	Tablet 30 mg (as hydrochloride) *(ARX-PIOGLITAZONE)*
Quetiapine	Tablet 25 mg (as fumarate) *(QUETIAPINE-WGR)*
	Tablet 100 mg (as fumarate) *(QUETIAPINE-WGR)*
	Tablet 200 mg (as fumarate) *(QUETIAPINE-WGR)*
	Tablet 300 mg (as fumarate) *(QUETIAPINE-WGR)*

Brands Deleted

Listed Drug	*Form and Brand*
Amiodarone	Tablet containing amiodarone hydrochloride 200 mg *(APO-Amiodarone)*
Amitriptyline	Tablet containing amitriptyline hydrochloride 10 mg *(APO-Amitriptyline 10)*
	Tablet containing amitriptyline hydrochloride 25 mg *(APO-Amitriptyline 25)*
	Tablet containing amitriptyline hydrochloride 50 mg *(APO-Amitriptyline 50)*
Atenolol	Tablet 50 mg *(APO-Atenolol)*
Atropine	Injection containing atropine sulfate monohydrate 600 micrograms in 1 mL *(Atropine Injection (Pfizer))*
Bosentan	Tablet 62.5 mg (as monohydrate) *(BOSLEER)*
	Tablet 125 mg (as monohydrate) *(BOSLEER)*
Calcitriol	Capsule 0.25 microgram *(APO-Calcitriol; Kosteo)*
Ciprofloxacin	Tablet 250 mg (as hydrochloride) *(APX-Ciprofloxacin)*
	Tablet 500 mg (as hydrochloride) *(APX-Ciprofloxacin)*
	Tablet 750 mg (as hydrochloride) *(APX-Ciprofloxacin)*
Diazepam	Tablet 2 mg *(APO-Diazepam)*
	Tablet 5 mg *(APO-Diazepam)*
Diclofenac	Tablet (enteric coated) containing diclofenac sodium 25 mg *(APO-Diclofenac)*
	Tablet (enteric coated) containing diclofenac sodium 50 mg *(APO-Diclofenac)*
Entecavir	Tablet 0.5 mg (as monohydrate) *(ENTECLUDE)*
	Tablet 1 mg (as monohydrate) *(ENTECLUDE)*
Gliclazide	Tablet 80 mg *(APO-Gliclazide; Glyade)*
Ibuprofen	Tablet 400 mg *(MEDICHOICE Ibuprofen 400 mg)*
Insulin neutral with insulin isophane	Injections (human), cartridges, 30 units-70 units per mL, 3 mL, 5 *(Mixtard 30/70 Penfill 3 mL)*
Irbesartan	Tablet 75 mg *(Karvea)*
Itraconazole	Capsule 100 mg *(APO-Itraconazole)*
Macrogol 3350	Sachets containing powder for oral solution 13.125 g with electrolytes, 30 *(Movicol)*
Nifedipine	Tablet 30 mg (controlled release) *(Addos XR 30)*
	Tablet 60 mg (controlled release) *(Addos XR 60)*

Pioglitazone	Tablet 15 mg (as hydrochloride) *(Acpio 15; Actaze)*
	Tablet 30 mg (as hydrochloride) *(Acpio 30; Actaze)*
	Tablet 45 mg (as hydrochloride) *(Acpio 45; Actaze)*
Quinapril	Tablet 10 mg (as hydrochloride) *(Accupril; ACQUIN)*
	Tablet 20 mg (as hydrochloride) *(Accupril; ACQUIN)*
Riluzole	Tablet 50 mg *(APO-Riluzole)*
Valaciclovir	Tablet 500 mg (as hydrochloride) *(Valaciclovir generichealth)*

Alteration of Brand Name

Listed Drug	***Form***	***Brand Name***	
Methoxyflurane	Liquid for inhalation 999 mg per g, 3 mL (with inhaler)	***From:*** *Penthrox*	***To:*** *Penthrox (Combination Pack)*

Addition of Maximum Quantity and Number of Repeats

Listed Drug	***Form***	***Brand Name***	***Maximum Quantity***	***Number of Repeats***
Methotrexate	Tablet 10 mg	*Methoblastin*	10	5

Alteration of Responsible Person Code

Listed Drug	***Form***	***Brand Name***	***Responsible Person***	
Azacitidine	Tablet 200 mg	*Onureg*	***From:*** CJ	***To:*** BQ
	Tablet 300 mg	*Onureg*	***From:*** CJ	***To:*** BQ
Electrolyte replacement, oral	Oral rehydration salts containing glucose monohydrate 3.56 g, sodium chloride 470 mg, potassium chloride 300 mg and sodium acid citrate 530 mg per sachet, 10	*O.R.S.*	***From:*** AF	***To:*** XT
Estradiol	Tablet 2 mg	*Zumenon*	***From:*** GO	***To:*** XT
Estradiol and estradiol with dydrogesterone	Pack containing 14 tablets estradiol 1 mg and 14 tablets estradiol 1 mg with dydrogesterone 10 mg	*Femoston 1/10*	***From:*** GO	***To:*** XT
	Pack containing 14 tablets estradiol 2 mg and 14 tablets estradiol 2 mg with dydrogesterone 10 mg	*Femoston 2/10*	***From:*** GO	***To:*** XT
Famciclovir	Tablet 250 mg	*Ezovir*	***From:*** AF	***To:*** XT
	Tablet 500 mg	*Ezovir*	***From:*** AF	***To:*** XT
Fluconazole	Capsule 50 mg	*Dizole 50*	***From:*** AF	***To:*** XT
	Capsule 100 mg	*Dizole 100*	***From:*** AF	***To:*** XT

	Capsule 200 mg	*Dizole 200*	***From:*** AF	***To:*** XT
Lenalidomide	Capsule 5 mg	*Revlimid*	***From:*** CJ	***To:*** BQ
	Capsule 10 mg	*Revlimid*	***From:*** CJ	***To:*** BQ
	Capsule 15 mg	*Revlimid*	***From:*** CJ	***To:*** BQ
	Capsule 25 mg	*Revlimid*	***From:*** CJ	***To:*** BQ
Macrogol 3350	Sachets containing powder for oral solution 13.125 g with electrolytes, 30	*Molaxole*	***From:*** GO	***To:*** XT
Metronidazole	Tablet 200 mg	*Metrogyl 200*	***From:*** AF	***To:*** XT
	Tablet 400 mg	*Metrogyl 400*	***From:*** AF	***To:*** XT
Ozanimod	Capsule 920 micrograms	*Zeposia*	***From:*** CJ	***To:*** BQ
	Pack containing 4 capsules 230 micrograms and 3 capsules 460 micrograms	*Zeposia*	***From:*** CJ	***To:*** BQ
Paracetamol	Tablet 665 mg (modified release)	*Parapane OSTEO*	***From:*** AF	***To:*** XT
Pomalidomide	Capsule 3 mg	*Pomalyst*	***From:*** CJ	***To:*** BQ
	Capsule 4 mg	*Pomalyst*	***From:*** CJ	***To:*** BQ
Thalidomide	Capsule 50 mg	*Thalomid*	***From:*** CJ	***To:*** BQ
	Capsule 100 mg	*Thalomid*	***From:*** CJ	***To:*** BQ
Zolmitriptan	Tablet 2.5 mg	*Zomig*	***From:*** AP	***To:*** AS

Deletion of Responsible Person

Responsible Person and Code

Celgene Pty Limited *(CJ)*

Supply Only – Period Ending

Listed Drug	***Form***
Carbomer 974	Ocular lubricating gel 3 mg per g, single dose units 0.5 g, 30
Hypromellose with dextran	Eye drops containing 3 mg hypromellose 2900 with 1 mg dextran 70 per mL, single dose units 0.4 mL, 28
Mepolizumab	Powder for injection 100 mg
Risankizumab	Injection 75 mg in 0.83 mL pre-filled syringe

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug

Amiodarone

Anastrozole

Apixaban

Auranofin

Avelumab

Buprenorphine

Buprenorphine with naloxone

Cefazolin

Cefepime

Cefotaxime

Ceftriaxone

Chlorpromazine

Dabigatran etexilate

Digoxin

Disopyramide

Eptinezumab

Exemestane

Ezetimibe

Ezetimibe and rosuvastatin

Ezetimibe with atorvastatin

Ezetimibe with simvastatin

Fentanyl

Flecainide

Fluconazole

Flutamide

Fremanezumab

Galcanezumab

Isoniazid

Itraconazole

Lanreotide

Letrozole

Lidocaine

Methadone

Olanzapine

Penicillamine

Perhexiline

Periciazine

Posaconazole

Quetiapine

Rifampicin

Risperidone

Rivaroxaban

Romosozumab

Sevelamer

Sotalol

Tamoxifen

Tirofiban

Voriconazole

Zuclopenthixol decanoate

Documents Incorporated by Reference

Listed Drug	*Document Incorporated*	*Document access*
Romosozumab	**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
Risperidone	**Diagnostic and statistical manual of mental disorders (DSM-5 or DSM-V)** 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 DSM-5/DSM-V is a widely used tool for the definition and classification of mental disorders.	The DSM-5 can be accessed at the National Library of Australia and state libraries of Victoria, New South Wales and South Australia. The DSM-5 can be accessed through other public libraries, which can be identified through the National Library's Trove online system, and Australian universities and tertiary colleges.
Lanreotide	**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 (November Update) Instrument 2024
(PB 111 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 (November 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, new 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

4 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 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 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 was 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 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 was 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 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 was 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 naloxone in the form nasal spray 1.8 mg (as hydrochloride dihydrate) in 0.1 mL single dose unit, 2 (s19A) 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 naloxone in the form nasal spray 1.8 mg (as hydrochloride dihydrate) in 0.1 mL single dose unit, 2. 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 19 July 2024. Patient access has not been affected by this delisting, as the approved form of the drug is now available and remains PBS-subsidised and accessible for patients.

The drug ribavirin 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 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 was 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.

Nikolai Tsyganov
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