EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

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

PB 52 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.

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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 forms of the listed drugs budesonide with formoterol, ivacaftor, and medroxyprogesterone. It also provides for the the alteration of circumstances in which prescriptions may be written for the supply of the listed drugs adalimumab, alogliptin, alogliptin with metformin, apremilast, dapagliflozin, dapagliflozin with metformin, deucravacitinib, dulaglutide, empagliflozin, empagliflozin with linagliptin, empagliflozin with metformin, inclisiran, lenvatinib, linagliptin, linagliptin with metformin, nivolumab, osimertinib, ozanimod, pembrolizumab, pioglitazone, ruxolitinib, saxagliptin, saxagliptin with dapagliflozin, saxagliptin with metformin, secukinumab, semaglutide, sitagliptin, sitagliptin with metformin, tafamidis, upadacitinib, ustekinumab, vildagliptin, vildagliptin with metformin, and vosoritide.

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

- the addition of 28 brands of existing pharmaceutical items
- the deletion of 27 brands of existing pharmaceutical items
- the addition of a number of repeats for an existing pharmaceutical item
- the alteration of a number of repeats for an existing pharmaceutical item
- the alteration of a responsible person code for a brand of an existing pharmaceutical item
- the addition of 2 responsible persons to the list of responsible persons
- the deletion of a responsible person from the list of responsible persons
- the addition of 2 pharmaceutical items covered under Supply Only arrangements

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- the deletion of 6 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 June 2024.

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

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ATTACHMENT

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT (JUNE 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 (June Update) Instrument 2024* and may also be cited as PB 52 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 June 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 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 code for an existing pharmaceutical item, the addition and deletion of responsible persons for 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

Forms Added

Listed Drug	***Form***
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 60 doses
Ivacaftor	Sachet containing granules 25 mg
Medroxyprogesterone	Injection containing medroxyprogesterone acetate 150 mg in 1 mL pre-filled syringe

Brands Added

Listed Drug	***Form and Brand***
Azacitidine	Powder for injection 100 mg *(AZACITIDINE EUGIA)*
Benzathine benzylpenicillin	Powder for injection 1,200,000 units with diluent 5 mL (S19A) *(Extencilline Benzathine Benzylpenicillin (France))*
Bortezomib	Powder for injection 3.5 mg *(BORTEZOMIB EUGIA)*

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Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses *(Bufomix Easyhaler 400/12)*
Dicloxacillin	Capsule 250 mg (as sodium) *(DICLOXACILLIN VIATRIS 250)*
Estradiol	Transdermal patches 585 micrograms, 8 *(Estradiol Transdermal System (Sandoz, USA))*
	Transdermal patches 1.17 mg, *(Estradiol Transdermal System (Sandoz, USA))*
	Transdermal patches 1.56 mg, 8 *(Estradiol Transdermal System (Sandoz, USA))*
Furosemide	Tablet 20 mg *(UREMIDE 20)*
Methotrexate	Tablet 2.5 mg *(ARX-Methotrexate)*
	Tablet 10 mg *(ARX-Methotrexate)*
Olanzapine	Tablet 10 mg *(APO-OLANZAPINE)*
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate) *(Ondansetron Tablets Viatris)*
	Tablet 8 mg (as hydrochloride dihydrate) *(Ondansetron Tablets Viatris)*
	Tablet (orally disintegrating) 8 mg *(Ondansetron ODT Viatris)*
Perindopril	Tablet containing perindopril arginine 2.5 mg *(Perindopril Arginine Sandoz)*
	Tablet containing perindopril arginine 5 mg *(Perindopril Arginine Sandoz)*
	Tablet containing perindopril arginine 10 mg *(Perindopril Arginine Sandoz)*
Plerixafor	Injection 24 mg in 1.2 mL *(PLERIXAFOR EUGIA)*
Quetiapine	Tablet (modified release) 50 mg (as fumarate) *(Quetiapine Sandoz XR)*
	Tablet (modified release) 150 mg (as fumarate) *(Quetiapine Sandoz XR)*
	Tablet (modified release) 200 mg (as fumarate) *(Quetiapine Sandoz XR)*
	Tablet (modified release) 300 mg (as fumarate) *(Quetiapine Sandoz XR)*
	Tablet (modified release) 400 mg (as fumarate) *(Quetiapine Sandoz XR)*
Ramipril	Tablet 2.5 mg *(Ramipril Viatris)*
Rosuvastatin	Tablet 10 mg (as calcium) *(APO-Rosuvastatin)*
Sumatriptan	Tablet 50 mg (as succinate) *(IMIGRAN MIGRAINE)*
Testosterone	I.M. injection containing testosterone undecanoate 1,000 mg in 4 mL *(Testosterone ADVZ 1000)*

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Brands Deleted

Listed Drug	*Form and Brand*
Ambrisentan	Tablet 5 mg *(Ambrisentan Mylan)*
Anastrozole	Tablet 1 mg *(Arimidex)*
Bortezomib	Powder for injection 1 mg *(Velcade)*
	Powder for injection 3 mg *(Velcade)*
	Powder for injection 3.5 mg *(Velcade)*
Bosentan	Tablet 62.5 mg (as monohydrate) *(Tracleer)*
	Tablet 125 mg (as monohydrate) *(Tracleer)*
Cefepime	Powder for injection 1 g (as hydrochloride) *(Omegapharm Pty Ltd)*
	Powder for injection 2 g (as hydrochloride) *(Omegapharm Pty Ltd)*
Ceftriaxone	Powder for injection 1 g (as sodium) *(Ceftriaxone Alphapharm)*
Dosulepin	Capsule containing dosulepin hydrochloride 25 mg *(Dosulepin Mylan)*
Enalapril	Tablet containing enalapril maleate 5 mg *(Enalapril generichealth)*
	Tablet containing enalapril maleate 10 mg *(Enalapril generichealth)*
Lamivudine with zidovudine	Tablet 150 mg-300 mg *(Lamivudine 150 mg + Zidovudine 300 mg Alphapharm)*
Mycophenolic acid	Tablet containing mycophenolate mofetil 500 mg *(Noumed Mycophenolate)*
Naltrexone	Tablet containing naltrexone hydrochloride 50 mg *(ARX-NALTREXONE)*
Nebivolol	Tablet 1.25 mg (as hydrochloride) *(Nebivolol Viatris)*
	Tablet 10 mg (as hydrochloride) *(Nebivolol Viatris)*
Pioglitazone	Tablet 30 mg (as hydrochloride) *(NOUMED PIOGLITAZONE; Pioglitazone Sandoz)*
	Tablet 45 mg (as hydrochloride) *(NOUMED PIOGLITAZONE; Pioglitazone Sandoz)*
Rosuvastatin	Tablet 5 mg (as calcium) *(Noumed Rosuvastatin)*
	Tablet 10 mg (as calcium) *(Noumed Rosuvastatin)*
	Tablet 20 mg (as calcium) *(Noumed Rosuvastatin)*
	Tablet 40 mg (as calcium) *(Noumed Rosuvastatin)*
Valaciclovir	Tablet 500 mg (as hydrochloride) *(NOUMED VALACICLOVIR)*

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Addition of Number of Repeats

Listed Drug	*Form*	*Brand*	*Maximum Quantity*	*Number of Repeats*
Secukinumab	Injection 150 mg in 1 mL pre-filled pen	*Cosentyx*	2	3

Alteration of Number of Repeats

Listed Drug	*Form*	*Brand*	*Maximum Quantity*	*Number of Repeats*
Teriparatide	Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled cartridge	*Terrosa*	2	***From:*** 5 ***To:*** 2

Alteration of Responsible Person Code

Listed Drug	*Form*	*Brand Name*	*Responsible Person*
Tobramycin	Solution for inhalation 300 mg in 5 mL	*Tobramycin WKT*	***From:*** LI ***To:*** JU

Addition of Responsible Person

Responsible Person and Code

EUGIA PHARMA (AUSTRALIA) PTY LTD *(YG)*

The Trustee for ORSPEC PHARMA UNIT TRUST *(YO)*

Deletion of Responsible Person

Responsible Person and Code

Luminarie Pty Ltd *(LI)*

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug

Adalimumab

Alogliptin

Alogliptin with metformin

Apremilast

Dapagliflozin

Dapagliflozin with metformin

Deucravacitinib

Dulaglutide

Empagliflozin

Empagliflozin with linagliptin

Empagliflozin with metformin

Ozanimod

Pembrolizumab

Pioglitazone

Ruxolitinib

Saxagliptin

Saxagliptin with dapagliflozin

Saxagliptin with metformin

Secukinumab

Semaglutide

Sitagliptin

Sitagliptin with metformin

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Inclisiran	Tafamidis
Lenvatinib	Upadacitinib
Linagliptin	Ustekinumab
Linagliptin with metformin	Vildagliptin
Nivolumab	Vildagliptin with metformin
Osimertinib	Vosoritide

Supply Only – Additions

Listed Drug	*Form*
Bisacodyl	Enemas 10 mg in 5 mL, 25
Ketoconazole	Cream 20 mg per g, 30 g

Supply Only – Deletions

Listed Drug	*Form*
Insulin neutral with insulin isophane	Injections (human), cartridges, 50 units-50 units per mL, 3 mL, 5
Macrogol 3350	Oral liquid 13.125 g in 25 mL with electrolytes, 500 mL
Pancrelipase	Capsule (containing enteric coated microtablets) providing not less than 25,000 BP units of lipase activity
Paraffin with retinol palmitate	Eye ointment, compound, containing liquid paraffin, light liquid paraffin, wool fat, white soft paraffin and retinol palmitate, 5 g
Raltegravir	Tablet 25 mg (as potassium) Tablet 100 mg (as potassium)

Documents Incorporated by Reference

Listed Drug	*Document incorporated*	*Document access*
Deucravacitinib Inclisarin Ivacaftor	**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

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Inclisarin	**Dutch Lipid Clinic Network Score (DLCNS)** 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 DLCNS is a validated set of criteria used to categorise the likelihood of a patient having Familial Hypercholesterolaemia, by evaluating family history of premature cardiovascular disease (CVD) in first degree relatives, the patient's own CVD history, their untreated lipid levels and physical signs such as the presence of tendon xanthomata or arcus cornealis prior to the age of 45.	The DLCNS is available for download for free from the Royal Australian College of General Practitioners website https://www.racgp.org.au/FSDEDEV/media/documents/Clinical%20Resources/Guidelines/Red%20Book/Appendix-2B.pdf
Adalimumab Secukinumab	**Hurley stages.** 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.* Hurley stages are used to classify the severity of Hidradenitis Suppurativa symptoms	A description of the Hurley stages is available for download for free from https://www.racgp.org.au/afp/2017/august/hidradenitis-suppurativa-management-comorbidities-and-monitoring/
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
Apremilast Deucravacitinib	**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.
Osimertinib	**World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status/Performance Status Score.** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*. The WHO/ECOG performance status is a standard medical diagnostic tool used to measure how cancer impacts a patient's daily living abilities, by evaluating a patient's level of functioning in terms of their ability to care for themself, daily activity, and physical ability (walking, working, etc.).	The WHO/ECOG Performance Status is available for download for free from the ECOG-ACRIN Cancer Research Group website: https://ecog-acrin.org/resources/ecog-performance-status

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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 Secukinumab	**Hidradenitis Suppurativa Clinical Response (HiSCR)**	The HiSCR is used to assess/determine an adequate response to a particular biological medicine for the treatment of Hidradenitis Suppurativa. HiSCR is defined as a ≥ 50% reduction in inflammatory lesion count (abscesses + inflammatory nodules), and no increase in abscesses or draining fistulas when compared with baseline.	The HiSCR is a diagnostic tool rather than a document incorporated Reference: Kimball, A., Jemec, G., Yang, M., Kageleiry, A., Signorovitch, J., Okun, M., Gu, Y., Wang, K., Mulani, P. and Sundaram, M. (2014), Assessing the validity, responsiveness and meaningfulness of the Hidradenitis Suppurativa Clinical Response (HiSCR) as the clinical endpoint for hidradenitis suppurativa treatment. Br J Dermatol, 171: 1434-1442. https://doi.org/10.1111/bjd.13270

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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 (June Update) Instrument 2024
(PB 52 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 (June 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 forms and brands of existing listed drugs, and ensuring the deletion of brands of listed drugs does not affect access to subsidised

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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 3 new forms of existing drugs, and the addition of 28 new brands across 28 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 bisacodyl in the form enemas 10 mg in 5 mL, 25 (Bisalax) was requested to be delisted from the PBS by the sponsor. The PBAC noted that there are alternative products 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 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 insulin neutral with insulin isophane in the form injections (human), cartridges, 50 units-50 units per mL, 3 mL, 5 (Mixtard 50/50 Penfill 3 mL) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the previous financial year and the alternatives available on the PBS Schedule. The PBAC noted the sponsor indicated that the product is no longer marketed in Australia and also that it had notified the TGA. The PBAC advised the delisting of this form would not result in an unmet clinical need. This item was available on the PBS Schedule under Supply Only arrangements for a period of 6 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug ketoconazole (Nizoral 2% Cream) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the sponsor's plans to discontinue manufacture of Nizoral 2% cream and that there are alternative products 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 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 macrogol 3350 in the form oral liquid 13.125 g in 25 mL with electrolytes, 500 mL (Movicol Liquid) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the substantial number of services in the last financial year and that the sachet form remains listed on the PBS Schedule. The PBAC noted the sponsor stated that there would be stock available until the fourth quarter of 2023. The PBAC advised the delisting of this product would not result in an unmet clinical need. This item was available on the PBS Schedule

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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 pancrelipase in the form capsule (containing enteric coated microtablets) providing not less than 25,000 BP units of lipase activity (Panzytrat 25000) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the last financial year and that the alternative s19A product is no longer available. The PBAC noted that the sponsor has advised there has been no supply of the product in Australia since November 2020 and that the product, which has now been discontinued, was removed from the ARTG in November 2021. The PBAC reaffirmed its previous advice at the March 2023 PBAC meeting (when this delisting was first considered) that delisting would not result in an unmet clinical need as there is an alternative on the PBS Schedule. This item was available on the PBS Schedule under Supply Only arrangements for a period of 6 months, allowing patients with a pre-existing valid prescription to access the item pending transition to an alternative treatment option.

The drug paraffin with retinol palmitate (VitA-POS) 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 2 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug raltegravir in the forms tablet 25 mg (as potassium) (Isentress) and tablet 100 mg (as potassium) (Isentress) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted there were no services in the last financial year and that there are multiple alternatives on the PBS Schedule. The PBAC advised the delisting of this form would not result in an unmet clinical need. These items were 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.

Conclusion

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

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