

## **EXPLANATORY STATEMENT**

### ***NATIONAL HEALTH ACT 1953***

#### ***NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2024 (No. 1)***

#### **PB 1 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 2012* (PB 71 of 2012) to make changes to the pharmaceutical benefits listed for the purposes of the Pharmaceutical Benefits Scheme (PBS), and related matters.

PB 71 of 2012 determines the pharmaceutical benefits that are on the Schedule of Pharmaceutical Benefits (the PBS Schedule) through declarations of drugs and medicinal preparations, and 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(4ACA) 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 71 of 2012 cited in this Instrument and explanatory statement, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary PB 71 of 2012.

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 71 of 2012 made by this Instrument**

Schedule 1 to this Instrument provides for the addition to the PBS Schedule of the drugs nivolumab with relatlimab, and tebentafusp, and forms of the listed drugs colestyramine, fluoxetine, natalizumab, and salbutamol. It also provides for the deletion of forms of the listed drugs amino acid formula with vitamins and minerals without methionine, amino acid formula with vitamins and minerals without phenylalanine and tyrosine, and amino acid formula with vitamins and minerals without valine, leucine and isoleucine, and the alteration of circumstances in which prescriptions may be written for the supply of the listed drugs ipilimumab, nivolumab and pembrolizumab.

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

- the addition of 14 brands of existing pharmaceutical items
- the deletion of 92 brands of existing pharmaceutical items
- the alteration of manufacturer codes for 4 existing pharmaceutical items
- the addition of 2 responsible persons to the list of responsible persons
- the deletion of 3 responsible persons from the list of responsible persons
- the deletion of 8 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 February 2024.

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

**PROVISION-BY-PROVISION DESCRIPTION OF NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2024 (No. 1)**

**Section 1 Name of Instrument**

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2024 (No. 1)* and may also be cited as PB 1 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 February 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 drugs, the addition and deletion of forms of listed drugs, the addition and deletion of brands, the alteration of manufacturer codes for brands of pharmaceutical items, the addition and deletion of responsible persons for 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**

Nivolumab with relatlimab

Tebentafusp

**Forms Added**

**Listed Drug**

**Form**

Colestyramine Sachet containing 4 g oral powder (s19A)

Fluoxetine Capsule 10 mg (Medreich) (S19A)

Natalizumab Injection 150 mg in 1 mL single dose pre-filled syringe

Salbutamol Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 20 (S19A)

## Forms Deleted

<b>Listed Drug</b>	<b>Form</b>
Amino acid formula with vitamins and minerals without methionine	Sachets containing oral powder 24 g, 30 (HCU gel)
Amino acid formula with vitamins and minerals without phenylalanine and tyrosine	Sachets containing oral powder 24 g, 30 (TYR gel)
Amino acid formula with vitamins and minerals without valine, leucine and isoleucine	Sachets containing oral powder 24 g, 30 (MSUD gel)

## Brands Added

<b>Listed Drug</b>	<b>Form and Brand</b>
Amantadine	Capsule containing amantadine hydrochloride 100 mg ( <i>AMANTAMED</i> )
Aripiprazole	Tablet 10 mg ( <i>ARIZOLE</i> )
	Tablet 15 mg ( <i>ARIZOLE</i> )
	Tablet 20 mg ( <i>ARIZOLE</i> )
	Tablet 30 mg ( <i>ARIZOLE</i> )
Gliclazide	Tablet 30 mg (modified release) ( <i>Gliclazide MR Viatris</i> )
Mycophenolic acid	Tablet (enteric coated) containing mycophenolate sodium equivalent to 180 mg mycophenolic acid ( <i>Mycophenolic Acid ARX</i> )
	Tablet (enteric coated) containing mycophenolate sodium equivalent to 360 mg mycophenolic acid ( <i>Mycophenolic Acid ARX</i> )
Nebivolol	Tablet 1.25 mg (as hydrochloride) ( <i>Nebivolol Viatris</i> )
	Tablet 10 mg (as hydrochloride) ( <i>Nebivolol Viatris</i> )
Palonosetron	Injection 250 micrograms (as hydrochloride) in 5 mL ( <i>PALONOSETRON Medsurge</i> )
Tenofovir	Tablet containing tenofovir disoproxil maleate 300 mg ( <i>Tenofovir Disoproxil Viatris</i> )
Trientine	Capsule containing trientine dihydrochloride 250 mg (equivalent to 166.7 mg trientine) ( <i>Trientine Dr. Reddy's</i> )
Varenicline	Box containing 11 tablets 0.5 mg (as tartrate) and 14 tablets 1 mg (as tartrate) in the first pack and 28 tablets 1 mg (as tartrate) in the second pack ( <i>VARENAPLIX</i> )

## Brands Deleted

<b>Listed Drug</b>	<b>Form and Brand</b>
Acarbose	Tablet 100 mg ( <i>Acarbose Mylan</i> )
Ambrisentan	Tablet 10 mg ( <i>Ambrisentan Mylan</i> )
Amisulpride	Tablet 100 mg ( <i>Amisulpride 100 Winthrop</i> )

Amlodipine	Tablet 5 mg (as besilate) ( <i>Amlodipine Amneal</i> )
	Tablet 10 mg (as besilate) ( <i>Amlodipine Amneal</i> )
Amoxicillin with clavulanic acid	Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) ( <i>Amoxyclav AN 500/125</i> )
	Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) ( <i>Amoxyclav AN 875/125</i> )
Aripiprazole	Tablet 30 mg ( <i>Aripiprazole generichealth</i> )
Atenolol	Tablet 50 mg ( <i>Atenolol Amneal</i> )
Azathioprine	Tablet 50 mg ( <i>Azathioprine GH</i> )
Bleomycin	Powder for injection containing bleomycin sulfate 15,000 I.U. ( <i>CIPLA BLEOMYCIN</i> )
Bosentan	Tablet 62.5 mg (as monohydrate) ( <i>Bosentan Cipla</i> )
Calcitriol	Capsule 0.25 microgram ( <i>Calcitriol AN</i> )
Cefepime	Powder for injection 1 g (as hydrochloride) ( <i>Cefepime Alphapharm</i> )
	Powder for injection 2 g (as hydrochloride) ( <i>Cefepime Alphapharm</i> )
Cinacalcet	Tablet 60 mg (as hydrochloride) ( <i>Cinacalcet Mylan</i> )
Citalopram	Tablet 10 mg (as hydrobromide) ( <i>Citalopram AN</i> )
	Tablet 20 mg (as hydrobromide) ( <i>Citalopram AN</i> )
	Tablet 40 mg (as hydrobromide) ( <i>Citalopram AN</i> )
Clarithromycin	Tablet 250 mg ( <i>Clarithromycin AN</i> )
Cyproterone	Tablet containing cyproterone acetate 50 mg ( <i>Cyprone 50</i> )
	Tablet containing cyproterone acetate 100 mg ( <i>Cyprone 100</i> )
Deferasirox	Tablet 90 mg ( <i>CIPLA DEFERASIROX</i> )
	Tablet 180 mg ( <i>CIPLA DEFERASIROX</i> )
	Tablet 360 mg ( <i>CIPLA DEFERASIROX</i> )
Desvenlafaxine	Tablet (modified release) 50 mg ( <i>Desvenlafaxine Actavis</i> )
	Tablet (modified release) 100 mg ( <i>Desvenlafaxine Actavis</i> )
Diclofenac	Tablet (enteric coated) containing diclofenac sodium 25 mg ( <i>Diclofenac AN</i> )
	Tablet (enteric coated) containing diclofenac sodium 50 mg ( <i>Diclofenac AN</i> )
Diltiazem	Tablet containing diltiazem hydrochloride 60 mg ( <i>Diltiazem AN</i> )

Ezetimibe with simvastatin	Tablet 10 mg-10 mg ( <i>EZEVYT 10/10</i> )
	Tablet 10 mg-20 mg ( <i>EZEVYT 10/20</i> )
	Tablet 10 mg-40 mg ( <i>EZEVYT 10/40</i> )
	Tablet 10 mg-80 mg ( <i>EZEVYT 10/80</i> )
Famciclovir	Tablet 125 mg ( <i>Famciclovir-GA</i> )
	Tablet 250 mg ( <i>Famciclovir-GA</i> )
	Tablet 500 mg ( <i>Famciclovir-GA</i> )
Fluticasone propionate with salmeterol	Pressurised inhalation containing fluticasone propionate 125 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation) ( <i>Seroflo 125/25</i> )
	Pressurised inhalation containing fluticasone propionate 250 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation) ( <i>Seroflo 250/25</i> )
Furosemide	Tablet 20 mg ( <i>FUROSEMIDE AN</i> )
	Tablet 40 mg ( <i>FUROSEMIDE AN</i> )
Gabapentin	Tablet 600 mg ( <i>Gabapentin AN</i> )
Glimepiride	Tablet 2 mg ( <i>Amaryl</i> )
Irbesartan	Tablet 75 mg ( <i>Irbesartan AMNEAL; Irbesartan AN</i> )
	Tablet 300 mg ( <i>Irbesartan AN</i> )
Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL ( <i>MEDITAB IRINOTECAN</i> )
	I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL ( <i>MEDITAB IRINOTECAN</i> )
Isosorbide mononitrate	Tablet 60 mg (sustained release) ( <i>Isosorbide AN; Monodur 60 mg</i> )
Isotretinoin	Capsule 10 mg ( <i>Rocta 10</i> )
	Capsule 20 mg ( <i>Rocta 20</i> )
Meloxicam	Capsule 7.5 mg ( <i>Chem mart Meloxicam; Terry White Chemists Meloxicam</i> )
	Capsule 15 mg ( <i>Chem mart Meloxicam; Terry White Chemists Meloxicam</i> )
Metformin	Tablet containing metformin hydrochloride 500 mg ( <i>Metformin AN</i> )
	Tablet containing metformin hydrochloride 850 mg ( <i>Chem mart Metformin; Metformin AN; Terry White Chemists Metformin</i> )
	Tablet containing metformin hydrochloride 1 g ( <i>Metformin AN</i> )
Methotrexate	Solution concentrate for I.V. infusion 1000 mg in 10 mL vial ( <i>Pfizer Australia Pty Ltd</i> )

Metoclopramide	Injection containing 10 mg metoclopramide hydrochloride (as monohydrate) in 2 mL ( <i>Maxolon</i> )
Mirtazapine	Tablet 15 mg (orally disintegrating) ( <i>Mirtazapine AN ODT</i> ) Tablet 30 mg ( <i>Mirtazon</i> ) Tablet 30 mg (orally disintegrating) ( <i>Mirtazapine AN ODT</i> ) Tablet 45 mg ( <i>Mirtazon</i> ) Tablet 45 mg (orally disintegrating) ( <i>Mirtazapine AN ODT</i> )
Moclobemide	Tablet 150 mg ( <i>Moclobemide AN</i> ) Tablet 300 mg ( <i>Moclobemide AN</i> )
Nitrofurantoin	Capsule 50 mg ( <i>APO-Nitrofurantoin</i> ) Capsule 100 mg ( <i>APO-Nitrofurantoin</i> )
Octreotide	Injection 100 micrograms (as acetate) in 1 mL ( <i>Octreotide MaxRx</i> )
Ondansetron	Tablet (orally disintegrating) 4 mg ( <i>Ondansetron AN ODT</i> ) Tablet 4 mg (as hydrochloride dihydrate) ( <i>Ondansetron AN</i> ) Tablet (orally disintegrating) 8 mg ( <i>Ondansetron AN ODT</i> ) Tablet 8 mg (as hydrochloride dihydrate) ( <i>Ondansetron AN</i> )
Pantoprazole	Tablet (enteric coated) 40 mg (as sodium sesquihydrate) ( <i>Pantoprazole AN</i> )
Paroxetine	Tablet 20 mg (as hydrochloride) ( <i>Paroxetine AN</i> )
Pegfilgrastim	Injection 6 mg in 0.6 mL single use pre-filled syringe ( <i>Ristempa</i> )
Perindopril	Tablet containing perindopril erbumine 4 mg ( <i>Perindopril generichealth</i> ) Tablet containing perindopril erbumine 8 mg ( <i>Perindopril generichealth</i> )
Quetiapine	Tablet 100 mg (as fumarate) ( <i>Quetiapine AN</i> ) Tablet 300 mg (as fumarate) ( <i>Quetiapine AN</i> )
Ramipril	Capsule 1.25 mg ( <i>APO-Ramipril</i> )
Rizatriptan	Tablet (orally disintegrating) 10 mg (as benzoate) ( <i>Rizatriptan AN ODT</i> )
Salbutamol	Nebuliser solution 5 mg (as sulfate) in 2.5 mL single dose units, 30 ( <i>Salbutamol AN</i> )
Sertraline	Tablet 50 mg (as hydrochloride) ( <i>Sertraline AN</i> ) Tablet 100 mg (as hydrochloride) ( <i>Sertraline AN</i> )
Sildenafil	Tablet 20 mg (as citrate) ( <i>Sildenafil AN PHT 20</i> )



Tenofovir with emtricitabine and efavirenz	Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg and efavirenz 600 mg ( <i>Tenofovir Disoproxil/Emtricitabine/Efavirenz Mylan 300/200/600</i> )
Tobramycin	Injection 80 mg in 2 mL ( <i>Tobramycin Mylan</i> )

### Alteration of Manufacturer Code

<b>Listed Drug</b>	<b>Form</b>	<b>Brand Name</b>	<b>Manufacturer Code</b>	
Methylprednisolone	Cream containing methylprednisolone aceponate 1 mg per g, 15 g	<i>Supriad Cream</i>	<b>From:</b> LG	<b>To:</b> XT
	Fatty ointment containing methylprednisolone aceponate 1 mg per g, 15 g	<i>Supriad Fatty Ointment</i>	<b>From:</b> LG	<b>To:</b> XT
	Ointment containing methylprednisolone aceponate 1 mg per g, 15 g	<i>Supriad Ointment</i>	<b>From:</b> LG	<b>To:</b> XT
Terbinafine	Cream containing terbinafine hydrochloride 10 mg per g, 15 g	<i>Lamisil</i>	<b>From:</b> GJ	<b>To:</b> NP

### Addition of Responsible Persons

#### **Responsible Person and Code**

Nice-Pak Products Pty. Ltd (*NP*)

MEDISON PHARMA AUSTRALIA PTY LIMITED (*WM*)

### Deletion of Responsible Persons

#### **Responsible Person and Code**

Apotex Pty Ltd (*CH*)

Amneal Pharmaceuticals Pty Ltd (*EF*)

Leo Pharma Pty Ltd (*LG*)

### Alteration of Circumstances in Which a Prescription May be Written

#### **Listed Drug**

Ipilimumab

Nivolumab

Pembrolizumab

### Supply Only – Deletions

<b>Listed Drug</b>	<b>Form</b>
Amino acid formula with vitamins and minerals without phenylalanine	Sachets containing oral powder 24 g, 30 (PKU gel) ( <i>PKU gel</i> )

Efavirenz	Tablet 200 mg ( <i>Stocrin</i> )
	Tablet 600 mg ( <i>Stocrin</i> )
Eprosartan	Tablet 400 mg (as mesilate) ( <i>Teveten</i> )
Ertugliflozin	Tablet 5 mg ( <i>Steglatro 5</i> )
	Tablet 15 mg ( <i>Steglatro 15</i> )
Ertugliflozin with sitagliptin	Tablet containing 5 mg ertugliflozin with 100 mg sitagliptin ( <i>Steglujan 5/100</i> )
	Tablet containing 15 mg ertugliflozin with 100 mg sitagliptin ( <i>Steglujan 15/100</i> )

## Documents Incorporated by Reference

<i>Listed Drug</i>	<i>Document incorporated</i>	<i>Document access</i>
Tebentafusp	<p><b>Approved Product Information/Australian Product Information/TGA-approved Product Information.</b></p> <p>The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the <i>Legislation Act 2003</i>.</p> <p>This document provides health professionals with a summary of the scientific information relevant to the safe and effective use of a prescription medicine.</p>	<p>TGA-approved Product Information is available for download for free from the TGA website: <a href="https://www.tga.gov.au/product-information-0">https://www.tga.gov.au/product-information-0</a></p>
Ipilimumab Nivolumab Nivolumab with relatlimab	<p><b>World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status/Performance Status Score.</b></p> <p>The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the <i>Legislation Act 2003</i>.</p> <p>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 themselves, daily activity, and physical ability (walking, working, etc.).</p>	<p>The WHO/ECOG Performance Status is available for download for free from the ECOG-ACRIN Cancer Research Group website: <a href="https://ecog-acrin.org/resources/ecog-performance-status">https://ecog-acrin.org/resources/ecog-performance-status</a></p>

## 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 Instrument 2024 (No. 1)*** **(PB 1 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 Instrument 2024 (No. 1)* (the Instrument) amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) (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 listed drugs, new forms and brands of existing listed drugs, and ensuring the deletion of forms of listed drugs 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, 4 new forms of existing drugs, and 14 new brands across 14 existing forms, which allows for greater patient access to these drugs.

When a sponsor submits a request to delist a drug from the PBS, subsection 101(4AAB) of the *National Health Act 1953* requires that the Minister or their delegate obtain advice from the Pharmaceutical Benefits Advisory Committee (PBAC), an independent and expert advisory body, before varying or revoking declarations under subsection 85(2) so as to delist the drug. In these instances, one of the matters which the PBAC provides advice on is whether the delisting of a drug will result in an unmet clinical need for patients. The PBAC also considers whether the delisting of a form of a drug will result in an unmet clinical need for patients.

Written advice from the PBAC is tabled with the monthly amendments to the Principal Instrument. An unmet clinical need would arise when a currently treated patient population would be left without treatment options once a delisting occurs. Alternative treatment options could include using a different: form, strength or drug. The PBAC considered the delisting of drugs and forms of drugs in the abovementioned instruments, would not result in an unmet clinical need, except where indicated for a particular drug or form of drug below. Where the PBAC has identified an unmet clinical need, a Supply Only period has been/will be instituted as outlined below to allow opportunity for patients to transition to an alternative treatment option. The delisting of these items will not affect access to the drugs (or an alternative treatment if required), as affected patients will be able to access alternative medicines through the PBS, and the delisting is unlikely to have an effect on the amount patients pay for those drugs, as co-payment amounts are capped, ensuring their rights to social security are maintained. From 1 January 2024, these amounts are \$31.60 for general patients and \$7.70 for concession card holders.

Where there are many brands of a listed drug and form, then the delisting of one brand will not adversely affect members of the public as they will be able to obtain any of the other equivalent brands. The delisting of brands in this Instrument will not affect access to the drugs, as affected patients will be able to access equivalent brands, at the same cost. Consequently, the brand delistings in this instrument do not result in an unmet clinical need. Note that delisting of maximum quantities, number of repeats, and pack sizes are equivalent to brand delistings.

The drug amino acid formula with vitamins and minerals without methionine in the form sachets containing oral powder 24 g, 30 (HCU gel) 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 multiple alternatives on the PBS. The PBAC noted the sponsor intends to discontinue manufacture of this product. The PBAC advised the delisting of this product would not result in an unmet clinical need.

The drug amino acid formula with vitamins and minerals without phenylalanine, in the form sachets containing oral powder 24 g, 30 (PKU gel), was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted there are multiple alternatives on the PBS and advised the delisting of this product would not result in an unmet clinical need. This item was available on the Schedule under Supply Only arrangements for a period of up to 12 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug amino acid formula with vitamins and minerals without phenylalanine and tyrosine in the form sachets containing oral powder 24 g, 30 (TYR gel) 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 multiple alternatives on the PBS. The PBAC noted the sponsor intends to discontinue manufacture of this product. The PBAC advised the delisting of this product would not result in an unmet clinical need.

The drug amino acid formula with vitamins and minerals without valine, leucine and isoleucine in the form sachets containing oral powder 24 g, 30 (MSUD gel) 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 multiple alternatives on the PBS. The PBAC noted the sponsor intends to discontinue manufacture of this product. The PBAC advised the delisting of this product would not result in an unmet clinical need.

The drug efavirenz, in the forms tablet 200 mg (Stocrin) and tablet 600 mg (Stocrin), 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 multiple alternatives available on the PBS. The PBAC noted the sponsor intends to discontinue supply of this product in Australia. The PBAC advised the delisting of this drug would not result in an unmet clinical need. These items were available on the Schedule under Supply Only arrangements for a period of up

to 12 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug eprosartan, in the form tablet 400 mg (as mesilate) (Teveten), was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted that there are multiple alternatives on the PBS, including an alternate strength of eprosartan and advised the delisting of this product would not result in an unmet clinical need. This item was available on the Schedule under Supply Only arrangements for a period of up to 12 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug ertugliflozin, in the forms tablet 5 mg (Steglatro 5) and tablet 15 mg (Steglatro 15), was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted there were a moderate number of services in the last financial year and that there are multiple alternatives available on the PBS. The PBAC noted the sponsor intends to discontinue supply of this product in Australia. The PBAC advised the delisting of this drug would not result in an unmet clinical need. These items were available on the Schedule under Supply Only arrangements for a period of up to 12 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug ertugliflozin with sitagliptin, in the forms tablet containing 5 mg ertugliflozin with 100 mg sitagliptin (Steglujan 5/100) and tablet containing 15 mg ertugliflozin with 100 mg sitagliptin (Steglujan 15/100), was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted there were a moderate number of services in the last financial year and that there are multiple alternatives available on the PBS. The PBAC noted the sponsor intends to discontinue supply of this product in Australia. The PBAC advised the delisting of this drug would not result in an unmet clinical need. These items were available on the Schedule under Supply Only arrangements for a period of up to 12 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**  
**Assistant Secretary**  
**Pricing and PBS Policy Branch**  
**Technology Assessment and Access Division**  
**Department of Health and Aged Care**