

## EXPLANATORY STATEMENT

### NATIONAL HEALTH ACT 1953

#### NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2023 (No. 7)

#### PB 67 of 2023

##### **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(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 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 eptinezumab and trabectedin, the deletion of the listed drug reteplase, the addition of forms of the listed drugs colestyramine and varenicline and 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 methionine, threonine and valine and low in isoleucine, amino acid formula with vitamins and minerals without phenylalanine and tyrosine, amino acid formula with vitamins and minerals without valine, leucine and isoleucine, epirubicin, larotrectinib, levodopa with carbidopa, morphine, and paclitaxel. It also provides for the alteration of circumstances in which prescriptions may be written for the supply of the listed drugs certolizumab pegol, diroximel fumarate, enzalutamide, golimumab, mifepristone and misoprostol, palbociclib, secukinumab, sitagliptin, tocilizumab, tofacitinib, and upadacitinib.

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

- the addition of 24 brands of existing pharmaceutical items
- the deletion of 4 brands of existing pharmaceutical items
- the alteration of a brand name for 1 existing pharmaceutical item
- the addition of a pack quantity for an existing pharmaceutical item
- the alteration of a maximum quantity for an existing pharmaceutical item
- the alteration of authorised prescribers for an existing pharmaceutical item
- the addition of a responsible person to the list of responsible persons

- the addition of 10 pharmaceutical items covered under Supply Only arrangements
- the deletion of a pharmaceutical item covered under Supply Only arrangements.

These changes are summarised, by subject matter, in the Attachment.

### **Consultation**

The involvement of interested parties through the membership of the PBAC constitutes a formal and ongoing process of consultation. The PBAC is an independent expert body established by section 100A of the Act which makes recommendations to the Minister about which drugs and medicinal preparations should be available to Australians as pharmaceutical benefits. The PBAC members are appointed following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC. In addition, an industry nominee has been appointed to the PBAC membership under the PBS Access and Sustainability Package of reforms announced in May 2015. When recommending the listing of a medicine on the PBS, PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

Pharmaceutical companies are consulted throughout the process of the listing of their medicines on the PBS and in relation to changes to those listings. This includes the company submission to the PBAC and involvement throughout the PBAC process, negotiations or consultation on price, guarantee of supply and agreement to final listing details.

It was considered that further consultation for this Instrument was unnecessary due to the nature of the consultation that had already taken place.

### **General**

A provision-by-provision description of this Instrument is contained in the Attachment.

This Instrument commences on 1 August 2023.

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 2023 (No. 7)**

**Section 1 Name of Instrument**

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 7)* and may also be cited as PB 67 of 2023.

**Section 2 Commencement**

Subsection 2(1) provides for commencement dates of each of the provisions specified in Column 1 of the table, in accordance with Column 2 of the table. In accordance with Column 2 of the table, Schedule 1 to the Instrument commences on 1 August 2023.

**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**

Section 4 provides that each instrument that is specified in a Schedule to the Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Instrument has effect according to its terms.

**Schedule 1 Amendments**

The amendments in Schedule 1 involve the addition and deletion of listed drugs, the addition and deletion of forms of listed drugs, the addition and deletion of brands, the alteration of a brand name, the addition of a pack quantity, the alteration of a maximum quantity for a listed drug, the alteration of authorised prescribers for a listed drug, the addition of a responsible person to the list of responsible persons, the addition and deletion of 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**

Eptinezumab

Trabectedin

**Drug Deleted**

**Listed Drug**

Reteplase

**Forms Added**

**Listed Drug**

**Form**

Colestyramine Sachet containing 4 g oral powder (s19A)

Varenicline Tablet 0.5 mg (as tartrate) (s19A)

## Forms Deleted

<b>Listed Drug</b>	<b>Form</b>
Amino acid formula with vitamins and minerals without methionine	Oral powder 500 g (XMET Maxamum)
Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine	Oral powder 500 g (XMTVI Maxamum)
Amino acid formula with vitamins and minerals without phenylalanine and tyrosine	Oral powder 500 g (XPhen, Tyr Maxamum)
Amino acid formula with vitamins and minerals without valine, leucine and isoleucine	Oral powder 500 g (MSUD AID III)
Epirubicin	Solution for injection containing epirubicin hydrochloride 50 mg in 25 mL
Larotrectinib	Oral solution 20 mg per mL (as sulfate), 100 mL
Levodopa with carbidopa	Tablet (prolonged release) 200 mg-50 mg
Morphine	Tablet containing morphine sulfate pentahydrate 30 mg
Paclitaxel	Solution concentrate for I.V. infusion 100 mg in 16.7 mL Solution concentrate for I.V. infusion 150 mg in 25 mL

## Brands Added

<b>Listed Drug</b>	<b>Form and Brand</b>
Acamprosate	Tablet (enteric coated) containing acamprosate calcium 333 mg ( <i>ACAMPROSATE VIATRIS</i> )
Acarbose	Tablet 50 mg ( <i>Acarbose Viatris</i> )
Atovaquone with proguanil	Tablet containing atovaquone 250 mg with proguanil hydrochloride 100 mg ( <i>AtovaquoPro Lupin 250/100</i> )
Bendamustine	Powder for injection containing bendamustine hydrochloride 25 mg ( <i>Bendamustine Sandoz; Bendamustine Viatris</i> )  Powder for injection containing bendamustine hydrochloride 100 mg ( <i>Bendamustine Sandoz; Bendamustine Viatris</i> )
Budesonide with formoterol	Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses ( <i>Rilast RAPIHALER 100/3</i> )  Pressurised inhalation containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses ( <i>Rilast RAPIHALER 200/6</i> )
Cefazolin	Powder for injection 2 g (as sodium) ( <i>Cephazolin Viatris</i> )

Cinacalcet	Tablet 90 mg (as hydrochloride) ( <i>Cinacalcet Viatris</i> )
Hyoscine	Injection containing hyoscine butylbromide 20 mg in 1 mL ( <i>HYOSCINE BUTYLBROMIDE-AFT</i> )
Lanreotide	Injection 60 mg (as acetate) in single dose pre-filled syringe ( <i>Mytolac</i> ) Injection 90 mg (as acetate) in single dose pre-filled syringe ( <i>Mytolac</i> ) Injection 120 mg (as acetate) in single dose pre-filled syringe ( <i>Mytolac</i> )
Meloxicam	Tablet 15 mg ( <i>Meloxicam Viatris</i> )
Perindopril	Tablet containing perindopril arginine 2.5 mg ( <i>APX-Perindopril Arginine</i> ) Tablet containing perindopril arginine 5 mg ( <i>APX-Perindopril Arginine</i> ) Tablet containing perindopril arginine 10 mg ( <i>APX-Perindopril Arginine</i> )
Perindopril with amlodipine	Tablet containing 5 mg perindopril arginine with 5 mg amlodipine (as besilate) ( <i>APX-Perindopril Arginine/Amlodipine 5/5</i> ) Tablet containing 5 mg perindopril arginine with 10 mg amlodipine (as besilate) ( <i>APX-Perindopril Arginine/Amlodipine 5/10</i> ) Tablet containing 10 mg perindopril arginine with 5 mg amlodipine (as besilate) ( <i>APX-Perindopril Arginine/Amlodipine 10/5</i> ) Tablet containing 10 mg perindopril arginine with 10 mg amlodipine (as besilate) ( <i>APX-Perindopril Arginine/Amlodipine 10/10</i> )
Tranexamic acid	Tablet 500 mg ( <i>Tranexamic Acid Lupin</i> )

## Brands Deleted

<b>Listed Drug</b>	<b>Form and Brand</b>
Dosulepin	Tablet containing dosulepin hydrochloride 75 mg ( <i>Dosulepin Mylan</i> )
Fluoxetine	Capsule 20 mg (as hydrochloride) ( <i>Blooms the Chemist Fluoxetine</i> )
Gefitinib	Tablet 250 mg ( <i>Iressa</i> )
Hydrocortisone	Tablet 20 mg ( <i>Hydrocortisone Mylan 20</i> )

## Alteration of Brand Name

<b>Listed Drug</b>	<b>Form</b>	<b>Brand Name</b>
Fluticasone propionate with salmeterol	Powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses	<b>From:</b> FLUTICASONE SALMETEROL CIPHALER 250/50 <b>To:</b> Fluticasone Salmeterol Ciphaler 250/50

### Addition of Pack Quantity

<i>Listed Drug</i>	<i>Form</i>	<i>Brand Name</i>	<i>Pack Quantity</i>
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	<i>DuoResp Spiromax</i>	1

### Alteration of Maximum Quantity

<i>Listed Drug</i>	<i>Form</i>	<i>Brand Name</i>	<i>Maximum Quantity</i>
Etanercept	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	<i>Enbrel</i>	<i>From: 1</i> <i>To: 2</i>

### Alteration of Authorised Prescriber

<i>Listed Drug</i>	<i>Form</i>	<i>Brand Name</i>	<i>Authorised Prescriber</i>
Mifepristone and misoprostol	Pack containing 1 tablet mifepristone 200 mg and 4 tablets misoprostol 200 micrograms	<i>MS-2 Step</i>	<i>From: MP</i> <i>To: MP NP</i>

### Addition of Responsible Person

Specialised Therapeutics Pharma Pty Ltd (ZL)

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

<i>Listed Drug</i>	
Certolizumab pegol	Secukinumab
Diroximel fumarate	Sitagliptin
Enzalutamide	Tocilizumab
Golimumab	Tofacitinib
Mifepristone and misoprostol	Upadacitinib
Palbociclib	

### Supply Only – Additions

<i>Listed Drug</i>	<i>Form and Brand</i>
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> )
Gentamicin	Eye drops 3 mg (as sulfate) per mL, 5 mL ( <i>Genoptic</i> )
Ketoconazole	Shampoo 20 mg per g, 60 mL ( <i>Nizoral 2%</i> )

### Supply Only – Deletion

<b>Listed Drug</b>	<b>Form and Brand</b>
Roxithromycin	Tablet for oral suspension 50 mg ( <i>Rulide D</i> )

### Documents Incorporated by Reference

<b>Listed Drug</b>	<b>Document incorporated</b>	<b>Document access</b>
Tofacitinib Upadacitinib	<b>Approved Product Information/Australian Product Information/TGA-approved Product Information.</b> 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> .  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: <a href="https://www.tga.gov.au/product-information-0">https://www.tga.gov.au/product-information-0</a>
Upadacitinib	<b>Assessment of Spondyloarthritis International Society (ASAS) criteria</b> The document is a self-described handbook on the clinical assessment of spondyloarthritis, with a focus on axial spondyloarthritis. Box 4 and 8, plus Table 2 within the document specifically give the clinician guidance in forming a diagnosis of non-radiographic axial spondyloarthritis.  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> .	The ASAS criteria are available for download for free from the ASAS group website: <a href="https://www.asas-group.org/wp-content/uploads/2020/07/ASAS-handbook.pdf">https://www.asas-group.org/wp-content/uploads/2020/07/ASAS-handbook.pdf</a>  The published literature reference is: Sieper J et al. The Assessment of SpondyloArthritis international Society (ASAS) handbook: a guide to assess spondyloarthritis. Ann Rheum Dis 2009; 68; ii1-ii44
Tofacitinib	<b>Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)</b> 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> .  The BASDAI is a widely used tool that enables measurement and evaluation of the level of disease activity in Ankylosing Spondylitis.	The BASDAI is available for download for free from the Services Australia website: <a href="http://www.servicesaustralia.gov.au">www.servicesaustralia.gov.au</a>
Trabectedin	<b>World Health Organization (WHO)/Eastern</b>	The WHO/ECOG Performance Status



**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 themselves, daily activity, and physical ability (walking, working, etc.).

is available for download for free from the ECOG-ACRIN Cancer Research Group website: <https://ecog-acrin.org/resources/ecog-performance-status>

**Diagnostic tools referenced in the Instrument**

*The following standard medical diagnostic tools are referenced in the Instrument but are not intended to incorporate a document by reference.*

<i>Listed Drug</i>	<i>Diagnostic tool</i>	<i>Purpose and use in the Instrument</i>	<i>Reason this reference does not serve to incorporate a document</i>
Tofacitinib	<b>Bath Ankylosing Spondylitis Metrology Index (BASMI)</b>	<p>The BASMI is a set of 10 questions designed to determine the degree of functional limitation in patients with Ankylosing Spondylitis (AS).</p> <p>BASMI is used to determine the severity of ankylosing spondylitis prior to initiation with a particular biological medicine for this condition.</p>	<p>BASMI is a diagnostic tool rather than a document incorporated.</p> <p>Reference:</p> <p>Jenkinson TR, Mallorie PA, Whitelock HC, Kennedy LG, Garrett SL, Calin A. Defining spinal mobility in ankylosing spondylitis (AS). The Bath AS Metrology Index. <i>J Rheumatol</i>. 1994 Sep;21(9):1694-8. PMID: 7799351</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 2023 (No. 7)*** **(PB 67 of 2023)**

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 2023 (No. 7)* (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 drugs, new forms and brands of existing listed drugs, and ensuring the deletion of listed drugs, 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 two new drugs, the addition of two new forms of existing drugs, and the addition of 24 new brands across 22 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 2023, these amounts are \$30.00 for general patients and \$7.30 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 oral powder 500 g (XMET Maxamum), was requested to be delisted from the PBS by the sponsor. The PBAC noted the low number of services in the last financial year and that there are multiple alternatives available on the PBS and advised the delisting of this product would not result in an unmet clinical need.

The drug amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine, in the form oral powder 500 g (XMTVI Maxamum), was requested to be delisted from the PBS by the sponsor. The PBAC noted the low number of services in the last financial year and that there are multiple alternatives available on the PBS and 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 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 will be 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 oral powder 500 g (XPhen, Tyr Maxamum), was requested to be delisted from the PBS by the sponsor. The PBAC noted there was only one service in the last financial year and that there are multiple alternatives available on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need.

The drug amino acid formula with vitamins and minerals without valine, leucine and isoleucine, in the form oral powder 500 g (MSUD AID III), was requested to be delisted from the PBS by the sponsor. The PBAC noted there were no services in the last financial year and that there are multiple alternatives available on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need.

The drug efavirenz, in the forms tablet 200 mg (Stocrin) and tablet 600 mg (Stocrin), was requested to be delisted from the PBS by the sponsor. The PBAC noted the low number of services in the last financial year and that there 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 will be 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 epirubicin, in the form solution for injection containing epirubicin hydrochloride 50 mg in 25 mL (Epirube), was requested to be delisted from the PBS by the sponsor. The PBAC noted that there are several alternatives on the PBS, including an alternate strength of epirubicin. The PBAC noted the sponsor advised it has discontinued supply of this product in Australia and advised that the delisting of this product would not result in an unmet clinical need.

The drug eprosartan, in the form tablet 400 mg (as mesilate) (Teveten), was requested to be delisted from the PBS 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 will be 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 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 will be 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 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 will be 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 gentamicin, in the form eye drops 3 mg (as sulfate) per mL, 5 mL (Genoptic), was requested to be delisted from the PBS by the sponsor. The PBAC reiterated the risk of antimicrobial resistance associated with reducing the range of antimicrobials on the PBS and advised the delisting of this product may result in an unmet clinical need. The Department sought to retain the product in line with this advice, however the sponsor indicated retention is unviable due to discontinuation of the product and wished to proceed with the delisting. This item will be 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 ketoconazole, in the form shampoo 20 mg per g, 60 mL (Nizoral 2%), was requested to be delisted from the PBS by the sponsor. The PBAC noted that the PBS listed miconazole lotion is an appropriate clinical alternative. The PBAC advised the delisting of this product would not result in an unmet clinical need. This item will be 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 larotrectinib, in the form oral solution 20 mg per mL (as sulfate), 100 mL (Vitrakvi), was requested to be delisted from the PBS by the sponsor. An alternative suitable product, oral solution 20 mg per mL (as sulfate), 50 mL, 2 (VITRAKVI), remains listed on the PBS, therefore the delisting of this product will not result in an unmet clinical need.

The drug levodopa with carbidopa, in the form tablet (prolonged release) 200 mg-50 mg (Sinemet CR Prolonged-Release Tablets), was requested to be delisted from the PBS by the sponsor. An alternative suitable product, tablet (modified release) 200 mg-50 mg (as monohydrate) (Sinemet CR), remains listed on the PBS, therefore the delisting of this product will not result in an unmet clinical need.

The drug morphine, in the form tablet containing morphine sulfate pentahydrate 30 mg (Anamorph), was requested to be delisted from the PBS by the sponsor. The PBAC noted that there are multiple alternatives available on the PBS, including other strengths of morphine and advised the delisting of this product would not result in an unmet clinical need.

The drug paclitaxel, in the forms solution concentrate for I.V. infusion 100 mg in 16.7 mL (Paclitaxin) and solution concentrate for I.V. infusion 150 mg in 25 mL (Paclitaxin), was requested to be delisted from the PBS by the sponsor. The PBAC noted that there are multiple alternatives available on the PBS, including other strengths of paclitaxel. The PBAC noted the sponsor advised it has discontinued supply of this product in Australia and the delisting of this product would not result in an unmet clinical need.

The drug reteplase, in the form pack containing 2 vials powder for injection 10 units, 2 single use pre-filled syringes with solvent, 2 reconstitution spikes and 2 needles (Rapilysin 10 U), was requested to be delisted from the PBS by the sponsor. The PBAC noted that there were no services in the last financial year and tenecteplase is a suitable PBS-listed alternative. The PBAC noted the sponsor advised it has discontinued supply of this product in Australia. The PBAC advised the delisting of this drug would not result in an unmet clinical need.

The drug roxithromycin, in the form tablet for oral suspension 50 mg (Rulide D), was requested to be delisted from the Pharmaceutical Benefits Scheme (PBS) by the sponsor. The PBAC noted that there is no suitable alternative for a small number of paediatric patients and advised that this delisting may result in an unmet clinical need. The Department sought to retain the product in line with this advice, however the sponsor indicated retention is unviable due to the product being discontinued from manufacture and wished to proceed with the delisting. 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.

## **Conclusion**

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

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