

## EXPLANATORY STATEMENT

### *NATIONAL HEALTH ACT 1953*

#### ***NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT (JULY UPDATE) INSTRUMENT 2025***

**PB 74 of 2025**

#### **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* determines the pharmaceutical benefits that are on the Schedule of Pharmaceutical Benefits (the PBS Schedule) through declarations of drugs and medicinal preparations, and for ready-prepared benefits: determinations of forms, manners of administration and brands. It also provides for related matters (equivalent brands, responsible persons, prescribing circumstances, maximum quantities, number of repeats, determined quantity and pack quantity, section 100 only status and prescriber bag only status).

#### **Authority**

This Instrument exercises various powers in Part VII of the Act, as set out below:

##### *Pharmaceutical benefits listed on the PBS*

Subsection 85(2) provides that the Minister may declare drugs and medicinal preparations to which Part VII applies. A drug or medicinal preparation for which there is a declaration in force under subsection 85(2) is a 'listed drug' (subsection 84(1)). Subsections 85(3) and 85(5) respectively provide that the Minister may determine the form or forms of a listed drug and the manner of administration of a form of a listed drug. A listed drug in a determined form with a determined manner of administration for that form is a pharmaceutical item (section 84AB). Subsection 85(6) provides that the Minister may determine a brand of a pharmaceutical item.

The Minister may also determine the responsible person for a brand of a pharmaceutical item (subsection 84AF(1)). Under the provisions of section 84AK the Minister may determine the determined quantity and pack quantity for a brand of a pharmaceutical item.

##### *Prescribing pharmaceutical benefits*

Paragraph 85A(2)(a) allows the Minister to determine the maximum quantity or number of units of the pharmaceutical item in a pharmaceutical benefit (or of the pharmaceutical benefit where there is no pharmaceutical item) that may, in one prescription, be directed to be supplied on one occasion. Paragraph 85A(2)(b) also allows the Minister to determine the maximum number of occasions on which the supply of the pharmaceutical benefit may, in one prescription, be directed to be repeated. The maximum quantities and repeats may be determined for all purposes or for particular purposes.

Subsection 85(7) provides that the Minister may determine the circumstances in which a prescription may be written for the supply of a pharmaceutical benefit.

Section 88 provides that the Minister may determine the pharmaceutical benefits that may be prescribed by different classes of prescribers, including medical practitioners (subsection 88(1)), participating dental practitioners (subsection 88(1A)), authorised optometrists (subsection 88(1C)), authorised midwives (subsection 88(1D)) and authorised nurse practitioners (subsection 88(1E)).

Paragraph 88(1EB) provides that the Minister can list pharmaceutical benefits without determining any authorised prescribers for the benefit allowing the benefit to be supplied only.

This legislative instrument is made pursuant to section 88 and subsection 100(2) of the Act.

### *Supplying pharmaceutical benefits*

Subsection 85(2A) provides that the Minister must declare that a particular listed drug can only be provided under a special arrangement under section 100 if the Pharmaceutical Benefits Advisory Committee (PBAC) has recommended under subsection 101(4AAD) that the drug be made available only under special arrangements under section 100.

Subsection 85(2AA) provides that the Minister must declare that a particular listed drug can only be provided under one or more of the prescriber bag provisions if the PBAC has recommended under subsection 101(4AACA) that the drug be made available only under one or more of the prescriber bag provisions.

Subsection 85(6A) provides that the Minister may also determine for the purposes of paragraph 103(2A)(b) that a brand of a pharmaceutical item determined under subsection 85(6) is to be treated as equivalent to one or more other brands of pharmaceutical items.

Paragraph 85(7A) provides that the Minister may determine that a particular pharmaceutical benefit may only be supplied under one or more of the prescriber bag provisions.

Paragraph 85(8)(a) provides that the Minister may determine that a particular pharmaceutical benefit may only be supplied under special arrangements under section 100.

Paragraph 85(8)(b) provides that the Minister may determine that a particular pharmaceutical benefit may only be supplied under special arrangements under section 100 for one or more of the circumstances determined for that pharmaceutical benefit under subsection 85(7).

### *Variation and revocation*

Unless there is an express power to revoke or vary PB 26 of 2024 cited in this Instrument and explanatory statement, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary PB 26 of 2024.

Subsection 101(4AAA) allows the Minister to, by legislative instrument, revoke or vary a subsection 85(2) declaration in relation to a drug or medicinal preparation. Advice from the PBAC is required if the effect of the legislative instrument would be that a drug or medicinal preparation would cease to be a listed drug (subsection 101(4AAB)).

### **Changes to PB 26 of 2024 made by this Instrument**

Schedule 1 to this Instrument provides for the addition to the PBS Schedule of the drugs ivosidenib and maribavir, and forms of the listed drugs azithromycin, methylphenidate, and naproxen. It also provides for the deletion of a form of the listed drugs dexamethasone, ezetimibe, and irinotecan, and the alteration of circumstances in which prescriptions may be written for the supply of the listed drugs abemaciclib, etanercept, faricimab, nivolumab, olaparib, and ribociclib.

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

- the addition of 22 brands of existing pharmaceutical items
- the deletion of 49 brands of existing pharmaceutical items
- the deletion of a maximum quantity and number of repeats for a brand of an existing pharmaceutical item
- the addition of a pack quantity for a brand of an existing pharmaceutical item
- the deletion of a pack quantity for 3 brands of existing pharmaceutical items
- the alteration of responsible person for 9 brands of existing pharmaceutical items
- the addition of 2 responsible persons to the list of responsible persons
- the deletion of 2 responsible persons from the list of responsible persons
- the supply only period commencing for a pharmaceutical item covered under Supply Only arrangements
- the supply only period ending for 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 July 2025.

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 (JULY UPDATE) INSTRUMENT 2025**

**Section 1 Name of Instrument**

This section provides that the name of the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment (July Update) Instrument 2025* and may also be cited as PB 74 of 2025.

**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 July 2025.

**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 deletion of a maximum quantity and number of repeats for a brand of an existing pharmaceutical benefit, the addition and deletion of a pack quantity for brands of existing pharmaceutical benefits, the alteration of responsible person for brands of existing pharmaceutical items, the addition and deletion of responsible persons for the list of responsible persons, the supply only period commencing and ending for pharmaceutical items 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***

**Drug Addition**

***Listed Drug***

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Ivosidenib

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Maribavir

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**Form Addition**

***Listed Drug***

***Form***

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Azithromycin	Tablet 500 mg (as dihydrate) (S19A)
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Methylphenidate	Tablet containing methylphenidate hydrochloride 18 mg (extended release) Concerta (Switzerland) (S19A)
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	Tablet containing methylphenidate hydrochloride 18 mg (extended release) (S19A)
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	Tablet containing methylphenidate hydrochloride 27 mg (extended release) (S19A)
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	Tablet containing methylphenidate hydrochloride 36 mg (extended release) Concerta (Switzerland) (S19A)
	Tablet containing methylphenidate hydrochloride 36 mg (extended release) (S19A)
	Tablet containing methylphenidate hydrochloride 54 mg (extended release) Concerta (Switzerland) (S19A)
	Tablet containing methylphenidate hydrochloride 54 mg (extended release) (S19A)
Naproxen	Oral suspension 125 mg per 5 mL, 474 mL (S19A)

## Form Deletion

<i>Listed Drug</i>	<i>Form</i>
Dexamethasone	Eye drops 1 mg per mL, 5 mL
Ezetimibe	Tablet 10 mg (S19A)
Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL

## Brand Addition

<i>Listed Drug</i>	<i>Form and Brand</i>
Aripiprazole	Powder for injection 400 mg (as monohydrate) with diluent ( <i>ARIPENA</i> )
Bendamustine	Powder for injection containing bendamustine hydrochloride 25 mg ( <i>BENDAMUSTINE EUGIA</i> )
	Powder for injection containing bendamustine hydrochloride 100 mg ( <i>BENDAMUSTINE EUGIA</i> )
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4 ( <i>Nepexto</i> )
Fingolimod	Capsule 500 micrograms (as hydrochloride) ( <i>FILOSIR</i> )
Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL ( <i>IRINOTECAN EUGIA</i> )
	I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in 25 mL ( <i>IRINOTECAN EUGIA</i> )
Methenamine	Tablet containing methenamine hippurate 1 g ( <i>APOHEALTH Urinary Tract Antibacterial; Chemists' Own Urinary Tract Antibacterial</i> )
Rivaroxaban	Tablet 2.5 mg ( <i>APO-Rivaroxaban</i> )
	Tablet 10 mg ( <i>APO-Rivaroxaban; Rivarelto</i> )
	Tablet 15 mg ( <i>APO-Rivaroxaban; Rivarelto</i> )
	Tablet 20 mg ( <i>APO-Rivaroxaban; Rivarelto</i> )
Sacubitril with valsartan	Tablet containing sacubitril 24.3 mg with valsartan 25.7 mg ( <i>Omtralo; Sacubitril/Valsartan Alphapharm</i> )

Tablet containing sacubitril 48.6 mg with valsartan 51.4 mg  
(*Omtralo; Sacubitril/Valsartan Alphapharm*)

Tablet containing sacubitril 97.2 mg with valsartan 102.8 mg  
(*Omtralo; Sacubitril/Valsartan Alphapharm*)

## Brand Deletion

<i>Listed Drug</i>	<i>Form and Brand</i>
Allopurinol	Tablet 100 mg ( <i>Allopurinol APOTEX</i> )
Amlodipine	Tablet 5 mg (as besilate) ( <i>Amlodipine APOTEX</i> )
Amoxicillin	Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL ( <i>Cilamox</i> )
Bivalirudin	Powder for I.V. injection 250 mg (as trifluoroacetate) ( <i>Bivalirudin APOTEX</i> )
Bosentan	Tablet 62.5 mg (as monohydrate) ( <i>Bosentan Mylan</i> )
Cefaclor	Powder for oral suspension 125 mg (as monohydrate) per 5 mL, 100 mL ( <i>Aclor 125</i> )
	Powder for oral suspension 250 mg (as monohydrate) per 5 mL, 75 mL ( <i>Aclor 250</i> )
	Tablet (sustained release) 375 mg (as monohydrate) ( <i>Karlor CD</i> )
Doxorubicin	Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 200 mg in 100 mL single dose vial ( <i>Adriamycin</i> )
Ezetimibe with simvastatin	Tablet 10 mg-10 mg ( <i>Zeklen 10/10 mg</i> )
	Tablet 10 mg-20 mg ( <i>Zeklen 10/20 mg</i> )
	Tablet 10 mg-40 mg ( <i>Zeklen 10/40 mg</i> )
	Tablet 10 mg-80 mg ( <i>Zeklen 10/80 mg</i> )
Felodipine	Tablet 2.5 mg (extended release) ( <i>Fendex ER</i> )
	Tablet 5 mg (extended release) ( <i>Fendex ER</i> )
	Tablet 10 mg (extended release) ( <i>Fendex ER</i> )
Gliclazide	Tablet 30 mg (modified release) ( <i>Glyade MR</i> )
Glimepiride	Tablet 1 mg ( <i>Glimepiride APOTEX</i> )
	Tablet 2 mg ( <i>Glimepiride APOTEX</i> )
	Tablet 3 mg ( <i>Glimepiride APOTEX</i> )
	Tablet 4 mg ( <i>Glimepiride APOTEX</i> )
Imiquimod	Cream 50 mg per g, 250 mg single use sachets, 12 ( <i>Aldiq</i> )
Ipratropium	Nebuliser solution containing ipratropium bromide 250 micrograms (as monohydrate) in 1 mL single dose units, 30 ( <i>Ipratrin</i> )

Nebuliser solution containing ipratropium bromide 500 micrograms (as monohydrate) in 1 mL single dose units, 30 (*Ipratrin Adult*)

Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL ( <i>Irinotecan Alphapharm; Omegapharm Irinotecan</i> )
	I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in 25 mL ( <i>Irinotecan Alphapharm</i> )
Leflunomide	Tablet 10 mg ( <i>Leflunomide APOTEX</i> )
	Tablet 20 mg ( <i>Leflunomide APOTEX</i> )
Lercanidipine	Tablet containing lercanidipine hydrochloride 10 mg ( <i>Lercanidipine APOTEX</i> )
Letrozole	Tablet 2.5 mg ( <i>Letrozole APOTEX</i> )
Levetiracetam	Tablet 250 mg ( <i>Kevtam 250; Levetiracetam Mylan</i> )
	Tablet 500 mg ( <i>Kevtam 500</i> )
	Tablet 1 g ( <i>Kevtam 1000; Levetiracetam Mylan</i> )
Lurasidone	Tablet containing lurasidone hydrochloride 40 mg ( <i>Latuda</i> )
	Tablet containing lurasidone hydrochloride 80 mg ( <i>Latuda</i> )
Morphine	Tablet containing morphine sulfate pentahydrate 10 mg (controlled release) ( <i>Morphine MR Mylan</i> )
	Tablet containing morphine sulfate pentahydrate 30 mg (controlled release) ( <i>Morphine MR Mylan</i> )
	Tablet containing morphine sulfate pentahydrate 60 mg (controlled release) ( <i>Morphine MR Mylan</i> )
	Tablet containing morphine sulfate pentahydrate 100 mg (controlled release) ( <i>Morphine MR Mylan</i> )
Norfloxacin	Tablet 400 mg ( <i>Nufloxib</i> )
Olanzapine	Tablet 2.5 mg ( <i>Olanzapine APOTEX</i> )
Pantoprazole	Tablet (enteric coated) 40 mg (as sodium sesquihydrate) ( <i>Pantoprazole APOTEX</i> )
Rosuvastatin	Tablet 20 mg (as calcium) ( <i>Rosuvastatin APOTEX</i> )
	Tablet 40 mg (as calcium) ( <i>Rosuvastatin APOTEX</i> )
Sevelamer	Tablet containing sevelamer carbonate 800 mg ( <i>Sevelamer Apotex</i> )
Sumatriptan	Tablet 50 mg (as succinate) ( <i>IMIGRAN MIGRAINE</i> )

## Maximum Quantity and Number of Repeats Deletion

<i>Listed Drug</i>	<i>Form and Brand</i>	<i>Maximum Quantity</i>	<i>Number of Repeats</i>
Aciclovir	Tablet 200 mg ( <i>Aciclovir APOTEX</i> )	90	5

### Pack Quantity Addition

<i>Listed Drug</i>	<i>Form and Brand</i>	<i>Pack Quantity</i>
Drospirenone	Pack containing 24 tablets 4 mg and 4 inert tablets ( <i>Slinda</i> )	1

### Pack Quantity Deletion

<i>Listed Drug</i>	<i>Form and Brand</i>	<i>Pack Quantity</i>
Carbamazepine	Tablet 200 mg (controlled release) ( <i>Tegretol CR 200</i> )	200
	Tablet 400 mg (controlled release) ( <i>Tegretol CR 400</i> )	200
Sumatriptan	Tablet 50 mg (as succinate) ( <i>Imigran</i> )	2

### Responsible Person Alteration

<i>Listed Drug</i>	<i>Form</i>	<i>Brand</i>	<i>Responsible Person</i>	
Amifampridine	Tablet 10 mg	<i>Ruzurgi</i>	<b>From:</b> OJ	<b>To:</b> LD
Cariprazine	Capsule 1.5 mg	<i>Reagila</i>	<b>From:</b> CS	<b>To:</b> IX
	Capsule 3 mg	<i>Reagila</i>	<b>From:</b> CS	<b>To:</b> IX
	Capsule 4.5 mg	<i>Reagila</i>	<b>From:</b> CS	<b>To:</b> IX
	Capsule 6 mg	<i>Reagila</i>	<b>From:</b> CS	<b>To:</b> IX
Sacubitril with valsartan	Tablet containing sacubitril 24.3 mg with valsartan 25.7 mg	<i>Valtresto</i>	<b>From:</b> RM	<b>To:</b> TX
	Tablet containing sacubitril 48.6 mg with valsartan 51.4 mg	<i>Valtresto</i>	<b>From:</b> RM	<b>To:</b> TX
	Tablet containing sacubitril 97.2 mg with valsartan 102.8 mg	<i>Valtresto</i>	<b>From:</b> RM	<b>To:</b> TX
Trastuzumab	Powder for I.V. infusion 420 mg	<i>Kanjinti</i>	<b>From:</b> JU	<b>To:</b> XT

### Responsible Person Addition

#### *Responsible Person*

Lacuna Pharma Pty Ltd (*LD*)

Pharmacor Pty Limited (*FY*)

### Responsible Person Deletion

#### *Responsible Person*

Omegapharm Pty Ltd (*OE*)

Pharmacor Pty Limited (*RM*)



## Supply Only – Period Commencing

<i>Listed Drug</i>	<i>Form</i>
Glyceryl trinitrate	Transdermal patch 54 mg

## Supply Only – Period Ending

<i>Listed Drug</i>	<i>Form</i>
Hypromellose with carbomer 980	Ocular lubricating gel 3 mg-2 mg per g, 10 g

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

<i>Listed Drug</i>
Abemaciclib
Etanercept
Faricimab
Nivolumab
Olaparib
Ribociclib

## Documents Incorporated by Reference

<i>Listed Drug</i>	<i>Document Incorporated</i>	<i>Document access</i>
Etanercept Nivolumab	<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>
Etanercept	<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>
Abemaciclib Ribociclib	<b>Nottingham grading system.</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 Nottingham grading system is the histologic grading system developed by Elston and Ellis as a modification of the Scarff-Bloom-Richardson grading system. It is used to grade	Elston, CW, Ellis, IO. Pathological prognostic factors in breast cancer. The value of histological grade in breast cancer: experience from a large study with long-term follow-up. <i>Histopathology</i> . 1991 Nov;19(5):403-10.

breast cancer cells by describing how different a cancer cell's appearance and growth patterns are from normal, healthy breast cells. <https://pubmed.ncbi.nlm.nih.gov/1757079/>

Etanercept	<p><b>Psoriasis Area Severity Index (PASI).</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>.</p> <p>The PASI is a widely used tool that enables measurement of the severity and extent of baseline and response of therapy in psoriasis.</p>	<p>The PASI calculation form is available for download for free from the Services Australia website: <a href="https://www.servicesaustralia.gov.au/">https://www.servicesaustralia.gov.au/</a> and forms part of the SA authority application process.</p>
Ivosidenib Nivolumab	<p><b>World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status/Performance Status Score.</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>.</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>

## 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>
Etanercept	<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: 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 (July Update) Instrument 2025***

**(PB 74 of 2025)**

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 (July Update) Instrument 2025* (the Instrument) amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (PB 26 of 2024) (the Principal Instrument) which determines the pharmaceutical benefits that are listed on the Schedule of Pharmaceutical Benefits (the Schedule) through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. It also provides for related matters (responsible persons, prescribing circumstances, schedule equivalence, maximum quantities, number of repeats, determined quantities, pack quantities, section 100 only status and prescriber bag only status).

#### **Human rights implications**

The Instrument engages Articles 9 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), specifically the rights to social security and health.

##### *The Right to Social Security*

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The UN Committee on Economic Social and Cultural Rights reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

##### *The Right to Health*

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The Committee has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the ‘highest attainable standard of health’ takes into account the country’s available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

#### **Analysis**

The Instrument advances the right to health and the right to social security by providing new drugs, new forms and brands of existing listed drugs, and ensuring the deletion of forms and brands of listed drugs does not affect access to subsidised medicines. The Pharmaceutical Benefits Scheme (PBS) is a benefit scheme which assists with advancement of these human rights by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the Schedule are evidence-based. The Instrument includes the addition of 2 new drugs, the addition of 9 new forms of existing drugs, and the addition of 22 new brands across 15 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 forms of drugs in the abovementioned instruments would not result in an unmet clinical need, except where indicated for a particular 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 dexamethasone in the form eye drops 1 mg per mL, 5 mL (Maxidex) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the large number of services in the previous financial year and that there are no suitable alternatives on the PBS. The PBAC advised the delisting of this product may result in an unmet clinical need and requested that the Department seek to retain this product if possible. However, the sponsor decided to proceed with the delisting due to commercial reasons and stated that the form will continue to be available on the private market.

The drug ezetimibe in the form tablet 10 mg (S19A) (Ezetimibe USP (Camber, USA)) was requested to be delisted from the PBS schedule following agreement from the sponsor. The temporary approval under section 19A of the *Therapeutic Goods Act 1989* granted by the Therapeutic Goods Administration in respect of this drug for importation and supply of a medicine not on the Australian Register of Therapeutic Goods lapsed on 31 March 2025. Patient access has not been affected as the Australian Register of Therapeutic Goods approved form of the drug is now available and remains PBS subsidised and accessible for patients.

The drug glyceryl trinitrate in the form transdermal patch 54 mg (Minitran 15) 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 compared to other topical nitrates and that there are alternatives on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need. This item will be available on the PBS Schedule under Supply Only arrangements for a period of 6 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment.

The drug hypromellose with carbomer 980 was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted there are multiple alternative lubricating eye gel products available. 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 6 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment.

The drug irinotecan in the form I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL (Omegapharm Irinotecan) was requested to be delisted from the PBS Schedule by the sponsor. There are other substitutable forms of irinotecan available on the PBS and the delisting of this product will not result in an unmet clinical need.

## **Conclusion**

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

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