

## EXPLANATORY STATEMENT

### NATIONAL HEALTH ACT 1953

#### NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2023 (No. 5)

#### PB 43 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 of forms of the listed drugs cefalexin, ciclosporin disopyramide, larotrectinib, minoxidil, and phenoxymethylpenicillin to the PBS Schedule. It also provides for the alteration of circumstances in which prescriptions may be written for the supply of the listed drugs abatacept, adalimumab, apalutamide, baricitinib, cannabidiol, certolizumab pegol, ciclosporin, escitalopram, etanercept, golimumab, infliximab, lenvatinib, nicotine, pembrolizumab, selinexor, tofacitinib, and upadacitinib.

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

- the addition of 29 brands of existing pharmaceutical items;
- the deletion of 26 brands of existing pharmaceutical items;
- the alteration of a brand name for 1 existing pharmaceutical item;
- 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 alteration of responsible persons code for 33 brands of pharmaceutical items;
- the addition of an authorised prescriber for an existing pharmaceutical item;
- the addition of a pharmaceutical item covered under Supply Only arrangements; and
- the deletion of 42 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 June 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. 5)**

**Section 1 Name of Instrument**

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 5)* and may also be cited as PB 43 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 June 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 of forms of listed drugs, the addition and deletion of brands, the alteration of a brand name, the addition and deletion of responsible persons from the list of responsible persons, the alteration of responsible persons code for brands of pharmaceutical benefits, the addition of an authorised prescriber for a pharmaceutical benefit, 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**

**Forms Added**

<i>Listed Drug</i>	<i>Form</i>
Cefalexin	Granules for oral suspension 250 mg (as monohydrate) per 5 mL, 100 mL (s19A)
Ciclosporin	Eye drops 900 micrograms per mL, single dose units 0.25 mL, 60
Disopyramide	Capsule 100 mg (s19A)
Larotrectinib	Oral solution 20 mg per mL (as sulfate), 50 mL, 2
Minoxidil	Tablet 10 mg (s19A)
Phenoxymethylpenicillin	Powder for oral liquid 250 mg (as potassium) per 5 mL, 100 mL (s19A)

**Brands Added**

<i>Listed Drug</i>	<i>Form and Brand</i>
Ambrisentan	Tablet 5 mg ( <i>Ambrisentan Viatris</i> )
Amlodipine	Tablet 5 mg (as besilate) ( <i>Blooms Amlodipine</i> )

	Tablet 10 mg (as besilate) ( <i>Blooms Amlodipine</i> )
Amoxicillin with clavulanic acid	Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) (s19A) ( <i>Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo – Pro Pharmaceuticals); Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs)</i> )
Ceftriaxone	Powder for injection 1 g (as sodium) ( <i>Ceftriaxone Viatriis</i> ) Powder for injection 2 g (as sodium) ( <i>Ceftriaxone Viatriis</i> )
Dosulepin	Capsule containing dosulepin hydrochloride 25 mg ( <i>Dosulepin Viatriis</i> )
Ezetimibe	Tablet 10 mg ( <i>BTC Ezetimibe</i> )
Fingolimod	Capsule 500 micrograms (as hydrochloride) ( <i>Fingolimod-Teva</i> )
Fluticasone propionate with salmeterol	Powder for oral inhalation in breath actuated device containing fluticasone propionate 500 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses ( <i>Fluticasone Salmeterol Ciphaler 500/50</i> )
Fosaprepitant	Powder for I.V. infusion 150 mg ( <i>FOSAPREPITANT-AFT</i> )
Gliclazide	Tablet 60 mg (modified release) ( <i>Gliclazide Lupin MR</i> )
Lenalidomide	Capsule 5 mg ( <i>Lenalidomide Viatriis</i> ) Capsule 10 mg ( <i>Lenalidomide Viatriis</i> ) Capsule 15 mg ( <i>Lenalidomide Viatriis</i> ) Capsule 25 mg ( <i>Lenalidomide Viatriis</i> )
Levothyroxine	Tablet containing 50 micrograms anhydrous levothyroxine sodium ( <i>Levothox</i> ) Tablet containing 75 micrograms anhydrous levothyroxine sodium ( <i>Levothox</i> ) Tablet containing 100 micrograms anhydrous levothyroxine sodium ( <i>Levothox</i> ) Tablet containing 125 micrograms anhydrous levothyroxine sodium ( <i>Levothox</i> ) Tablet containing 200 micrograms anhydrous levothyroxine sodium ( <i>Levothox</i> )
Olmesartan	Tablet containing olmesartan medoxomil 20 mg ( <i>Olsetan</i> ) Tablet containing olmesartan medoxomil 40 mg ( <i>Olsetan</i> )
Paracetamol	Tablet 665 mg (modified release) ( <i>Parapane OSTEO</i> )
Paroxetine	Tablet 20 mg (as hydrochloride) ( <i>Blooms The Chemist Paroxetine</i> )
Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg ( <i>Tenofovir Disoproxil Emtricitabine Viatriis 300/200</i> )
Vinorelbine	Capsule 20 mg (as tartrate) ( <i>Velabine</i> ) Capsule 30 mg (as tartrate) ( <i>Velabine</i> )

## Brands Deleted

<i>Listed Drug</i>	<i>Form and Brand</i>
Amisulpride	Tablet 200 mg ( <i>Amisulpride 200 Winthrop</i> )
Azacitidine	Powder for injection 100 mg ( <i>AZACITIDINE DR.REDDY'S; Azadine</i> )
Bortezomib	Powder for injection 3.5 mg ( <i>Bortezomib-Dr.Reddy's</i> )
Ciprofloxacin	Tablet 500 mg (as hydrochloride) ( <i>Ciprofloxacin GH</i> )
Donepezil	Tablet containing donepezil hydrochloride 5 mg ( <i>Donepezil-DRLA</i> ) Tablet containing donepezil hydrochloride 10 mg ( <i>Donepezil-DRLA</i> )
Levonorgestrel with ethinylestradiol	Pack containing 6 tablets 50 micrograms-30 micrograms, 5 tablets 75 micrograms-40 micrograms, 10 tablets 125 micrograms-30 micrograms and 7 inert tablets ( <i>Triphasil 28</i> )
Lisinopril	Tablet 5 mg ( <i>Lisinopril generichealth</i> ) Tablet 10 mg ( <i>Lisinopril generichealth</i> )
Mometasone	Lotion containing mometasone furoate 1 mg per g, 30 mL ( <i>Momasone</i> )
Olanzapine	Tablet 2.5 mg ( <i>Olanzapine-DRLA</i> ) Tablet 5 mg ( <i>Olanzapine-DRLA</i> ) Tablet 7.5 mg ( <i>Olanzapine-DRLA</i> ) Tablet 10 mg ( <i>Olanzapine-DRLA</i> )
Ondansetron	Tablet (orally disintegrating) 4 mg ( <i>Ondansetron ODT GH</i> ) Tablet (orally disintegrating) 8 mg ( <i>Ondansetron ODT GH</i> )
Pravastatin	Tablet containing pravastatin sodium 80 mg ( <i>Pravastatin generichealth</i> )
Pregabalin	Capsule 25 mg ( <i>Pregabalin GH</i> )
Quinapril	Tablet 20 mg (as hydrochloride) ( <i>Quinapril generichealth</i> )
Ranitidine	Tablet 150 mg (as hydrochloride) ( <i>Zantac</i> ) Tablet 300 mg (as hydrochloride) ( <i>Zantac</i> )
Rasagiline	Tablet 1 mg (as mesilate) ( <i>Rasazil</i> )
Telmisartan	Tablet 80 mg ( <i>Telmisartan GH</i> )
Telmisartan with hydrochlorothiazide	Tablet 40 mg-12.5 mg ( <i>Telmisartan HCT GH 40/12.5</i> ) Tablet 80 mg-12.5 mg ( <i>Telmisartan HCT GH 80/12.5</i> )

### Alteration of Brand Name

<i>Listed Drug</i>	<i>Form</i>	<i>Brand Name</i>
Amoxicillin with clavulanic acid	Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) (s19A)	<b>From:</b> Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg <b>To:</b> Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo - Medsurge)

### Addition of Responsible Person

Pro Pharmaceuticals Group Pty. Ltd. (QZ)

AbbVie Pty Ltd (VB)

### Deletion of Responsible Person Code

Allergan Australia Pty Limited (AG)

Allergan Australia Pty Limited (PE)

### Alteration of Responsible Person Code

<i>Listed Drug</i>	<i>Form</i>	<i>Brand Name</i>	<i>Responsible Person</i>
Bimatoprost	Eye drops 300 micrograms per mL, single dose units 0.4 mL, 30	<i>Lumigan PF</i>	From: <b>AG</b> To: <b>VE</b>
	Eye drops 300 micrograms per mL, 3 mL	<i>Lumigan</i>	From: <b>AG</b> To: <b>VE</b>
Bimatoprost with timolol	Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, single dose units 0.4 mL, 30	<i>GANfort PF 0.3/5</i>	From: <b>AG</b> To: <b>VE</b>
	Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, 3 mL	<i>Ganfort 0.3/5</i>	From: <b>AG</b> To: <b>VE</b>
Botulinum toxin type A purified neurotoxin complex	Lyophilised powder for injection 100 units	<i>Botox</i>	From: <b>AG</b> To: <b>VE</b>
Brimonidine	Eye drops containing brimonidine tartrate 1.5 mg per mL, 5 mL	<i>Alphagan P 1.5</i>	From: <b>AG</b> To: <b>VE</b>
	Eye drops containing brimonidine tartrate 2 mg per mL, 5 mL	<i>Alphagan</i>	From: <b>AG</b> To: <b>VE</b>
		<i>Enidin</i>	From: <b>PE</b> To: <b>VB</b>
Brimonidine with timolol	Eye drops containing brimonidine tartrate 2 mg with timolol 5 mg (as maleate) per mL, 5 mL	<i>Combigan</i>	From: <b>AG</b> To: <b>VE</b>
Carmellose	Eye drops containing carmellose sodium 5 mg per mL, single dose units 0.4 mL, 30	<i>Cellufresh</i>	From: <b>AG</b> To: <b>VE</b>
	Eye drops containing carmellose sodium 5 mg per mL, 15 mL	<i>Refresh Tears Plus</i>	From: <b>AG</b> To: <b>VE</b>
	Eye drops containing carmellose sodium 10 mg per mL, single dose units 0.4 mL, 30	<i>Celluvisc</i>	From: <b>AG</b> To: <b>VE</b>
	Eye drops containing carmellose sodium 10 mg per mL, 15 mL	<i>Refresh Liquigel</i>	From: <b>AG</b> To: <b>VE</b>
Carmellose with glycerin	Eye drops containing carmellose sodium 5 mg with glycerin 9 mg per mL, 15 mL	<i>Optive</i>	From: <b>AG</b> To: <b>VE</b>
Dexamethasone	Intravitreal injection 700 micrograms	<i>Ozurdex</i>	From: <b>AG</b> To: <b>VE</b>

Fentanyl	Transdermal patch 2.063 mg	<i>Fenpatch 12</i>	From: <b>ZP</b>	To: <b>RW</b>
	Transdermal patch 4.125 mg	<i>Fenpatch 25</i>	From: <b>ZP</b>	To: <b>RW</b>
	Transdermal patch 8.25 mg	<i>Fenpatch 50</i>	From: <b>ZP</b>	To: <b>RW</b>
	Transdermal patch 12.375 mg	<i>Fenpatch 75</i>	From: <b>ZP</b>	To: <b>RW</b>
	Transdermal patch 16.5 mg	<i>Fenpatch 100</i>	From: <b>ZP</b>	To: <b>RW</b>
Fluorometholone	Eye drops 1 mg per mL, 5 mL	<i>FML Liquifilm</i>	From: <b>AG</b>	To: <b>VE</b>
Gentamicin	Eye drops 3 mg (as sulfate) per mL, 5 mL	<i>Genoptic</i>	From: <b>AG</b>	To: <b>VE</b>
Leflunomide	Tablet 10 mg	<i>Lunava 10</i>	From: <b>ZP</b>	To: <b>RW</b>
	Tablet 20 mg	<i>Lunava 20</i>	From: <b>ZP</b>	To: <b>RW</b>
Ofloxacin	Eye drops 3 mg per mL, 5 mL	<i>Ocuflox</i>	From: <b>AG</b>	To: <b>VE</b>
Omeprazole	Tablet 20 mg	<i>Ozmep</i>	From: <b>ZP</b>	To: <b>RW</b>
Paraffin	Pack containing 2 tubes eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g	<i>Refresh Night Time</i>	From: <b>AG</b>	To: <b>VE</b>
Polyvinyl alcohol	Eye drops 14 mg per mL, 15 mL	<i>Liquifilm Tears</i>	From: <b>AG</b>	To: <b>VE</b>
		<i>PVA Tears</i>	From: <b>PE</b>	To: <b>VB</b>
Prednisolone with phenylephrine	Eye drops containing prednisolone acetate 10 mg with phenylephrine hydrochloride 1.2 mg per mL, 10 mL	<i>Prednefrin Forte</i>	From: <b>AG</b>	To: <b>VE</b>
Venlafaxine	Capsule (modified release) 37.5 mg (as hydrochloride)	<i>Elaxine SR 37.5</i>	From: <b>ZP</b>	To: <b>RW</b>
	Capsule (modified release) 75 mg (as hydrochloride)	<i>Elaxine SR 75</i>	From: <b>ZP</b>	To: <b>RW</b>
	Capsule (modified release) 150 mg (as hydrochloride)	<i>Elaxine SR 150</i>	From: <b>ZP</b>	To: <b>RW</b>

### **Addition of Authorised Prescriber**

<b>Listed Drug</b>	<b>Form</b>	<b>Brand Name</b>	<b>Authorised Prescriber</b>
Naltrexone	Tablet containing naltrexone hydrochloride 50 mg	<i>Naltrexone GH</i>	From: <b>MP</b> To: <b>MP, NP</b>

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

#### **Listed Drug**

Abatacept	Golimumab
Adalimumab	Infliximab
Apalutamide	Lenvatinib
Baricitinib	Nicotine
Cannabidiol	Pembrolizumab
Certolizumab pegol	Selinexor
Ciclosporin	Tofacitinib
Escitalopram	Upadacitinib



Etanercept

### Supply Only – Additions

*Note: Supply Only benefits are available on the Schedule for dispensing only, for a period of up to 12 months.*

#### **Listed Drug**      **Form and Brand**

Labetalol              Tablet containing labetalol hydrochloride 200 mg (*Trandate*)

### Supply Only – Deletions

#### **Listed Drug**              **Form and Brand**

Abatacept              Injection 125 mg in 1 mL single dose autoinjector (*Orencia ClickJect*)

Injection 125 mg in 1 mL single dose pre-filled syringe (*Orencia*)

Powder for I.V. infusion 250 mg (*Orencia*)

Adalimumab              Injection 20 mg in 0.2 mL pre-filled syringe (*Humira*)

Injection 20 mg in 0.4 mL pre-filled syringe (*Amgevita*)

Injection 40 mg in 0.4 mL pre-filled pen (*Humira*)

Injection 40 mg in 0.4 mL pre-filled syringe (*Humira*)

Injection 40 mg in 0.8 mL pre-filled pen (*Amgevita; Hadlima; Hyrimoz; Idacio*)

Injection 40 mg in 0.8 mL pre-filled syringe (*Amgevita; Hadlima; Hyrimoz; Idacio*)

Ampicillin              Powder for injection 1 g (as sodium) (*Ampicyn*)

Baricitinib              Tablet 2 mg (*Olumiant*)

Tablet 4 mg (*Olumiant*)

Certolizumab pegol      Injection 200 mg in 1 mL single use pre-filled syringe (*Cimzia*)

Solution for injection 200 mg in 1 mL pre-filled pen (*Cimzia*)

Dipyridamole with  
aspirin              Capsule 200 mg (sustained release)-25 mg (*Diasp SR*)

Donepezil              Tablet containing donepezil hydrochloride 5 mg (*Donepezil-DRLA*)

Tablet containing donepezil hydrochloride 10 mg (*Donepezil-DRLA*)

Doxepin              Capsule 10 mg (as hydrochloride) (*Deptran 10*)

Capsule 25 mg (as hydrochloride) (*Deptran 25*)

Tablet 50 mg (as hydrochloride) (*Deptran 50*)

Etanercept              Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes  
solvent 1 mL (*Enbrel*)

	Injection 50 mg in 1 mL single use auto-injector, 4 ( <i>Enbrel; Brenzys</i> )
	Injections 50 mg in 1 mL single use pre-filled syringes, 4 ( <i>Enbrel; Brenzys</i> )
Golimumab	Injection 50 mg in 0.5 mL single use pre-filled pen ( <i>Simponi</i> )
	Injection 50 mg in 0.5 mL single use pre-filled syringe ( <i>Simponi</i> )
Infliximab	Powder for I.V. infusion 100 mg ( <i>Inflectra; Remicade; Renflexis</i> )
	Solution for injection 120 mg in 1 mL pre-filled pen ( <i>Remsima SC</i> )
	Solution for injection 120 mg in 1 mL pre-filled syringe ( <i>Remsima SC</i> )
Pindolol	Tablet 5 mg ( <i>Barbloc 5</i> )
Risedronic acid and calcium	Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium 500 mg (as carbonate) ( <i>Acris Combi</i> )
Tofacitinib	Tablet 5 mg ( <i>Xeljanz</i> )
Upadacitinib	Tablet 15 mg ( <i>Rinvoq</i> )

## Documents Incorporated by Reference

<i>Listed Drug</i>	<i>Document incorporated</i>	<i>Document access</i>
Cannabidiol	<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>
Ciclosporin	<p><b>Ocular Surface Disease Index (OSDI).</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 Ocular Surface Disease Index (OSDI) is a 12-item questionnaire created by the Outcomes Research Group at Allergan Inc, Irvine, CA, USA, to assess dry eye symptoms and the effects on vision-related function. The questionnaire has 3 subscales: ocular symptoms, vision-related function, and environmental triggers. Patients rate their responses on a 0 to 4 scale with 0 corresponding to 'none of the time' and 4 corresponding to 'all of the time'. A final score is calculated which ranges from 0 to 100 with scores 0 to 12 representing normal, 13 to 22 representing mild dry eye disease, 23 to 32 representing moderate dry eye disease, and greater than 33 representing severe dry eye disease.</p>	<p>Walt J, Rowe M, Stern K. Evaluating the functional impact of dry eye: the Ocular Surface Disease Index. <i>Drug Information Journal</i>. 1997;31:1436</p> <p>The Ocular Surface Disease Index (OSDI) is available at:  <a href="http://eyecalc.org/osdi/">http://eyecalc.org/osdi/</a></p>
Ciclosporin	<p><b>Optometry guidelines for use of schedule medicine</b></p> <p>Published by the Optometry Board of Australia.</p>	<p>The Optometry guidelines are freely available at:</p>

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*. <https://www.optometryboard.gov.au/policies-codes-guidelines.aspx>

The Optometry Board of Australia (the Board) has developed these Guidelines for use of scheduled medicines under section 39 of the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law).

National Board guidelines describe the professional standards the Board expects of registered practitioners.

Guidelines approved by the Board may be used as evidence of what constitutes appropriate professional conduct or practice for optometry in proceedings against a health practitioner under the National Law, or a law of a co-regulatory jurisdiction.

Lenvatinib Pembrolizumab	<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>
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**Diagnostic tools referenced in the Instrument**

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

<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>
Ciclosporin	<b>An equivalent scale to the Oxford scale</b>	To objectively grade the severity of the condition to restrict PBS subsidy to patients with severe disease.	These are not documents, but are scales referenced in the medical literature. Equivalence is undefined. Equivalence is dependent on the prescriber being satisfied that the scale is equivalent to the Oxford scale.
Cannabidiol	<b>Electroencephalogram (EEG)</b>	An electroencephalogram (EEG) is a test that measures electrical activity in the brain using small, metal discs (electrodes) attached to the scalp. Brain cells communicate via electrical impulses and are active all the time, even during asleep. This activity shows up as wavy lines on an EEG recording. EEG is used to diagnose epilepsy, which causes abnormalities in EEG readings.	The EEG is part of the standard diagnostic work-up for Seizures of LGS and does not constitute a written record of information that must be referred to in order to determine whether statutory conditions have been met.

Measurements must be confirmed for LGS diagnosis and documented as part of the authority application.

Ciclosporin	<b>Modified Oxford scale</b>	To objectively grade the severity of the condition to restrict PBS subsidy to patients with severe disease.	This is not a document, but is a scale referenced in the medical literature. A literature reference is provided in an administrative NOTE.
Ciclosporin	<b>Oxford scale</b>	To objectively grade the severity of the condition to restrict PBS subsidy to patients with severe disease.	This is not a document, but is a scale referenced in the medical literature. A literature reference is provided in an administrative NOTE.

## **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. 5)*** **(PB 43 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. 5)* (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 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 six new forms of existing drugs, and the addition of 29 new brands across 17 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 ampicillin in the form powder for injection 1 g (as sodium) (Ampicyn) was requested to be delisted from the PBS by the sponsor. The PBAC advised that 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 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 dipyridamole with aspirin in the form capsule 200 mg (sustained release)-25 mg (Diasp SR) was requested to be delisted from the PBS by the sponsor. The PBAC noted the low utilisation, available clinical alternatives and that the sponsor had discontinued supply of the product. The PBAC advised the delisting of this drug 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 doxepin in the forms capsule 10 mg (as hydrochloride) (Deptran 10), capsule 25 mg (as hydrochloride) (Deptran 25), tablet 50 mg (as hydrochloride) (Deptran 50) was requested to be delisted from the PBS by the sponsor. The PBAC noted the range of clinical alternatives available and that the sponsor intends to continue supply of the products privately. The PBAC advised that the delisting of this drug 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 labetalol in the form tablet containing labetalol hydrochloride 200 mg (Trandate) was requested to be delisted from the PBS by the sponsor. The PBAC noted that the 100 mg strength of labetalol tablets will remain listed 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 pindolol in the form tablet 5 mg (Barbloc 5) was requested to be delisted from the PBS by the sponsor. The PBAC noted the low utilisation, available clinical alternatives and sponsor's intent to discontinue supply of the product. The PBAC advised the delisting of this drug 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 risedronic acid and calcium in the pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium 500 mg (as carbonate) (Acris Combi) was requested to be delisted from the PBS by the sponsor. The PBAC noted the low utilisation, available clinical alternatives and sponsor's intent to discontinue supply of the product. The PBAC advised the delisting of this drug would not result in an unmet clinical need. This item was available on the Schedule under Supply Only arrangements for a period of 6 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

### **Conclusion**

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

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