EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2021 (No. 10)

PB 109 of 2021

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 on the Pharmaceutical Benefits Scheme (PBS) and related matters.

PB 71 of 2012 determines the pharmaceutical benefits that are on the PBS 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 *National Health Act 1953* (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 the listed drugs budesonide with glycopyrronium and formoterol, and darolutamide, and the addition of forms of the listed drugs bortezomib, daratumumab, and tocilizumab to the Schedule of Pharmaceutical Benefits. It also provides for the deletion of a form of the listed drug pindolol. Additionally, it provides for the alteration of circumstances in which a prescription may be written for the supply of the listed drugs abatacept, abemaciclib, abiraterone, acalabrutinib, adalimumab, baricitinib, beclometasone with formoterol and glycopyrronium, botulinum toxin type A purified neurotoxin complex, certolizumab pegol, daratumumab, entrectinib, enzalutamide, etanercept, evolocumab, fluticasone furoate with umeclidinium and vilanterol, golimumab, imatinib, incobotulinumtoxinA, infliximab, leuprorelin, lorlatinib, tofacitinib, topiramate, triptorelin, and upadacitinib.

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

- the addition of 7 brands of existing pharmaceutical items;
- the deletion of 3 brands of existing pharmaceutical items;
- the addition of 2 Maximum Number of Repeats for an existing pharmaceutical item;
- the deletion of 1 Maximum Quantity and Number of Repeats for an existing pharmaceutical item;
- the alteration of 2 responsible person names on the list of responsible persons;

- the addition of 1 responsible persons to the list of responsible persons;
- the deletion of 2 responsible persons from the list of responsible persons;
- the alteration of responsible person codes for 60 existing brands of pharmaceutical items; and
- the addition of 1 brand of existing pharmaceutical items to supply only.

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 November 2021.

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

ATTACHMENT

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2021 (No. 10)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2021 (No. 10)* and may also be cited as PB 109 of 2021.

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 November 2021.

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 listed drugs, the addition and deletion of forms of listed drugs, the addition and deletion of brands, the addition of a maximum number of repeats, the deletion of a maximum quantity and number of repeats, the alteration of responsible person codes for brands of pharmaceutical benefits, the alteration of responsible person names for brands of pharmaceutical benefits, the addition and deletion of responsible persons from the list of responsible persons, the addition of 1 brand of pharmaceutical items to supply only status, 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

Listed Drugs Added

Listed Drug

Budesonide with glycopyrronium and formoterol

Darolutamide

Forms Added

Listed Drug	***Form***
Bortezomib	Powder for injection 2.5 mg
Daratumumab	Solution for subcutaneous injection containing daratumumab 1800 mg in 15 mL
Tocilizumab	Concentrate for injection 80 mg in 4 mL s19A
	Concentrate for injection 200 mg in 10 mL s19A
	Concentrate for injection 400 mg in 20 mL s19A

Forms Deleted

Listed Drug	*Form*
Pindolol	Tablet 5 mg (USP)

Brands Added

Listed Drug	*Form and Brand*
Aprepitant	Capsule 165 mg *(APREPITANT SCP)*
Ezetimibe with simvastatin	Tablet 10 mg-10 mg *(EZESIM 10/10)*
	Tablet 10 mg-20 mg *(EZESIM 10/20)*
	Tablet 10 mg-40 mg *(EZESIM 10/40)*
	Tablet 10 mg-80 mg *(EZESIM 10/80)*
Nitrazepam	Tablet 5 mg *(Alodorm)*
Perindopril with indapamide	Tablet containing perindopril erbumine 4 mg with indapamide hemihydrate 1.25 mg *(APO-Perindopril/Indapamide)*

Brands Deleted

Listed Drug	*Form and Brand*
Azacitidine	Powder for injection 100 mg *(Vidaza)*
Bivalirudin	Powder for I.V. injection 250 mg (as trifluoroacetate) *(Angiomax)*
Cyproterone	Tablet containing cyproterone acetate 100 mg *(Cyprostat-100)*

Additional Maximum Number of Repeats

Listed Drug	*Form*	*Brand Name*	*Number of Repeats*
Certolizumab pegol	Injection 200 mg in 1 mL single use pre-filled syringe	*Cimzia*	4
	Solution for injection 200 mg in 1 mL pre-filled pen	*Cimzia*	4

Deletion of Maximum Quantity and Number of Repeats

Listed Drug	*Form*	*Brand Name*	*Maximum Quantity*	*Number of Repeats*
Electrolyte replacement, oral	Oral rehydration salts containing glucose monohydrate 3.56 g, sodium chloride 470 mg, potassium chloride 300 mg and sodium acid citrate 530 mg per sachet, 10	restore O.R.S.	1	0

Addition of Responsible Person Code

Strides Pharma Science Pty Ltd *(ZS)*

Deletion of Responsible Person Code

Eris Pharmaceuticals (Australia) Pty Ltd *(ER)*

The Medicines Company (Australia) Pty Limited *(XM)*

Alteration of Responsible Person Name

From:	***To:***
Ascensia Diabetes Care Australia Pty Ltd *(DX)*	Ascensia Diabetes Care Australia Pty Limited *(DX)*
Ego Pharmaceuticals Proprietary Limited *(EO)*	Ego Pharmaceuticals Pty Ltd *(EO)*

Alteration of Responsible Person Code

Listed Drug	***Form***	***Brand Name***	***Responsible Person***	
Azacitidine	Powder for injection 100 mg	*Celazadine*	***From:*** JU	***To:*** CJ
Azathioprine	Tablet 50 mg	*Imazan*	***From:*** ER	***To:*** ZS
Bicalutamide	Tablet 50 mg	*Bicalox*	***From:*** ER	***To:*** ZS
Calcitriol	Capsule 0.25 microgram	*Calciprox*	***From:*** ER	***To:*** ZS
Carvedilol	Tablet 3.125 mg	*Volirop 3.125*	***From:*** DO	***To:*** ZS
	Tablet 6.25 mg	*Volirop 6.25*	***From:*** DO	***To:*** ZS
	Tablet 12.5 mg	*Volirop 12.5*	***From:*** DO	***To:*** ZS
	Tablet 25 mg	*Volirop 25*	***From:*** DO	***To:*** ZS
Escitalopram	Tablet 10 mg (as oxalate)	*Cilopam-S*	***From:*** ER	***To:*** ZS
	Tablet 20 mg (as oxalate)	*Cilopam-S*	***From:*** ER	***To:*** ZS
Furosemide	Tablet 40 mg	*Frusax*	***From:*** ER	***To:*** ZS
Interferon gamma-1b	Injection 2,000,000 I.U. in 0.5 mL	*Imukin*	***From:*** EU	***To:*** LM
Isotretinoin	Capsule 10 mg	*Dermatane*	***From:*** ER	***To:*** ZS
	Capsule 20 mg	*Dermatane*	***From:*** ER	***To:*** ZS
	Capsule 40 mg	*Dermatane*	***From:*** ER	***To:*** ZS
Lamotrigine	Tablet 25 mg	*Reedos 25*	***From:*** DO	***To:*** ZS
	Tablet 50 mg	*Reedos 50*	***From:*** DO	***To:*** ZS
	Tablet 100 mg	*Reedos 100*	***From:*** DO	***To:*** ZS
	Tablet 200 mg	*Reedos 200*	***From:*** DO	***To:*** ZS
Letrozole	Tablet 2.5 mg	*Gynotril*	***From:*** ER	***To:*** ZS
Levetiracetam	Oral solution 100 mg per mL, 300 mL	*Kerron*	***From:*** DO	***To:*** ZS
	Tablet 250 mg	*Levactam*	***From:*** ER	***To:*** ZS
	Tablet 500 mg	*Levactam*	***From:*** ER	***To:*** ZS
	Tablet 1 g	*Levactam*	***From:*** ER	***To:*** ZS

Metformin	Tablet containing metformin hydrochloride 500 mg	*Glucobete 500*	***From:*** DO	***To:*** ZS
	Tablet containing metformin hydrochloride 850 mg	*Glucobete 850*	***From:*** DO	***To:*** ZS
	Tablet containing metformin hydrochloride 1 g	*Glucobete 1000*	***From:*** DO	***To:*** ZS
Metoprolol	Tablet containing metoprolol tartrate 50 mg	*Mistrom*	***From:*** ER	***To:*** ZS
	Tablet containing metoprolol tartrate 100 mg	*Mistrom*	***From:*** ER	***To:*** ZS
Olanzapine	Tablet 2.5 mg	*Ozin 2.5*	***From:*** DO	***To:*** ZS
	Tablet 5 mg	*Ozin 5*	***From:*** DO	***To:*** ZS
	Tablet 7.5 mg	*Ozin 7.5*	***From:*** DO	***To:*** ZS
	Tablet 10 mg	*Ozin 10*	***From:*** DO	***To:*** ZS
Pantoprazole	Tablet (enteric coated) 20 mg (as sodium sesquihydrate)	*Panthron*	***From:*** ER	***To:*** ZS
	Tablet (enteric coated) 40 mg (as sodium sesquihydrate)	*Panthron*	***From:*** ER	***To:*** ZS
Perindopril	Tablet containing perindopril arginine 2.5 mg	*PREXUM 2.5*	***From:*** RW	***To:*** RX
	Tablet containing perindopril arginine 5 mg	*PREXUM 5*	***From:*** RW	***To:*** RX
	Tablet containing perindopril arginine 10 mg	*PREXUM 10*	***From:*** RW	***To:*** RX
Perindopril with amlodipine	Tablet containing 5 mg perindopril arginine with 5 mg amlodipine (as besilate)	*Reaptan 5/5*	***From:*** RW	***To:*** RX
	Tablet containing 5 mg perindopril arginine with 10 mg amlodipine (as besilate)	*Reaptan 5/10*	***From:*** RW	***To:*** RX
	Tablet containing 10 mg perindopril arginine with 5 mg amlodipine (as besilate)	*Reaptan 10/5*	***From:*** RW	***To:*** RX
	Tablet containing 10 mg perindopril arginine with 10 mg amlodipine (as besilate)	*Reaptan 10/10*	***From:*** RW	***To:*** RX
Perindopril with indapamide	Tablet containing perindopril arginine 2.5 mg with indapamide hemihydrate 0.625 mg	*PREXUM Combi LD 2.5/0.625*	***From:*** RW	***To:*** RX
	Tablet containing perindopril arginine 5 mg with indapamide hemihydrate 1.25 mg	*Prexum Combi 5/1.25*	***From:*** RW	***To:*** RX
Pioglitazone	Tablet 15 mg (as hydrochloride)	*Actos*	***From:*** TK	***To:*** EW
	Tablet 30 mg (as hydrochloride)	*Actos*	***From:*** TK	***To:*** EW
	Tablet 45 mg (as hydrochloride)	*Actos*	***From:*** TK	***To:*** EW
Quetiapine	Tablet 25 mg (as fumarate)	*Kaptan*	***From:*** ER	***To:*** ZS
	Tablet 100 mg (as fumarate)	*Kaptan*	***From:*** ER	***To:*** ZS
	Tablet 200 mg (as fumarate)	*Kaptan*	***From:*** ER	***To:*** ZS
	Tablet 300 mg (as fumarate)	*Kaptan*	***From:*** ER	***To:*** ZS

Raloxifene	Tablet containing raloxifene hydrochloride 60 mg	*Fixta 60*	***From:*** DO	***To:*** ZS
Risperidone	Tablet 0.5 mg	*Rispernia*	***From:*** ER	***To:*** ZS
	Tablet 1 mg	*Rispernia*	***From:*** ER	***To:*** ZS
	Tablet 2 mg	*Rispernia*	***From:*** ER	***To:*** ZS
	Tablet 3 mg	*Rispernia*	***From:*** ER	***To:*** ZS
	Tablet 4 mg	*Rispernia*	***From:*** ER	***To:*** ZS
Trastuzumab	Powder for I.V. infusion 150 mg	*Kanjinti*	***From:*** AN	***To:*** JU
	Powder for I.V. infusion 420 mg	*Kanjinti*	***From:*** AN	***To:*** JU
Valaciclovir	Tablet 500 mg (as hydrochloride)	*Shilova 500*	***From:*** DO	***To:*** ZS

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug	***Listed Drug***
Abatacept	Evolocumab
Abemaciclib	Fluticasone furoate with umeclidinium and vilanterol
Abiraterone	Golimumab
Acalabrutinib	Imatinib
Adalimumab	IncobotulinumtoxinA
Baricitinib	Infliximab
Beclometasone with formoterol and glycopyrronium	Leuprorelin
Botulinum toxin type A purified neurotoxin complex	Lorlatinib
Certolizumab pegol	Tofacitinib
Daratumumab	Topiramate
Entrectinib	Triptorelin
Enzalutamide	Upadacitinib
Etanercept	

Supply Only Status

Note: *From 1 November 2020 Supply Only benefits are available on the Schedule for dispensing but not for prescribing, usually for a period of up to 12 months from when it is deleted.*

Listed Drug	***Form and Brand***
Calcipotriol with betamethasone	Gel containing calcipotriol 50 micrograms with betamethasone 500 micrograms (as dipropionate) per g, 60 g *(Daivobet 50/500 gel)*

Documents Incorporated by Reference

Listed Drug	*Document incorporated*	*Document access*
Beclometasone with formoterol and glycopyrronium Budesonide with glycopyrronium and formoterol Fluticasone furoate with umeclidinium and vilanterol	**Approved Product Information.** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*. This document provides health professionals with a summary of the scientific information relevant to the safe and effective use of a prescription medicine.	TGA-approved Product Information is available for download for free from the TGA website: https://www.tga.gov.au/product-information-0
Abatacept Infliximab	**Therapeutic Goods Administration (TGA)-approved Product Information.** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*. This document provides health professionals with a summary of the scientific information relevant to the safe and effective use of a prescription medicine.	TGA-approved Product Information is available for download for free from the TGA website: https://www.tga.gov.au/product-information-0
Abemaciclib Abiraterone Darolutamide Enzalutamide	**World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status.** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*. The WHO/ECOG performance status is a standard medical diagnostic tool used to measure how cancer impacts a patient's daily living abilities, by evaluating a patient's level of functioning in terms of their ability to care for themself, daily activity, and physical ability (walking, working, etc.).	The WHO/ECOG Performance Status is available for download for free from the ECOG-ACRIN Cancer Research Group website: https://ecog-acrin.org/resources/ecog-performance-status

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 2021 (No. 10)

(PB 109 of 2021)

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 2021 (No. 10)* amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (the Principal Instrument) which determines the pharmaceutical benefits that are on the Pharmaceutical Benefits Scheme (PBS) 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).

The amendments in Schedule 1 involve the addition of listed drugs, the addition and deletion of forms of listed drugs, the addition and deletion of brands, the addition of a maximum number of repeats, the deletion of a maximum quantity and number of repeats, the alteration of responsible person codes for brands of pharmaceutical benefits, the alteration of responsible person names for brands of pharmaceutical benefits, the addition and deletion of responsible persons from the list of responsible persons, the addition of 1 brand of pharmaceutical items to supply only status, and the alteration of circumstances for prescribing various pharmaceutical benefits available on the Pharmaceutical Benefits Scheme.

Human rights implications

This Instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The 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 PBS are evidence-based. The pharmaceutical industry now has a nominee on the PBAC membership.

Conclusion

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

Nikolai Tsyganov
Assistant Secretary (Acting)
Pricing and PBS Policy Branch
Technology Assessment and Access Division
Department of Health