EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT (SEPTEMBER UPDATE) INSTRUMENT 2025

PB 94 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 drug palovarotene, and forms of the listed drugs benzathine benzylpenicillin, denosumab, dupilumab, ivacaftor, methylphenidate, peginterferon alfa-2a, prazosin, rivaroxaban, and secukinumab. It also provides for the deletion of the listed drugs amino acid formula with fat, carbohydrate, vitamins, minerals, and trace elements, without methionine and supplemented with docosahexaenoic acid, amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexaenoic acid, and amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexaenoic acid, and forms of the listed drugs acarbose, artemether with lumefantrine, fentanyl, and morphine, and the alteration of circumstances in which prescriptions may be written for the supply of the listed drugs adalimumab, cabozantinib, dupilumab, etanercept, ruxolitinib, secukinumab, and ustekinumab.

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

- the addition of 5 brands of existing pharmaceutical items
- the deletion of 49 brands of existing pharmaceutical items
- the addition of maximum quantities and number of repeats for 3 brands of existing pharmaceutical items
- the alteration of responsible person for 12 brands of existing pharmaceutical items
- the addition of 2 responsible persons to the list of responsible persons
- the deletion of 4 responsible persons from the list of responsible persons
- 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 September 2025.

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 (SEPTEMBER 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 (September Update) Instrument 2025* and may also be cited as PB 94 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 September 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 and deletion of drugs, the addition and deletion of forms of listed drugs, the addition and deletion of brands, the addition of maximum quantities and number of repeats 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 ending for a pharmaceutical item 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
Palovarotene

Drug Deletion

Listed Drug
Amino acid formula with fat, carbohydrate, vitamins, minerals, and trace elements, without methionine and supplemented with docosahexaenoic acid
Amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexaenoic acid
Amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexaenoic acid

Form Addition

Listed Drug	*Form*
Benzathine benzylpenicillin	Powder for injection 1,200,000 units with diluent 4 mL (S19A)
Denosumab	Injection 120 mg in 1 mL single use pre-filled syringe
Dupilumab	Injection 200 mg in 1.14 mL single dose pre-filled pen
	Injection 300 mg in 2 mL single dose pre-filled pen
Ivacaftor	Sachet containing granules 13.4 mg
Methylphenidate	Capsule containing methylphenidate hydrochloride 10 mg (modified release) (s19A)
	Capsule containing methylphenidate hydrochloride 20 mg (modified release) (s19A)
	Capsule containing methylphenidate hydrochloride 30 mg (modified release) (s19A)
	Capsule containing methylphenidate hydrochloride 60 mg (modified release) (s19A)
Peginterferon alfa-2a	Injection 135 micrograms in 0.5 mL single use pre-filled syringe (s19A)
	Injection 180 micrograms in 0.5 mL single use pre-filled syringe (s19A)
Prazosin	Capsule 2 mg (as hydrochloride) (S19A)
Rivaroxaban	Capsule 15 mg
	Capsule 20 mg
Secukinumab	Injection 300 mg in 2 mL pre-filled pen

Form Deletion

Listed Drug	*Form*
Acarbose	Tablet 50 mg (S19A)
Artemether with lumefantrine	Tablet (dispersible) 20 mg-120 mg
Fentanyl	Transdermal patch 1.28 mg
	Transdermal patch 2.063 mg
	Transdermal patch 2.55 mg
	Transdermal patch 4.125 mg
	Transdermal patch 5.10 mg
	Transdermal patch 7.65 mg
	Transdermal patch 8.25 mg
	Transdermal patch 10.20 mg

	Transdermal patch 12.375 mg
	Transdermal patch 16.5 mg
Morphine	Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 1 mL (S19A)
	Oral solution containing morphine sulfate 2 mg per mL in 100 mL bottle, 1 mL (S19A)
	Oral solution containing morphine sulfate 2 mg per mL in 500 mL bottle, 1 mL (S19A)

Brand Addition

Listed Drug	*Form and Brand*
Abiraterone	Tablet containing abiraterone acetate 250 mg *(ABIRATERONE VIATRIS)*
	Tablet containing abiraterone acetate 500 mg *(ABIRATERONE VIATRIS)*
Denosumab	Injection 60 mg in 1 mL pre-filled syringe *(CORORA)*
	Injection 120 mg in 1.7 mL *(GANVADO)*
Lamivudine	Tablet 300 mg *(Lamivudine Viatris)*

Brand Deletion

Listed Drug	*Form and Brand*
Aciclovir	Tablet 200 mg *(Aciclovir APOTEX)*
Allopurinol	Tablet 300 mg *(Allopurinol APOTEX)*
Amisulpride	Tablet 400 mg *(Amipride 400)*
Amlodipine	Tablet 5 mg (as besilate) *(Blooms the Chemist Amlodipine)*
	Tablet 10 mg (as besilate) *(Blooms the Chemist Amlodipine)*
Amoxicillin with clavulanic acid	Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *(Amoxycillin/Clavulanic Acid 500/125 APOTEX)*
Candesartan with hydrochlorothiazide	Tablet containing candesartan cilexetil 16 mg with hydrochlorothiazide 12.5 mg *(Blooms the Chemist Candesartan HCTZ 16/12.5)*
Celecoxib	Capsule 100 mg *(Blooms the Chemist Celecoxib; Celecoxib APOTEX)*
	Capsule 200 mg *(Blooms the Chemist Celecoxib; Celecoxib APOTEX)*
Imatinib	Capsule 100 mg (as mesilate) *(Imatinib-APOTEX)*
Irbesartan	Tablet 300 mg *(Blooms the Chemist Irbesartan)*
Irbesartan with hydrochlorothiazide	Tablet 150 mg-12.5 mg *(Blooms the Chemist Irbesartan HCTZ 150/12.5)*
	Tablet 300 mg-12.5 mg *(Blooms the Chemist Irbesartan HCTZ 300/12.5)*
	Tablet 300 mg-25 mg *(Blooms the Chemist Irbesartan HCTZ 300/25)*

Montelukast	Tablet, chewable, 5 mg (as sodium) *(Montelukast Mylan)*
Morphine	Tablet containing morphine sulfate pentahydrate 10 mg (controlled release) *(MORPHINE MR APOTEX)*
	Tablet containing morphine sulfate pentahydrate 30 mg (controlled release) *(MORPHINE MR APOTEX)*
	Tablet containing morphine sulfate pentahydrate 60 mg (controlled release) *(MORPHINE MR APOTEX)*
	Tablet containing morphine sulfate pentahydrate 100 mg (controlled release) *(MORPHINE MR APOTEX)*
Mycophenolic acid	Tablet containing mycophenolate mofetil 500 mg *(MycoCept)*
Olmesartan with amlodipine	Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate) *(Olmesartan/Amlodipine 20/5 APOTEX)*
Omeprazole	Capsule 20 mg *(Pemzo)*
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate) *(APO-Ondansetron)*
	Tablet 8 mg (as hydrochloride dihydrate) *(APO-Ondansetron)*
Paroxetine	Tablet 20 mg (as hydrochloride) *(APO-Paroxetine)*
Pemetrexed	Powder for I.V. infusion 500 mg (as disodium) *(Pemetrexed APOTEX)*
Perindopril	Tablet containing perindopril erbumine 2 mg *(Blooms the Chemist Perindopril)*
	Tablet containing perindopril erbumine 4 mg *(Blooms the Chemist Perindopril)*
	Tablet containing perindopril erbumine 8 mg *(Blooms the Chemist Perindopril)*
Pioglitazone	Tablet 15 mg (as hydrochloride) *(APOTEX-Pioglitazone)*
Pramipexole	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 375 micrograms *(APO-Pramipexole ER)*
	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 750 micrograms *(APO-Pramipexole ER)*
	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 1.5 mg *(APO-Pramipexole ER)*
	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 2.25 mg *(APO-Pramipexole ER)*
	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 3 mg *(APO-Pramipexole ER)*
	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 3.75 mg *(APO-Pramipexole ER)*
	Tablet (extended release) containing pramipexole dihydrochloride monohydrate 4.5 mg *(APO-Pramipexole ER)*

Pregabalin	Capsule 25 mg *(Blooms The Chemist Pregabalin)*
	Capsule 150 mg *(Blooms The Chemist Pregabalin)*
	Capsule 300 mg *(Blooms The Chemist Pregabalin)*
Rivaroxaban	Tablet 15 mg *(Relaban)*
	Tablet 20 mg *(Relaban)*
Rosuvastatin	Tablet 5 mg (as calcium) *(Rosuvastatin APOTEX)*
Roxithromycin	Tablet 150 mg *(APO-Roxithromycin)*
	Tablet 300 mg *(APO-Roxithromycin)*
Valaciclovir	Tablet 500 mg (as hydrochloride) *(Valaciclovir APOTEX)*
Vinorelbine	Solution for I.V. infusion 50 mg (as tartrate) in 5 mL *(Navelbine)*

Maximum Quantity and Number of Repeats Addition

Listed Drug	***Form and Brand***	***Maximum Quantity***	***Number of Repeats***
Adalimumab	Injection 20 mg in 0.2 mL pre-filled syringe *(Humira)*	2	4
	Injection 20 mg in 0.4 mL pre-filled syringe *(Abrilada; Amgevita)*	2	4

Responsible Person Alteration

Listed Drug	***Form***	***Brand***	***Responsible Person***	
Benzylpenicillin	Powder for injection 600 mg (as sodium)	*BenPen*	***From:*** CS	***To:*** SZ
	Powder for injection 3 g (as sodium)	*BenPen*	***From:*** CS	***To:*** SZ
Chlormethine	Gel 160 micrograms (as hydrochloride) per g, 60 g	*Ledaga*	***From:*** JZ	***To:*** XT
Fosnetupitant with palonosetron	Solution concentrate for I.V. infusion containing fosnetupitant 235 mg (as chloride hydrochloride) and palonosetron 250 microgram (as hydrochloride)	*Akynzeo IV*	***From:*** JZ	***To:*** XT
Iron sucrose	Concentrate for solution for infusion 2.7 g (equivalent to 100 mg iron (III)) in 5 mL	*Venofer*	***From:*** VL	***To:*** CS
Isotretinoin	Capsule 5 mg	*Oratane*	***From:*** OU	***To:*** RF
	Capsule 30 mg	*Oratane*	***From:*** OU	***To:*** RF
Metronidazole	Oral suspension containing metronidazole benzoate 320 mg per 5 mL, 100 mL	*Flagyl S*	***From:*** SW	***To:*** VJ
	Suppositories 500 mg, 10	*Flagyl*	***From:*** SW	***To:*** VJ
	Tablet 400 mg	*Flagyl*	***From:*** SW	***To:*** VJ

Netupitant with Palonosetron	Capsule containing netupitant 300 mg with palonosetron 500 microgram (as hydrochloride)	*Akynzeo*	***From:*** JZ	***To:*** XT
Sucroferric oxyhydroxide	Tablet, chewable, 2.5 g (equivalent to 500 mg iron)	*Velphoro*	***From:*** VL	***To:*** CS

Responsible Person Addition

Responsible Person
Amgen Australia Pty Limited *(GV)*
VITALION PTY LTD *(VJ)*

Responsible Person Deletion

Responsible Person
Apotex Pty Ltd *(IB)*
Juniper Biologics Pty Ltd *(JZ)*
Oraderm Pharmaceuticals Pty Ltd *(OU)*
Vifor Pharma Pty Limited *(VL)*

Supply Only – Period Ending

Listed Drug	***Form***
Amino acid formula with vitamins and minerals without lysine and low in tryptophan	Sachets containing oral powder 24 g, 30 (GA gel)

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug
Adalimumab
Cabozantinib
Dupilumab
Etanercept
Ruxolitinib
Secukinumab
Ustekinumab

Documents Incorporated by Reference

Listed Drug	*Document Incorporated*	*Document access*
Adalimumab Dupilumab Palovarotene Ruxolitinib Ustekinumab	**Approved Product Information/Australian Product Information/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
Dupilumab	**Asthma Control Questionnaire (ACQ-5) and/or Asthma Control Questionnaire interviewer administered version (ACQ-IA).** 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 ACQ-5 and the ACQ-IA are widely used tools for measuring how well a patient's asthma symptoms are being controlled.	Prescribers can contact the suppliers of these asthma medications directly to obtain free copies of the ACQ calculation sheets. Contact details for the suppliers can be found online at www.pbs.gov.au
Dupilumab	**Dermatology Life Quality Index (DLQI).** 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 DLQI is designed to measure the health-related quality of life of adult patients suffering from a skin disease.	The DLQI is available for download for free from the Cardiff University website: Adults: https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index Children: https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/childrens-dermatology-life-quality-index
Dupilumab	**Eczema Area and Severity Index (EASI).** 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 EASI is a validated scoring system that grades the physical signs of atopic dermatitis/eczema.	The Eczema Area and Severity Index (EASI) is described in the following literature publications: Chalmers JR et al. Report from the third international consensus meeting to harmonise core outcome measures for atopic eczema/dermatitis clinical trials (HOME). British Journal of Dermatology 2014; December;171(6):1318-25. https://pubmed.ncbi.nlm.nih.gov/24980543/ Schmitt J et al. HOME initiative collaborators. The Harmonising Outcome Measures for Eczema (HOME) statement to assess clinical signs of atopic eczema in trials. The Journal of Allergy and Clinical Immunology 2014 October;134(4):800-7 https://pubmed.ncbi.nlm.nih.gov/25282560/
Secukinumab	**Hurley stages.** 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*.	A description of the Hurley stages is available for download for free from: https://www.racgp.org.au/afp/2017/august/hidradenitis-suppurativa-management-comorbidities-and-monitoring/

	Hurley stages are used to classify the severity of Hidradenitis Suppurativa symptoms.	
Adalimumab	**Mayo clinic score and partial Mayo clinic score.** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*. The Mayo clinic score and the partial Mayo clinic score (an abbreviated form of the Mayo clinic score) are medical diagnostic tools used to measure disease activity, in a standardised way, in Ulcerative Colitis through the evaluation of symptoms.	The Mayo clinic score and the partial Mayo clinic score are available to download for free from the Inflammatory Bowel Diseases Journal via the Oxford University Press website: https://academic.oup.com/ibdjournal/article/14/12/1660/4654949?login=true
Adalimumab	**Paediatric Crohn's Disease Activity Index (PCDAI).** 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 PCDAI is a tool used widely to classify the severity of Crohn's disease in pediatric patients.	The Paediatric Crohn's Disease Activity Index (PCDAI) is available for download for free from the Services Australia website: https://www.servicesaustralia.gov.au/
Adalimumab	**Paediatric Ulcerative Colitis Activity Index (PUCAI).** 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 PUCAI is a standard medical diagnostic tool used to measure disease activity in children and adolescents with Ulcerative Colitis through the evaluation of symptoms.	The PUCAI is available for download for free from the Inflammatory Bowel Diseases Journal via the Oxford University Press website: https://academic.oup.com/ibdjournal/article/15/8/1218/4643533
Dupilumab	**Physicians Global Assessment (PGA) (5-point scale).** 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 PGA is a 5-point scale that measures the severity of atopic dermatitis.	The Physician's Global Assessment is not publicly available, but can be obtained free of charge from Sanofi Medical Information, along with instructions on the use of the Physician's Global Assessment (5-point scale) by phoning 1800 818 806 or email MedInfo.Australia@sanofi.com
Adalimumab Etanercept Ustekinumab	**Psoriasis Area Severity Index (PASI).** 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 PASI is a widely used tool that enables measurement of the severity and extent of baseline and response of therapy in psoriasis.	The PASI calculation form is available for download for free from the Services Australia website: https://www.servicesaustralia.gov.au/ and forms part of the SA authority application process.

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.

Listed Drug	***Diagnostic tool***	***Purpose and use in the Instrument***	***Reason this reference does not serve to incorporate a document***
Secukinumab	**Hidradenitis Suppurativa Clinical Response (HiSCR)**	The HiSCR is used to assess/determine an adequate response to a particular biological medicine for the treatment of Hidradenitis Suppurativa. HiSCR is defined as a ≥ 50%	The HiSCR itself does not determine PBS eligibility and is considered a diagnostic tool as opposed to a 'document'. Reference: Kimball, A., Jemec, G., Yang, M., Kageleiry, A., Signorovitch, J., Okun,

	reduction in inflammatory lesion count (abscesses + inflammatory nodules), and no increase in abscesses or draining fistulas when compared with baseline.	M., Gu, Y., Wang, K., Mulani, P. and Sundaram, M. (2014), Assessing the validity, responsiveness and meaningfulness of the Hidradenitis Suppurativa Clinical Response (HiSCR) as the clinical endpoint for hidradenitis suppurativa treatment. Br J Dermatol, 171: 1434-1442. https://doi.org/10.1111/bjd.13270

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 (September Update) Instrument 2025

(PB 94 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 (September 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, forms and brands of existing listed drugs, and ensuring the deletion of drugs, 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 a new drug, the addition of 15 new forms of existing drugs, and the addition of 5 new brands across 5 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 form of drug below. Where the PBAC has identified an unmet clinical need, a Supply Only period 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 acarbose in the form tablet 50 mg (S19A) (Acarbose 50 mg tablets (Morningside, UK)) 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 May 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 amino acid formula with fat, carbohydrate, vitamins, minerals, and trace elements, without methionine and supplemented with docosahexaenoic acid in the form oral liquid 125 mL, 36 (HCU Anamix junior LQ) 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 and that there are limited alternatives available 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 the product on the PBS, if possible. However, the sponsor decided to proceed with the delisting due to commercial reasons.

The drug amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexaenoic acid in the form oral liquid 125 mL, 36 (TYR Anamix junior LQ) 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 and that there are limited alternatives available 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 the product on the PBS, if possible. However, the sponsor decided to proceed with the delisting due to commercial reasons.

The drug amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexaenoic acid in the form oral liquid 125 mL, 36 (MSUD Anamix Junior LQ) 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 and that there are limited alternatives available 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 the product on the PBS, if possible. However, the sponsor decided to proceed with the delisting due to commercial reasons.

The drug artemether with lumefantrine in the form tablet (dispersible) 20 mg-120 mg (Riamet 20mg/120mg Dispersible) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the last financial year. The PBAC advised the delisting of this product would not result in an unmet clinical need.

The drug fentanyl in each of the forms transdermal patch 1.28 mg (Denpax), transdermal patch 2.55 mg (Denpax), transdermal patch 5.10 mg (Denpax), transdermal patch 7.65 mg (Denpax), and transdermal patch 10.20 mg (Denpax) were requested to be delisted from the PBS Schedule by the sponsor. There are other substitutable forms of fentanyl available on the PBS and the delisting of this product will not result in an unmet clinical need.

The drug fentanyl in each of the forms transdermal patch 2.063 mg (Fenpatch 12), transdermal patch 4.125 mg (Fenpatch 25), transdermal patch 8.25 mg (Fenpatch 50), transdermal patch 12.375 mg (Fenpatch 75), and transdermal patch 16.5 mg (Fenpatch 100) were requested to be delisted from the PBS Schedule by the sponsor. There are other substitutable forms of fentanyl available on the PBS and the delisting of this product will not result in an unmet clinical need.

The drug morphine in each of the forms oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 1 mL (S19A) (Morphini HCl Streuli), oral solution containing morphine sulfate 2 mg per mL in 100 mL bottle, 1 mL (S19A) (Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL)) and oral solution containing morphine sulfate 2 mg per mL in 500 mL bottle, 1 mL (S19A) (Morphine Sulfate (Hikma) 10 mg/5 mL (2 mg/mL)) were 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 27 May 2025. Patient access has not been affected as the Australian Register of Therapeutic Goods approved forms of the drug are now available and remain PBS subsidised and accessible for patients.

Conclusion

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

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