EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT (OCTOBER UPDATE) INSTRUMENT 2026

PB 113 of 2026

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.

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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 following changes:

- the addition of the drug tofersen
- the addition of a form of the listed drugs ciclosporin, glycomacropeptide formula with long chain polyunsaturated fatty acids and docosahexaenoic acid and low in phenylalanine, and tacrolimus
- the deletion of a form of the listed drugs beclometasone, cefuroxime, insulin glulisine, and salbutamol
- the alteration of forms of the listed drug nilotinib
- the addition of 31 brands of existing pharmaceutical items
- the deletion of 13 brands of existing pharmaceutical items
- the alteration of responsible person for 5 brands of existing pharmaceutical items
- the addition of 2 responsible persons to the list of responsible persons
- the deletion of a responsible person from the list of responsible persons
- the alteration of circumstances in which prescriptions may be written for the supply of the listed drugs abemaciclib, asciminib, dasatinib, dupilumab, edaravone, imatinib, lumasiran, modafinil, nilotinib, pembrolizumab, ponatinib, ribociclib, sunitinib, tocilizumab, and triptorelin.

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

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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 October 2026.

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

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ATTACHMENT

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT (OCTOBER UPDATE) INSTRUMENT 2026*

Section 1 Name of Instrument

This section provides that the name of the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment (October Update) Instrument 2026* and may also be cited as PB 113 of 2026.

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 October 2026.

Section 3 Authority

This section specifies that sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953* provide the authority for the making of this Instrument.

Section 4 Schedules

This section provides that each instrument that is specified in a Schedule to the Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Instrument has effect according to its terms.

Schedule 1 Amendments

The amendments in Schedule 1 involve the addition of a drug, the addition, deletion and alteration of forms of listed drugs, the addition and deletion of brands, the alteration of responsible person for brands of existing pharmaceutical items, the addition and deletion of responsible persons for the list of responsible persons, 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
Tofersen

Form Addition

Listed Drug	***Form***
Ciclosporin	Eye drops 1 mg per mL, 2 mL
Glycomacropeptide formula with long chain polyunsaturated fatty acids and docosahexaenoic acid and low in phenylalanine	Sachets containing oral powder 40 g, pack of 30 (PKU GMPro Delight)
Tacrolimus	Ointment 1 mg per g, 30 g

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Form Deletion

Listed Drug	*Form*
Beclometasone	Pressurised inhalation in breath actuated device containing beclometasone dipropionate 50 micrograms per dose, 200 doses (CFC-free formulation) *(Supply Only - period ending)*
Cefuroxime	Powder for oral suspension 125 mg (as axetil) per 5 mL, 70 mL (S19A)
Insulin glulisine	Injection (human analogue) 100 units per mL, 10 mL *(Supply Only - period ending)*
Salbutamol	Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 30 *(Supply Only - period ending)*

Form Alteration

Listed Drug	*Form*
Nilotinib	***From:*** Capsule 150 mg (as hydrochloride monohydrate) ***To:*** Capsule 150 mg (as hydrochloride)
	From: Capsule 200 mg (as hydrochloride monohydrate) ***To:*** Capsule 200 mg (as hydrochloride)

Brand Addition

Listed Drug	*Form and Brand*
Adalimumab	Injection 20 mg in 0.2 mL pre-filled syringe *(Yuflyma)*
Apixaban	Tablet 2.5 mg *(Apixaban Dr.Reddy's; Apixaban Viatris; MSN-APIXABAN)*
	Tablet 5 mg *(Apixaban Dr.Reddy's; Apixaban Viatris; MSN-APIXABAN)*
Bleomycin	Powder for injection containing bleomycin sulfate 15,000 I.U. *(Bleomycin Accord)*
Cefuroxime	Tablet 250 mg (as axetil) *(ARX-Cefuroxime)*
Gabapentin	Tablet 800 mg *(APX-GABAPENTIN)*
Guanfacine	Tablet 1 mg (as hydrochloride) *(Guanfacine MHC)*
	Tablet 2 mg (as hydrochloride) *(Guanfacine MHC)*
	Tablet 3 mg (as hydrochloride) *(Guanfacine MHC)*
	Tablet 4 mg (as hydrochloride) *(Guanfacine MHC)*
Nilotinib	Capsule 150 mg (as hydrochloride) *(Ceahani; MSN-NILOTINIB; NILOTAS)*
	Capsule 200 mg (as hydrochloride) *(Ceahani; MSN-NILOTINIB; NILOTAS)*

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Omalizumab	Injection 75 mg in 0.5 mL single dose pre-filled pen *(Omlyclo)*
	Injection 150 mg in 1 mL single dose pre-filled pen *(Omlyclo)*
Paclitaxel, nanoparticle albumin-bound	Powder for I.V. injection containing 100 mg paclitaxel *(nab-Paclitaxel Accord)*
Risedronic acid	Tablet containing risedronate sodium 150 mg *(Risedronate Way)*
Tocilizumab	Concentrate for injection 80 mg in 4 mL *(Avtozma)*
	Concentrate for injection 200 mg in 10 mL *(Avtozma)*
	Concentrate for injection 400 mg in 20 mL *(Avtozma)*
	Injection 162 mg in 0.9 mL single use pre-filled pen *(Avtozma)*
	Injection 162 mg in 0.9 mL single use pre-filled syringe *(Avtozma)*
Varenicline	Box containing 11 tablets 0.5 mg and 42 tablets 1 mg *(VASSIX)*
	Tablet 1 mg *(VASSIX)*

Brand Deletion

Listed Drug	***Form and Brand***
Allopurinol	Tablet 300 mg *(NOUMED ALLOPURINOL)*
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4 *(Nepexto)*
Gabapentin	Tablet 800 mg *(Gabapentin APOTEX)*
Lenalidomide	Capsule 5 mg *(Lenalidomide Dr.Reddy's)*
	Capsule 10 mg *(Lenalidomide Dr.Reddy's)*
	Capsule 15 mg *(Lenalidomide Dr.Reddy's)*
	Capsule 25 mg *(Lenalidomide Dr.Reddy's)*
Levetiracetam	Tablet 500 mg *(Levetiracetam Mylan)*
Olmesartan	Tablet containing olmesartan medoxomil 20 mg *(APX-Olmesartan)*
	Tablet containing olmesartan medoxomil 40 mg *(APX-Olmesartan)*

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Olmesartan with hydrochlorothiazide	Tablet containing olmesartan medoxomil 20 mg with hydrochlorothiazide 12.5 mg *(APX-Olmesartan/HCTZ)*
	Tablet containing olmesartan medoxomil 40 mg with hydrochlorothiazide 12.5 mg *(APX-Olmesartan/HCTZ)*
	Tablet containing olmesartan medoxomil 40 mg with hydrochlorothiazide 25 mg *(APX-Olmesartan/HCTZ)*

Responsible Person Alteration

Listed Drug	*Form and Brand*	*Responsible Person*	
Corifollitropin alfa	Solution for injection 100 micrograms in 0.5 mL single dose pre-filled syringe *(Elonva)*	***From:*** OQ	***To:*** AF
	Solution for injection 150 micrograms in 0.5 mL single dose pre-filled syringe *(Elonva)*	***From:*** OQ	***To:*** AF
Follitropin beta	Solution for injection 300 I.U. in 0.36 mL multi-dose cartridge *(Puregon 300 IU/0.36 mL)*	***From:*** OQ	***To:*** AF
	Solution for injection 600 I.U. in 0.72 mL multi-dose cartridge *(Puregon 600 IU/0.72 mL)*	***From:*** OQ	***To:*** AF
	Solution for injection 900 I.U. in 1.08 mL multi-dose cartridge *(Puregon 900 IU/1.08 mL)*	***From:*** OQ	***To:*** AF

Responsible Person Addition

Responsible Person
MSN LABORATORIES AUSTRALIA PTY LTD *(VM)*
SEED PHARMA PTY. LTD. *(HK)*

Responsible Person Deletion

Responsible Person
Avallon Pharmaceuticals Pty Limited *(VO)*

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug	*Listed Drug*
Abemaciclib	Nilotinib
Asciminib	Pembrolizumab
Dasatinib	Ponatinib
Dupilumab	Ribociclib
Edaravone	Sunitinib
Imatinib	Tocilizumab
Lumasiran	Triptorelin
Modafinil	

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Documents Incorporated by Reference

Listed Drug	*Document Incorporated*	*Document access*
Edaravone Tofersen	**Amyotrophic lateral sclerosis (ALS) Functional Rating Scale – Revised (ALSFRS-R) 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 ALSFRS-R questionnaire is routinely administered to patients with ALS by neurologists at every clinic visit, typically 3 monthly. It is not proprietary and can be accessed online, being reproduced on multiple medical websites (e.g. https://www.mdcalc.com/calc/10166/revised-amyotrophic-lateral-sclerosis-functional-rating-scale-alsfrs-r). There are also websites that allow the neurologist to input a patient's ratings to obtain a printable or digital copy of their score (https://neurotoolkit.com/alsfrs-r/).	An ALSFRS-R calculator is available via the MiNDAUS ALS registry: https://www.mindaus.org/wp-content/uploads/2023/09/22094546/DataDictionaryPROMMindausHansenJuly2023V01.1.pdf
Tocilizumab	**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
Abemaciclib Ribociclib	**Nottingham grading system** 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 Nottingham grading system is the histologic grading system developed by Elston and Ellis as a modification of the Scarff-Bloom-Richardson grading system. It is used to grade breast cancer cells by describing how different a cancer cell's appearance and growth patterns are from normal, healthy breast cells.	Elston, CW, Ellis, IO. Pathological prognostic factors in breast cancer. The value of histological grade in breast cancer: experience from a large study with long-term follow-up. Histopathology. 1991 Nov;19(5):403-10. https://pubmed.ncbi.nlm.nih.gov/1757079/
Asciminib Sunitinib	**World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status/Performance Status Score.** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003.* The WHO/ECOG performance status is a standard medical diagnostic tool used to measure how cancer impacts a patient's daily living abilities, by evaluating a patient's level of functioning in terms of their ability to care for 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

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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.

Listed Drug	***Diagnostic tool***	***Purpose and use in the Instrument***	***Reason this reference does not serve to incorporate a document***
Asciminib Dasatinib Imatinib Nilotinib Ponatinib	The international scale for BCR-ABL	To determine the peripheral blood BCR-ABL level. The BCR-ABL test may be used to see if cancer treatment is effective or if a patient has developed a resistance to certain treatment. That means a treatment that used to be effective is no longer working.	A BCR-ABL test is most often used to diagnose or rule out chronic myeloid leukemia (CML) or a specific form of acute lymphoblastic leukemia (ALL) called Ph-positive ALL. Ph-positive means a Philadelphia chromosome was found. The test is not used to diagnose other types of leukemia.

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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 (October Update) Instrument 2026

(PB 113 of 2026)

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 (October Update) Instrument 2026* (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 (the Committee) 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, and ensuring the deletion of drugs, forms and brands 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 1 new drug, the addition

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of 3 new forms of existing drugs, and the addition of 31 new brands across 23 existing forms, which allows for greater patient access to these drugs.

When a sponsor submits a request to delist a drug from the PBS, subsection 101(4AAB) of the *National Health Act 1953* requires that the Minister or their delegate obtain advice from the Pharmaceutical Benefits Advisory Committee (PBAC), an independent and expert advisory body, before varying or revoking declarations under subsection 85(2) so as to delist the drug. In these instances, one of the matters which the PBAC provides advice on is whether the delisting of a drug will result in an unmet clinical need for patients. The PBAC also considers whether the delisting of a form of a drug will result in an unmet clinical need for patients.

Written advice from the PBAC is tabled with the monthly amendments to the Principal Instrument. An unmet clinical need would arise when a currently treated patient population would be left without treatment options once a delisting occurs. Alternative treatment options could include using a different: form, strength or drug. The PBAC considered the delisting of forms of drugs in the abovementioned instrument would not result in an unmet clinical need, except where indicated for a particular form of drug below. Where the PBAC has identified an unmet clinical need, a Supply Only period has been 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 2026, these amounts are $25.00 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 beclometasone in the form pressurised inhalation in breath actuated device containing beclometasone dipropionate 50 micrograms per dose, 200 doses (CFC-free formulation) (Qvar 50 Autohaler) was requested to be delisted from the PBS schedule by the sponsor. The sponsor advised this item is being discontinued because it is no longer commercially viable to continue supply and will be withdrawn from Australia entirely. The PBAC noted the inhaler has been discontinued and advised this delisting would not result in an unmet clinical need. This item was available on the PBS Schedule under Supply Only arrangements for a period of 6 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment.

The drug cefuroxime in the form powder for oral suspension 125 mg (as axetil) per 5 mL, 70 mL (S19A) (Zinnat (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 (ARTG) lapsed on 30 June 2026. The ARTG-listed cefuroxime oral suspension form has also been discontinued. However, other PBS-subsidised cefuroxime presentations, including tablet formulations, remain listed and available on the PBS for eligible patients where clinically appropriate.

The drug insulin glulisine in the form injection (human analogue) 100 units per mL, 10 mL (Apidra) 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 and advised this delisting would not result in an unmet clinical need. This item was available on the PBS Schedule under Supply Only arrangements for a period of 6 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment.

The drug salbutamol in the form nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 30 (Salbutamol Cipla) was requested to be delisted from the PBS schedule by the sponsor. This item is unavailable to be supplied due to global capacity constraints and long-term commercial viability. An equivalent product remains available on the PBS Schedule. The PBAC noted the low number of services in the last financial year and advised this delisting would not result in an unmet clinical need. This item was available on the PBS Schedule under Supply Only arrangements for a period of 6 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment.

Conclusion

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

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