EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM) SPECIAL ARRANGEMENT AMENDMENT (AUGUST UPDATE) INSTRUMENT 2025

PB 88 of 2025

Purpose

This is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (August Update) Instrument 2025* (PB 88 of 2025) (this Instrument). The purpose of this Instrument, made under subsection 100(2) of the *National Health Act 1953* (the Act), is to amend the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* (PB 27 of 2021) (the Special Arrangement), to make changes to the Special Arrangement relating to the Highly Specialised Drugs (HSD) Program.

The amendments made by this Instrument reflect amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (PB 26 of 2024), which commence on the same day. The *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (PB 26 of 2024), and amendments to that instrument, are made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the Act.

Schedule 1 to this Instrument provides for the addition of the drugs eflornithine and foslevodopa with foscarbidopa, the addition of forms of the listed drug omalizumab, and the addition of a brand of the listed drugs omalizumab and ustekinumab. It also provides for the deletion of a form of the listed drug tenofovir with emtricitabine, the deletion of a brand of the listed drugs omalizumab and tenofovir, and the alteration of circumstances in which a prescription may be written for the listed drugs ivacaftor, omalizumab, and ustekinumab under the Special Arrangement. These changes are summarised, by subject matter, in the Attachment.

Authority

Subsection 100(1) of the Act enables the Minister, by legislative instrument, to make special arrangements for the supply of pharmaceutical benefits.

Subsection 100(2) of the Act provides that the Minister may, by legislative instrument, vary or revoke a special arrangement made under subsection 100(1).

Subsection 100(3) of the Act provides that Part VII of the Act, and instruments made for the purposes of Part VII have effect subject to a special arrangement made under subsection 100(1).

Consultation

The amendments made by this Instrument accord with recommendations made by the Pharmaceutical Benefits Advisory Committee (PBAC).

An ongoing and formal process of consultation in relation to matters relevant to the Special Arrangement includes the involvement of interested parties through the membership of the PBAC.

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 as pharmaceutical benefits. 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 PBAC, and that would enable them to contribute meaningfully to the deliberations of PBAC. In addition, an industry nominee has been appointed to the PBAC membership. When recommending the listing of a medicine on the Pharmaceutical Benefits Scheme (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 were consulted throughout the process of changes to the listings on the PBS. This includes consultation through the PBAC process.

Further consultation for this Instrument was considered unnecessary due to the nature of the consultation that has already taken place in the decision to list the medications outlined under 'Purpose'.

Details of this Instrument are set out in the Attachment.

This Instrument commences on 1 August 2025.

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

ATTACHMENT

DETAILS OF THE *NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM) SPECIAL ARRANGEMENT AMENDMENT (AUGUST UPDATE) INSTRUMENT 2025*

Section 1 Name of Instrument

This section provides that the name of the Instrument is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (August Update) Instrument 2025* and may also be cited as PB 88 of 2025.

Section 2 Commencement

This section provides that this Instrument commences on 1 August 2025.

Section 3 Authority

This section states that this Instrument is made under subsection 100(2) of the *National Health Act 1953*.

Section 4 Schedules

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

Schedule 1 Amendments

The amendments in Schedule 1 involve the addition of drugs, the addition and deletion of forms of drugs, the addition and deletion of brands of existing pharmaceutical benefits, and the alteration of circumstances in which a prescription may be written for various listed drugs available under the Special Arrangement. These changes are summarised below.

SUMMARY OF CHANGES TO THE *HIGHLY SPECIALISED DRUGS PROGRAM* MADE BY THIS INSTRUMENT

Drug Added

Listed Drug
Eflornithine
Foslevodopa with foscarbidopa

Form Added

Listed Drug	***Form***
Omalizumab	Injection 75 mg in 0.5 mL single dose pre-filled pen
	Injection 150 mg in 1 mL single dose pre-filled pen
	Injection 300 mg in 2 mL single dose pre-filled pen

Form Deleted

Listed Drug	*Form*
Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg (S19A)

Brand Added

Listed Drug	*Form and Brand*
Omalizumab	Injection 75 mg in 0.5 mL single dose pre-filled syringe *(Omlyclo)*
	Injection 150 mg in 1 mL single dose pre-filled syringe *(Omlyclo)*
Ustekinumab	Solution for I.V. infusion 130 mg in 26 mL *(Steqeyma)*

Brand Deleted

Listed Drug	*Form and Brand*
Omalizumab	Injection 150 mg in 1 mL single dose pre-filled syringe *(Xolair)*
Tenofovir	Tablet containing tenofovir disoproxil fumarate 300 mg *(Tenofovir APOTEX)*

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug
Ivacaftor
Omalizumab
Ustekinumab

Documents Incorporated by Reference

Listed Drug	*Document Incorporated*	*Document access*
Eflornithine Ivacaftor Omalizumab 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
Omalizumab	**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

Ustekinumab	**Crohn's Disease Activity Index (CDAI).** 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 Crohn's Disease Activity Index (CDAI) is a research tool used to quantify the symptoms of patients with Crohn's disease.	The Crohn's Disease Activity Index (CDAI) is available for download for free from the PubMed website: https://pubmed.ncbi.nlm.nih.gov/12786607/ A CDAI score calculation form is included in the Services Australia application form.
Ustekinumab	**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
Omalizumab	**Urticaria Activity Score (UAS).** 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 Urticaria Activity Score (UAS) is a commonly used diary-based patient-reported outcome measure that assesses itch severity and hive count in chronic spontaneous urticaria (CSU), using once- or twice-daily diary-based documentation.	The UAS is available for download for free from the PubMed website at: https://pmc.ncbi.nlm.nih.gov/articles/PMC5978890/ It forms part of the article "Comparison of Urticaria Activity Score Over 7 Days (UAS7) Values Obtained from Once-Daily and Twice-Daily Versions: Results from the ASSURE-CSU Study – PMC" found at that web address.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (August Update) Instrument 2025

(PB 88 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 purpose of this Instrument, made under subsection 100(2) of the *National Health Act 1953* (the Act), is to amend the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* (PB 27 of 2021) (the Special Arrangement), to make changes to the Special Arrangement relating to the Highly Specialised Drugs Program.

The pharmaceutical benefits supplied under the Special Arrangement are for the treatment of chronic conditions which, because of their clinical use or other special features, may only be supplied to patients receiving specialised treatment.

Human Rights Implications

This 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 UN Committee on Economic, Social and Cultural Rights (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

This Instrument advances the right to health and the right to social security by ensuring that the amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (the Listing Instrument), that affect the pharmaceutical benefits that may be supplied under the Special Arrangement, are made concurrently. This Instrument provides for the addition of the drugs eflornithine

and foslevodopa with foscarbidopa, the addition of forms of the listed drug omalizumab, and the addition of a brand of the listed drugs omalizumab and ustekinumab. It also provides for the deletion of a form of the listed drug tenofovir with emtricitabine and the deletion of a brand of the listed drugs omalizumab and tenofovir.

The Listing Instrument 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. The 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 PBS are evidence-based.

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. 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 Listing 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 a form of a drug in the above-mentioned 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 tenofovir with emtricitabine in the form tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg (S19A) (Emtricitabine and Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets (Laurus Labs, USA)) was requested to be delisted from the PBS schedule following agreement from the sponsor. The temporary approval under section 19A of the *Therapeutic Goods Act 1989* granted by the Therapeutic Goods Administration in respect of this drug for importation and supply of a medicine not on the Australian Register of Therapeutic Goods lapsed on 31 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.

Conclusion

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

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