EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM) SPECIAL ARRANGEMENT AMENDMENT (NOVEMBER UPDATE) INSTRUMENT 2024

PB 115 of 2024

Purpose

This is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (November Update) Instrument 2024* (PB 115 of 2024) (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) is made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the Act.

Schedule 1 to this Instrument provides for the deletion of the listed drug ribavirin, the deletion of a form of the listed drug mepolizumab, and the deletion of brands of the listed drugs bosentan and entecavir. It also provides for the alteration of circumstances in which a prescription may be written for the listed drugs buprenorphine, buprenorphine with naloxone, lanreotide, methadone, onasemnogene abeparvovec, and risdiplam under the Special Arrangement.

These changes are summarised, by subject matter, in the Attachment.

Authority

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

Subsection 100(2) of the Act provides that the Minister may 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).

Background for lanreotide amendments

The circumstances in which lanreotide could be prescribed on the Highly Specialised Drugs (HSD) Program is being amended upon a recommendation by the Pharmaceutical Benefits Advisory Committee (PBAC). The amendments will enable prescriptions for patients commencing treatment with lanreotide to be accessed through the HSD Program Community Access arrangements. Enabling access to lanreotide through HSD Program Community Access arrangements means prescriptions written by authorised medical practitioners for patients receiving treatment from a public or private hospital can be dispensed from any Pharmaceutical Benefits Scheme (PBS) Approved Supplier, including community pharmacies. These amendments will enable patients to have a greater choice in where they can access their treatment, particularly for those in rural and remote areas.

Consultation

The amendments made by this Instrument accord with recommendations made by the 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 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 November 2024.

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 (NOVEMBER UPDATE) INSTRUMENT 2024*

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 (November Update) Instrument 2024* and may also be cited as PB 115 of 2024.

Section 2 Commencement

This section provides that this Instrument commences on 1 November 2024.

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

Item 1 Definition of *community access medication*

This item amends the definition of *community access medication* in section 6 of the Special Arrangement to remove the limitations which made lanreotide a community access medication only:

- where the description of its form did not include "Powder for suspension for injection"; and
- for continuing treatment.

The reference to "continuing treatment" in the definition had limited lanreotide community access to a patient's continuing treatment phase. The removal of this limitation means that lanreotide will be a community access medication available for community access supply in relation to a patient's initial and continuing treatment phases.

The removal of the reference to "Powder for suspension for injection" from the definition of *community access medication* involves the removal of redundant wording from the provision, as there are currently no forms of lanreotide that have the form "Powder for suspension for injection".

Item 2 Definition of *authorised prescriber*

This item repeals current subsection 7(4) of the Special Arrangement (definition of *authorised prescriber*) and substitutes a new subsection. The effect of this amendment is to make a medical practitioner an *authorised prescriber* for HSD pharmaceutical benefits that have the drug lanreotide, regardless of the form of the drug and regardless of whether the patient is in the initial or continuing phase of their treatment.

The reference to "continuing treatment" in the definition had limited lanreotide community access to a patient's continuing treatment phase.

The removal of the reference to "Powder for suspension for injection" from subsection 7(4) involves the removal of redundant wording from the provision, as there are currently no forms of lanreotide that have the form "Powder for suspension for injection".

The prescribing restrictions for lanreotide in Schedule 3 of the Special Arrangement (as amended by this Instrument) clarify that, for a patient's initial treatment phase, the patient will still need to be treated by either:

- a specialist practicing in a hospital who is either an endocrinologist or an oncologist or
- a medical practitioner working under the direct supervision of one of these specialists in a hospital setting.

Items 3 to 26 involve the deletion of a listed drug, the deletion of a form of a listed drug, the deletion of brands of listed drugs, 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 Deleted

Listed Drug

Ribavirin

Form Deleted

Listed Drug	***Form***
Mepolizumab	Powder for injection 100 mg

Brands Deleted

Listed Drug	***Form and Brand***
Bosentan	Tablet 62.5 mg (as monohydrate) *(BOSLEER)*
	Tablet 125 mg (as monohydrate) *(BOSLEER)*
Entecavir	Tablet 0.5 mg (as monohydrate) *(ENTECLUDE)*
	Tablet 1 mg (as monohydrate) *(ENTECLUDE)*

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug

Buprenorphine	Methadone
Buprenorphine with naloxone	Onasemnogene abeparvovec
Lanreotide	Risdiplam

Documents Incorporated by Reference

Listed Drug	*Document incorporated*	*Document access*
Onasemnogene abeparvovec Risdiplam	**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
Lanreotide	**World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status.** 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

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 (November Update) Instrument 2024

(PB 115 of 2024)

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 deletion of the listed drug

ribavirin, the deletion of a form of the listed drug mepolizumab, and the deletion of brands of the listed drugs bosentan and entecavir. This Instrument also provides for the alteration of circumstances in which a prescription may be written for a number of listed drugs, including lanreotide, under the Special Arrangement.

The amendment to the circumstances in which lanreotide could be prescribed on the Highly Specialised Drugs (HSD) Program is a result of a recommendation by the PBAC. The amendment will enable prescriptions for patients commencing treatment with lanreotide to be accessed through the HSD Program Community Access arrangements. Enabling access to lanreotide through HSD Program Community Access arrangements means prescriptions written by authorised medical practitioners for patients receiving treatment from a public or private hospital can be dispensed from any PBS Approved Supplier, including community pharmacies. This amendment will enable patients to have a greater choice in where they can access their treatment, particularly for those in rural and remote areas. This increase in choice promotes Article 12 of the ICESCR.

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. 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 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 drugs and forms of drugs in the abovementioned instruments, would not result in an unmet clinical need, except where indicated for a particular drug or form of drug below. Where the PBAC has identified an unmet clinical need, a Supply Only period has been/will be instituted as outlined below to allow opportunity for patients to transition to an alternative treatment option. The delisting of these items will not affect access to the drugs (or an alternative treatment if required), as affected patients will be able to access alternative medicines through the PBS, and the delisting is unlikely to have an effect on the amount patients pay for those drugs, as co-payment amounts are capped, ensuring their rights to social security are maintained. From 1 January 2024, these amounts are $31.60 for general patients and $7.70 for concession card holders.

If 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 deletion 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 mepolizumab in the form powder for injection 100 mg (Nucala) 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 that there are alternatives available on the PBS. The PBAC advised the delisting of this product would not result in an unmet clinical need. This item was available on the PBS Schedule under Supply Only arrangements for a period of 3 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment.

The drug ribavirin 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.

Conclusion

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

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