EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM) SPECIAL ARRANGEMENT AMENDMENT (DECEMBER UPDATE) INSTRUMENT 2022

PB 114 of 2022

Purpose

This is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (December Update) Instrument 2022* (PB 114 of 2022) (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 2012* (PB 71 of 2012), which commence on the same day. The *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) is made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the Act.

Schedule 1 to this Instrument provides for the addition of the listed drug pegcetacoplan, and a brand of the listed drugs mycophenolic acid, and valganciclovir to the Special Arrangement. It also provides for the deletion of a form of the listed drug benralizumab, and the alteration of circumstances in which a prescription may be written for the listed drugs ambrisentan, bosentan, eculizumab, epoprostenol, iloprost, infliximab, macitentan, natalizumab, ravulizumab, riociguat, sildenafil, and tadalafil 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).

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 December 2022.

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 (DECEMBER UPDATE) INSTRUMENT 2022*

Section 1 Name of Instrument

This section provides the name of this Instrument as the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (December Update) Instrument 2022* and may also be cited as PB 114 of 2022.

Section 2 Commencement

This section provides that this Instrument commences on 1 December 2022.

Section 3 Authority

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

Section 4 Schedules

Section 4 provides that each instrument that is specified in a Schedule to the Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Instrument has effect according to its terms.

Schedule 1 Amendments

The amendments in Schedule 1 involve the addition of a listed drug, the deletion of a form of a listed drug, the addition of a brand of listed drugs and the alteration of circumstances in which a prescription may be written for a listed drug available under the Special Arrangement. These changes are summarised below.

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

Listed drug added

Listed Drug
Pegcetacoplan

Form Deleted

Listed Drug	***Form***
Benralizumab	Injection 30 mg in 1 mL single dose pre-filled syringe

Brands Added

Listed Drug	***Form and Brand***
Mycophenolic acid	Tablet containing mycophenolate mofetil 500 mg (*Noumed Mycophenolate*)
Valganciclovir	Tablet 450 mg (as hydrochloride) (*Valganciclovir Viatris*)

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug	***Listed Drug***
Ambrisentan	Macitentan

Bosentan	Natalizumab
Eculizumab	Ravulizumab
Epoprostenol	Riociguat
Iloprost	Sildenafil
Infliximab	Tadalafil

Documents Incorporated by Reference

Listed Drug	*Document incorporated*	*Document access*
Ambrisentan Bosentan Burosumab Eculizumab Epoprostenol Iloprost Infliximab Macitentan Pegcetacoplan Ravulizumab Riociguat Sildenafil Tadalafil	**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.	Product Information is available for download for free from the TGA website: https://www.tga.gov.au/product-information-0
Infliximab	**Bath Ankylosing Spondylitis Disease Activity Index (BASDAI).** 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 BASDAI is a widely used tool that enables measurement and evaluation of the level of disease activity in Ankylosing Spondylitis.	The BASDAI is available for download for free from the Services Australia website www.servicesaustralia.gov.au
Infliximab	**Crohn 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.	Crohn 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
Eculizumab Ravulizumab	**New York Heart Association (NYHA) classification**. 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 NYHA classification system is used to	The NYHA classification system is available for download for free from the Heart Foundation website (contained within the heart failure clinical guidelines): https://www.heartfoundation.org.au/Conditions/Heart-failure-

	define the degree of heart failure.	clinical-guidelines
Infliximab	**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/
Infliximab	**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.
Ambrisentan Bosentan Epoprostenol Iloprost Macitentan Riociguat Sildenafil Tadalafil	**WHO Functional Classes for pulmonary arterial hypertension (PAH)**. 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 Functional Class system for PAH is used to define the severity of PAH symptoms and the impact they have on a patient's day-to-day activities.	The WHO Functional Class system for PAH is available for download for free from the Pulmonary Hypertension Association Australia website: https://www.phaaustralia.com/page/11/classification-of-pulmonary-hypertension

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***
Ambrisentan Bosentan Epoprostenol Iloprost Macitentan Riociguat Sildenafil Tadalafil	**Right heart catherization (RHC) composite assessment**	RHC is a diagnostic procedure used to measure pulmonary artery pressures and thus evaluate whether a patient has pulmonary hypertension or not, and sometimes what is causing the pulmonary hypertension. RHC composite assessment is a range of haemodynamic assessment comprising the measurement of cardiac output, mixed venous oxygen saturation, mean pulmonary arterial pressure, pulmonary artery wedge pressure, right atrial pressure and right	The RHC composite assessment is part of the standard diagnostic work-up for Pulmonary Arterial Hypertension and does not constitute a written record of information that must be referred to in order to determine whether statutory conditions have been met.

		ventricular pressure. Measurement must be reported on as part of the authority application for a number of PBS listed drugs.	
Ambrisentan Bosentan Epoprostenol Iloprost Macitentan Riociguat Sildenafil Tadalafil	**Echocardiography (ECHO) composite assessment**	ECHO is an ultrasound of the heart used to estimate the pulmonary artery pressures using mathematical equations and thus evaluate whether a patient has pulmonary hypertension. ECHO composite assessment is a range of haemodynamic assessment comprising the measurement of pulmonary artery systolic pressure, right ventricular systolic pressure, right atrial pressure. Measurement must be reported on as part of the authority application for a number of PBS listed drugs.	The ECHO composite assessment is part of the standard diagnostic work-up for Pulmonary Arterial Hypertension and does not constitute a written record of information that must be referred to in order to determine whether statutory conditions have been met.
Ambrisentan Bosentan Epoprostenol Iloprost Macitentan Riociguat Sildenafil Tadalafil	**Six Minute Walk Test (6MWT)**	To measure patient motor functioning (physical movement abilities) in any assessment of whether the drug is providing the patient with a clinically meaningful response to treatment.	The PBS restriction requires use of standardised measures of patient motor function in assessing whether their treatment has resulted in a clinically meaningful response, but only where it is practical to do so. Such measures are not limited to this particular instrument. Therefore the reference does not serve to incorporate a document.

Statement of Compatibility with Human Rights

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

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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 2012* (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 listed drug pegcetacoplan, the addition of a brand of the listed drugs mycophenolic acid, and valganciclovir, and the deletion of a form of the listed drug benralizumab.

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.

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 benralizumab in the form injection 30 mg in 1 mL single dose pre-filled syringe (Fasenra®) was requested to be delisted from the PBS by the sponsor. The PBAC noted benralizumab in the form injection 30 mg in 1 mL single dose pre-filled pen (Fasenra Pen®) was a suitable alternative to Fasenra and considered that the delisting of Fasenra would not result in an unmet clinical need. Fasenra Pen remains listed on the PBS.

Conclusion

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

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