EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2020 (No. 7)

PB 82 of 2020

Authority

Subsection 100(1) of the *National Health Act 1953* (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).

Purpose

This is the *National Health (Highly specialised drugs program) Special Arrangement Amendment Instrument 2020 (No.7)* (this Instrument). The purpose of this Instrument, made under subsection 100(2) of the Act, is to amend the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010) (the Special Arrangement), to make changes to the Special Arrangement relating to the Highly Specialised Drugs 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 deletion of a brand of an existing pharmaceutical item, the alteration of responsible person codes for three existing brands of pharmaceutical benefits, the alteration of the name of two brands of existing pharmaceutical benefits, and the alteration of one responsible person name. It also provides for the alteration of circumstances for prescribing various pharmaceutical benefits available under the Special Arrangement, in order to correct minor historical typographical/transcription errors identified upon review. These changes are summarised, by subject matter, in the Attachment.

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 had already taken place in the decision to list the medication.

Details of this Instrument are set out in the Attachment.

This Instrument commences on 1 September 2020.

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

ATTACHMENT

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2020 (No. 7)*

Section 1 Name of Instrument

This section provides the name of this Instrument as the *National Health (Highly specialised drugs program) Special Arrangement Amendment Instrument 2020 (No. 7)* and may also be cited as PB 82 of 2020.

Section 2 Commencement

This section provides that this Instrument commences on 1 September 2020.

Section 3 Amendment of *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010)

This section provides that Schedule 1 amends the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010).

Schedule 1 Amendments

The amendments in Schedule 1 involve the deletion of a brand, the alteration of responsible person codes for brands of pharmaceutical benefits, the alteration of brand names of pharmaceutical benefits, and the alteration of a responsible person name. They also include the alteration of circumstances for prescribing various pharmaceutical benefits available under the Special Arrangement, in order correct minor historical typographical/transcription errors identified under review. These changes are summarised below.

SUMMARY OF CHANGES TO THE *NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM) SPECIAL ARRANGEMENT 2010* MADE BY THIS INSTRUMENT

Brands Deleted

Listed Drug	*Form and Brand*
Adefovir	Tablet containing adefovir dipivoxil 10 mg (*Hepsera*)

Alteration of Responsible Person

Listed Drug	*Form*	*Brand Name*	*Responsible Person Code*
Deferiprone	Tablet 500 mg	*Ferriprox*	***From:*** TX ***To:*** EU
	Tablet 1000 mg	*Ferriprox*	***From:*** TX ***To:*** EU
	Oral solution 100 mg per mL, 250 mL	*Ferriprox*	***From:*** TX ***To:*** EU

Alteration of Brand Name

Listed Drug	*Form*	*Brand Name*
Desferrioxamine	Powder for injection containing desferrioxamine mesilate 500 mg	***From:*** Hospira Pty Limited ***To:*** DBL Desferrioxamine Mesilate
	Powder for injection containing desferrioxamine mesilate 2 g	***From:*** Hospira Pty Limited ***To:*** DBL Desferrioxamine Mesilate

Alteration of Responsible Person

Responsible Person Code	*Responsible Person (Name)*
EU	***From:*** Emerge Health Pty Ltd ***To:*** Chiesi Australia Pty Ltd

Alteration of Circumstances in Which a Prescription May be Written*

**The amendments made by this instrument correct minor historical typographical/transcription errors only.*

Listed Drug	*Listed Drug*
Abacavir	Abacavir with Lamivudine
Abacavir with Lamivudine and Zidovudine	Adefovir
Atazanavir	Clozapine
Dolutegravir	Dornase alfa
Eculizumab	Efavirenz
Everolimus	Fosamprenavir
Interferon alfa-2a	Lamivudine
Lamivudine with zidovudine	Lanthanum
Lenalidomide	Lopinavir with ritonavir
Mycophenolic Acid	Nevirapine
Octreotide	Peginterferon alfa-2a
Raltegravir	Rilpivirine
Riociguat	Ritonavir
Saquinavir	Sevelamer
Sirolimus	Sucroferric oxyhydroxide
Tenofovir with emtricitabine and efavirenz	Zidovudine

Document/s incorporated by reference

Listed Drug	*Document incorporated*	*Document access*
Lenalidomide	International Prognostic Scoring System (IPSS). 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 IPSS is a medical diagnostic tool used to help assess the severity of myelodysplastic syndrome, through the evaluation of the proportion of blast cells in a patient's bonemarrow, the type of chromosomal changes (if any) in the marrow cells, and the presence of one or more low blood cell counts (cytopenias).	The International Prognostic Scoring System (IPSS) is available for download for free from the Blood Journal website: https://ashpublications.org/blood *Blood* (1997) 89 (6): 2079–2088.
Riociguat	Therapeutic Goods Administration (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
Riociguat	WHO Functional Classes for chronic thromboembolic pulmonary hypertension	The WHO Functional Class system for CTEPH is available for download

	(CTEPH). 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 CTEPH is used to define the severity of CTEPH symptoms and the impact they have on a patient's day-to-day activities.	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***
Riociguat	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 ventricular pressure. Measurement must be reported on as part of the authority application for a number of PBS listed drugs.	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.
Riociguat	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.
Riociguat	Six Minute Walk Test (6MWT)	The 6MWT is an assessment of performance ability in a variety of cardiopulmonary disease. It provides important functional information that is not captured in standardized pulmonary function testing. Measurement must be reported on as part of the authority application for a number of PBS listed drugs.	The 6MWT is a process for obtaining physiological measurements and does not constitute a written record of information that must be referred to in order to determine whether statutory conditions have been met. The 6MWT is part of the standard diagnostic work-up for Pulmonary Arterial Hypertension.

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 Instrument 2020 (No. 7)

(PB 82 of 2020)

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 2010* (PB 116 of 2010) (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.

The amendments in Schedule 1 involve the deletion of a brand, the alteration of responsible person codes for brands of pharmaceutical benefits, the alteration of brand names of pharmaceutical benefits, and the alteration of a responsible person name. They also include the alteration of circumstances for prescribing various pharmaceutical benefits available under the Special Arrangement, in order correct minor historical typographical/transcription errors.

Human Rights Implications

This Instrument engages Article 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The Pharmaceutical Benefits Scheme (PBS) is a benefit scheme which assists with advancement of this human right 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.

Conclusion

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

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