

EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM) SPECIAL ARRANGEMENT AMENDMENT (DECEMBER UPDATE) INSTRUMENT 2021

PB 121 of 2021

Purpose

This is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (December Update) Instrument 2021* (PB 121 of 2021) (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 2021* (PB 27 of 2021) (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 addition of a form of the listed drug ribavirin, and the addition of six brands of pharmaceutical items to the Special Arrangement. It also provides for the deletion of four brands of pharmaceutical items, and the alteration of circumstances in which a prescription may be written for the supply of the listed drugs ambrisentan, azacitidine, bosentan, epoprostenol, etanercept, macitentan, sildenafil, tadalafil, and tocilizumab under the Special Arrangement. These changes are summarised, by subject matter, in the Attachment.

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).

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 December 2021.

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

PROVISION-BY-PROVISION DESCRIPTION OF NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM) SPECIAL ARRANGEMENT AMENDMENT (DECEMBER UPDATE) INSTRUMENT 2021

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 2021* and may also be cited as PB 121 of 2021.

Section 2 Commencement

This section provides that this Instrument commences on 1 December 2021.

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 form of a listed drug, the addition and deletion of brands, and the alteration of circumstances for prescribing 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

Form Added

<i>Listed Drug</i>	<i>Form</i>
Ribavirin	Tablet 200 mg

Brands Added

<i>Listed Drug</i>	<i>Form and Brand</i>
Ciclosporin	Capsule 25 mg (<i>APO-Ciclosporin</i>)
	Capsule 50 mg (<i>APO-Ciclosporin</i>)
	Capsule 100 mg (<i>APO-Ciclosporin</i>)
Deferasirox	Tablet 90 mg (<i>DEFERASIROX-TEVA</i>)
	Tablet 180 mg (<i>DEFERASIROX-TEVA</i>)
	Tablet 360 mg (<i>DEFERASIROX-TEVA</i>)

Brands Deleted

<i>Listed Drug</i>	<i>Form and Brand</i>
Entecavir	Tablet 0.5 mg (as monohydrate) (<i>Entecavir Amneal</i>) Tablet 1 mg (as monohydrate) (<i>Entecavir Amneal</i>)
Mycophenolic Acid	Tablet containing mycophenolate mofetil 500 mg (<i>Mycophenolate AN</i>)
Nevirapine	Tablet 400 mg (extended release) (<i>Nevirapine XR APOTEX</i>)

Alteration of Circumstances in Which a Prescription May be Written

<i>Listed Drug</i>	<i>Listed Drug</i>
Ambrisentan	Macitentan
Azacitidine	Sildenafil
Bosentan	Tadalafil
Epoprostenol	Tocilizumab
Etanercept	

Documents incorporated by reference

<i>Listed Drug</i>	<i>Document incorporated</i>	<i>Document access</i>
Azacitidine	Product Information. The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the <i>Legislation Act 2003</i> . 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
Ambrisentan Bosentan Epoprostenol Macitentan Sildenafil Tadalafil	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 <i>Legislation Act 2003</i> . 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
Ambrisentan Bosentan Epoprostenol Macitentan 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 <i>Legislation Act 2003</i> . 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.

<i>Listed Drug</i>	<i>Diagnostic tool</i>	<i>Purpose and use in the Instrument</i>	<i>Reason this reference does not serve to incorporate a document</i>
Ambrisentan Bosentan Macitentan Sildenafil Tadalafil	Right heart catheterisation (RHC) composite assessment	<p>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.</p> <p>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.</p> <p>Measurement must be reported on as part of the authority application for a number of PBS listed drugs.</p>	<p>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.</p>
Ambrisentan Bosentan Macitentan Sildenafil Tadalafil	Echocardiography (ECHO) composite assessment	<p>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.</p> <p>ECHO composite assessment is a range of haemodynamic assessment comprising the measurement of pulmonary artery systolic pressure, right ventricular systolic pressure, right atrial pressure.</p> <p>Measurement must be reported on as part of the authority application for a number of PBS listed drugs.</p>	<p>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.</p>
Ambrisentan Bosentan Macitentan Sildenafil Tadalafil	Six Minute Walk Test (6MWT)	<p>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.</p> <p>Measurement must be reported on as part of the authority application for a number of PBS listed drugs.</p>	<p>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.</p>

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 (December Update) Instrument 2021

(PB 121 of 2021)

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

The right to social security is contained in Article 9 of the International Covenant on Economic Social and Cultural Rights (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 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. The pharmaceutical industry now has a nominee on the PBAC membership.

Whether there is any detriment to patients by the delisting of these drugs, and if so, how this is compatible with the right to social security

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.

Sponsors are private entities that make their own decisions regarding their products and cannot be compelled by the Government to continue to list a product on the PBS. 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. However, if the final brand of a form of a drug is delisted, this delisting will be considered by PBAC. This includes additional processes to ensure that where a delisting will result in there being only one brand of that form remaining listed on the PBS, that patients will not be negatively affected by having to pay brand premiums. 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.

Patients accessing PBS subsidised medicines are usually required to pay a co-payment towards their cost. From 1 January 2021, these fees are up to \$41.30 for general patients and up to \$6.60 for concession card

holders. These co-payments are payable for accessing all PBS subsidised medicines. The delisting of the drugs specified below is therefore unlikely to result in a negative financial impact for patients. This is due to the same maximum co-payments applying to all PBS listed medicines.

Conclusion

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

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