

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 2) Determination 2021

PB 108 of 2021

Authority

Subsection 89A(3) of the *National Health Act 1953* (the Act) provides that the Minister may, by legislative instrument, determine the pharmaceutical benefits that may be supplied by an approved pharmacist without a prescription, and the conditions that must be satisfied when making a supply of those pharmaceutical benefits.

Purpose

The purpose of the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 2) Determination 2021* (Amendment Determination) is to amend the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2021* (the Determination) to specify new pharmaceutical benefits that may be supplied under the Pharmaceutical Benefits Scheme without a prescription, subject to the conditions specified in the Determination.

The Determination permits an approved pharmacist to supply a substitute pharmaceutical benefit when the pharmaceutical benefit prescribed for the patient is the subject of a Therapeutic Goods Administration (TGA) Serious Scarcity Substitution Instrument (SSSI).

The pharmaceutical benefits relating to the Monodur 120 mg and Imdur 120 mg brands of the drug isosorbide mononitrate (tablet 120 mg (sustained release)) are currently subject to an SSSI (see the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Isosorbide Mononitrate) Instrument 2021*). The Amendment Determination specifies brands of isosorbide mononitrate tablet 60 mg (sustained release), including APO-Isosorbide Mononitrate, Duride, GenRx Isosorbide Mononitrate, ISOBIDE MR, Isomonit, Isosorbide AN, Imdur Durule and Monodur 60 mg, that can be supplied without a prescription in substitution for Monodur 120 mg and Imdur 120 mg.

As a result, the Determination permits the supply by an approved pharmacist of a specified brand of isosorbide mononitrate tablet 60 mg (sustained release), where it may be dispensed in accordance with section 30EL of the *Therapeutic Goods Act 1989* and it is supplied:

- to a person with a PBS prescription for either Monodur 120 mg or Imdur 120 mg (isosorbide mononitrate tablet 120 mg (sustained release));
- where it is not practicable to obtain a PBS prescription from a PBS prescriber for isosorbide mononitrate tablet 60 mg (sustained release) before the person needs the supply of the Monodur 120 mg or Imdur 120 mg (isosorbide mononitrate tablet 120 mg (sustained release));
- where the pharmacist has provided cost information to the patient or their agent so that they are able to make an informed decision before proceeding with the supply of isosorbide mononitrate tablet 60 mg (sustained release). This includes the cost to the

patient if the substitution is subsidised through the PBS and the cost to the patient if the substitution is a private prescription; and

- isosorbide mononitrate tablet 60 mg (sustained release) is eligible for dispensing as a pharmaceutical benefit as outlined in this instrument.

In order for isosorbide mononitrate tablet 60 mg (sustained release) to be dispensed in accordance with section 30EL of the *Therapeutic Goods Act 1989*, among other things the pharmacist must:

- Ensure that the amount of isosorbide mononitrate tablet 60 mg (sustained release) dispensed would result in the patient receiving sufficient medicine to ensure an equivalent dosage regimen and duration to their prescription for Monodur 120 mg or Imdur 120 mg (isosorbide mononitrate tablet 120 mg (sustained release)); and
- Advise the patient or their agent of the number of dose units of isosorbide mononitrate tablet 60 mg (sustained release) that must be taken by the patient in substitution for the prescribed dose of Monodur 120 mg or Imdur 120 mg (isosorbide mononitrate tablet 120 mg (sustained release)) (as appropriate).

The Amendment Determination commences on 18 September 2021.

The Amendment Determination is a legislative instrument for the purposes of the *Legislation Act 2003*.

A provision-by-provision description of the Amendment Determination is contained in the Attachment.

Consultation

The Amendment Determination reflects the intention of previous consultation.

Details of the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 2) Determination 2021*

Section 1 Name

This section provides that the name of the Amendment Determination is the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 2) Determination 2021*.

This section also provides that the instrument may be cited as PB 108 of 2021.

Section 2 Commencement

This section provides that the Amendment Determination commences on 18 September 2021.

Section 3 Authority

This section provides that the Amendment Determination is made under subsection 89A(3) of the *National Health Act 1953*.

Section 4 Schedules

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

Schedule 1 - Amendments

National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2021

Item 1 – Subsection 5(8) (at the end of the table)

This item adds one new item to the table at subsection 5(8) of the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2021*:

	Column 2 Pharmaceutical benefit in shortage	Column 3 Approved substitute benefit
5	Listed drug: Isosorbide mononitrate Form: Tablet 120 mg (sustained release) Manner of administration: Oral Brand: either of the following: (a) Imdur 120 mg (b) Monodur 120 mg	Listed drug: Isosorbide mononitrate Form: Tablet 60 mg (sustained release) Manner of administration: Oral Brand: any of the following: (a) APO-Isosorbide Mononitrate; (b) Duride; (c) GenRx Isosorbide Mononitrate; (d) Imdur Durule; (e) ISOBIDE MR; (f) Isomonit; (g) Isosorbide AN; (h) Monodur 60 mg

Column 3 of this table sets out, for the purposes of subsection 89A(3) of the *National Health Act 1953*, the pharmaceutical benefits that may be supplied without a prescription where the conditions in the Determination are met.

Statement of Compatibility with Human Rights

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

National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 2) Determination 2021

This Disallowable legislative 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 Disallowable Legislative Instrument

The purpose of the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 2) Determination 2021* (Amendment Determination) is to amend the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2021* (the Determination) to specify new pharmaceutical benefits that may be supplied under the Pharmaceutical Benefits Scheme without a prescription, subject to the conditions specified in the Determination.

The Determination permits an approved pharmacist to supply a substitute pharmaceutical benefit when the pharmaceutical benefit prescribed for the patient is the subject of a Therapeutic Goods Administration (TGA) Serious Scarcity Substitution Instrument (SSSI).

The pharmaceutical benefits relating to the Imdur 120 mg and Monodur 120 mg brands of the drug isosorbide mononitrate tablet 120 mg (sustained release) are currently subject to an SSSI (see the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Isosorbide Mononitrate) Instrument 2021*).

The Amendment Determination specifies alternative brands of isosorbide mononitrate tablet 60 mg (sustained release) that can be supplied without a prescription in substitution for Imdur 120 mg or Monodur 120 mg (isosorbide mononitrate tablet 120 mg (sustained release)) where the conditions in the Determination are met.

These include that the supply by an approved pharmacist of isosorbide mononitrate tablet 60 mg (sustained release) is in accordance with section 30EL of the *Therapeutic Goods Act 1989* and it is supplied:

- to a person with a PBS prescription for Imdur 120 mg or Monodur 120 mg (isosorbide mononitrate tablet 120 mg (sustained release));
- where it is not practicable to obtain a PBS prescription from a PBS prescriber for isosorbide mononitrate tablet 60 mg (sustained release) before the person needs the supply of Imdur 120 mg or Monodur 120 mg (isosorbide mononitrate tablet 120 mg (sustained release));
- where the pharmacist has provided cost information to the patient or their agent so that they are able to make an informed decision before proceeding with the supply of isosorbide mononitrate tablet 60 mg (sustained release). This includes the cost to the patient if the substitution is subsidised through the PBS and the cost to the patient if the substitution is a private prescription; and

- isosorbide mononitrate tablet 60 mg (sustained release) is eligible for dispensing as a pharmaceutical benefit as outlined in this instrument.

Human rights implications

The Amendment Determination engages Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). The Amendment Determination assists in 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 providing subsidised access for people to medicines. This is a positive and supportive step towards attaining the highest standard of health for all Australians. Efficient operational arrangements for the PBS support effective administration of the scheme. The Amendment Determination assists in 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 by ensuring that patients have continued access to medicines.

Conclusion

The Amendment Determination is compatible with human rights, as it promotes the protection of human rights.

Nikolai Tsyganov
Acting Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division
Department of Health