EXPLANATORY STATEMENT

National Health Act 1953

National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 2) Determination 2026

PB 112 of 2026

Purpose

The purpose of the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 2) Determination 2026* (Amendment Determination) is to amend the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2021* (Principal Determination) to specify new pharmaceutical benefits that may be supplied under the Pharmaceutical Benefits Scheme (PBS) without a prescription, subject to the conditions specified in the Principal Determination.

The Principal 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).

Pharmaceutical benefits containing diltiazem hydrochloride 360 mg, in the manner of oral administration and marketed under the brands Cardizem CD and Vasocardol CD, are affected by the discontinuation of the two marketed 360 mg controlled-release capsule products in Australia by their sponsors. Cardizem CD was deleted from the market on 3 June 2026 and was subsequently delisted from the PBS on 1 September 2026. Vasocardol CD is scheduled for deletion from the market on 1 November 2026, with reduced supply expected until existing stock is exhausted.

In response, the TGA intends to make the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Diltiazem) Instrument 2026*. The SSSI will declare Cardizem CD diltiazem hydrochloride 360 mg capsule bottle and Vasocardol CD diltiazem hydrochloride 360 mg capsule bottle to be scarce medicines. It will allow pharmacists to supply the specified diltiazem hydrochloride 180 mg controlled-release capsules at an equivalent dose, in accordance with the substitution protocol and provided the conditions specified in the SSSI are met.

The purpose of the Amendment Determination is to allow PBS subsidisation of the substitution arrangements that will be specified in the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Diltiazem) Instrument 2026*. For PBS purposes, the Amendment Determination will only declare Vasocardol CD diltiazem hydrochloride 360 mg capsule bottle to be a scarce medicine. Cardizem CD 360 mg will not be included in the Amendment Determination because it was delisted from the PBS on 1 September 2026.

The Amendment Determination will specify that a different strength of diltiazem capsules, at an equivalent dose, can be supplied without a new prescription, in accordance with the substitution protocol and conditions set out in the TGA SSSI. This will minimise the burden on healthcare professionals and assist Australians to maintain timely access to their prescribed medicines.

The Amendment Determination permits an approved pharmacist to supply a specified substitute pharmaceutical benefit containing the drug diltiazem hydrochloride, in the manner

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of oral administration, where the substitute benefit may be supplied in accordance with section 30EL of the *Therapeutic Goods Act 1989* and the following conditions are met:

- the patient, or person acting on behalf of the patient, has evidence of a valid prescription for the scarce medicine, unless otherwise permitted by law;
- the pharmacist does not have access to the scarce medicine;
- the prescriber has not indicated on the prescription for the scarce medicine that substitution is not permitted;
- the pharmacist has exercised professional judgement and determined that the patient is suitable to receive the substitutable medicine;
- the amount of substitutable medicine dispensed would result in the patient receiving sufficient medicine to ensure an equivalent dosage regimen and duration to that prescribed in relation to the scarce medicine;
- the patient, or person acting on behalf of the patient, has consented to receiving the substitutable medicine;
- the pharmacist makes a record of dispensing the substitutable medicine in substitution of the scarce medicine at the time of dispensing; and
- the pharmacist has an established procedure to notify the prescriber of the substitution at the time of, or as soon as practicable after, dispensing the substitutable medicine.

In order for the specified substitute pharmaceutical benefits to be dispensed in accordance with section 30EL of the *Therapeutic Goods Act 1989*, the following specific circumstances of substitution are:

The pharmacist has advised the patient, or person acting on behalf of the patient, of

(a) the differences between the scarce medicine and substitutable medicine.
(b) the number of dose units of substitutable medicine that must be taken by the patient in substitution for the prescribed dose of scarce medicine
(c) suitable instructions in relation to the administration of the substitutable medicine.

The Amendment Determination commences on 1 October 2026.

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.

In relation to the Amendment Determination, consultation was undertaken with the Chair and relevant expert members of the Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert advisory body that recommends medicines for listing on the PBS. Consultation with PBAC experts focused on specific advice about the appropriateness of PBS subsidisation for the Amendment Determination. The PBAC experts endorsed the proposed approach, noting that the substitution arrangement was necessary to support timely access to diltiazem for affected patients, given the limited alternative options available following the discontinuation of the 360 mg products.

It is noted the Therapeutic Goods Administration conducted consultation on the appropriateness of the substitutions and consultation on this Amendment Determination was

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limited to the appropriateness of a PBS subsidy for the substitute medicines. No further consultation was deemed necessary, as consultation with the PBAC Chair drew on the knowledge of relevant experts.

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ATTACHMENT

Details of the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 2) Determination 2026*

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 2026*

This section also provides that the Amendment Determination may be cited as PB 112 of 2026

Section 2 Commencement

This section provides that the Amendment Determination commences on 1 October 2026.

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.

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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 2026

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 2026* (Amendment Determination) is to amend the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2021* (Principal Determination) to specify new pharmaceutical benefits that may be supplied under the Pharmaceutical Benefits Scheme (PBS) without a prescription, subject to the conditions specified in the Principal 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 benefit containing diltiazem hydrochloride 360 mg, in the manner of oral administration and marketed under the brand Vasocardol CD will be subject to the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Diltiazem) Instrument 2026*. While the TGA SSSI will also declare Cardizem CD diltiazem hydrochloride 360 mg capsule bottle to be a scarce medicine, Cardizem CD was delisted from the PBS on 1 September 2026 and will therefore not be included in the Amendment Determination.

The Amendment Determination specifies that a different strength of diltiazem hydrochloride capsules at an equivalent dose can be effectively substituted at the pharmacy level without the need to obtain a new prescription from the prescriber at PBS subsidised prices for the duration of the TGA approval, where conditions in the Principal Determination are met and the supply is in accordance with section 30EL of the *Therapeutic Goods Act 1989.*

This means that eligible patients accessing a substitute pharmaceutical benefit containing diltiazem hydrochloride under these arrangements will be paying PBS co-payment rates for the supply and will not be out of pocket. This minimises the burden of the shortage on health care professionals by reducing the need for interdisciplinary consultations and assists Australians with timely and equitable access to diltiazem during the period in which the SSSI is in force. It further bolsters the intended public health outcome of the serious shortage intervention by ensuring the substitution remains an affordable and practical alternative for patients.

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.

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The PBS is a benefit scheme providing Australians with subsidised access 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. By ensuring that patients have continued access to their medicines while their supply is disrupted, the Amendment Determination assists in the progressive realisation by all appropriate means, of the universal right to the enjoyment of the highest attainable standard of physical and mental health.

Conclusion

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

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