# EXPLANATORY STATEMENT

*Therapeutic Goods Act 1989*

*Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Diltiazem) Instrument 2026*

The *Therapeutic Goods Act 1989* (the Act) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy or performance, and timely availability of therapeutic goods that are used in, or exported from, Australia. The Act also provides for a scheme allowing pharmacists to substitute certain medicine for other medicine if the Minister has declared there is a serious scarcity of the other medicine. The Act is administered by the Therapeutic Goods Administration (the TGA) within the Australian Government Department of Health, Disability and Ageing.

Subsection 30EK(1) of the Act provides that the Minister may, by legislative instrument, declare that there is a serious scarcity of a specified medicine (the scarce medicine) across the whole or a specified part or parts of Australia, and specify the medicine (the substitutable medicine) that pharmacists are permitted to dispense in substitution for the scarce medicine and the circumstances in which that substitution is permitted.

Subsection 30EK(2) of the Act provides that the Minister may only make an instrument under subsection 30EK(1) if satisfied that the supply of the scarce medicine in Australia is not currently meeting the demand for that medicine for all of the patients in Australia who take that medicine, or that there is an imminent risk that supply of the scarce medicine in Australia will not, or will not be likely to, meet the demand for that medicine for all of the patients in Australia who take, or who may need to take, that medicine. In either case, the Minister must also be satisfied there is a significant risk of adverse health consequences for patients in Australia if they are not able to take the scarce medicine.

Subsection 30EK(3) of the Act provides that both the scarce medicine and the substitutable medicine must contain one or more substances included in Schedule 4 to the current Poisons Standard (i.e. prescription medicines) and must not contain any substances included in Schedule 8 to the current Poisons Standard (i.e. substances for which particular levels of control are required or recommended in order to avoid abuse, misuse or dependence).

The *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Diltiazem) Instrument 2026* (the Instrument) is a legislative instrument made under section 30EK(1) of the Act. It declares that there is a serious scarcity across Australia of the specified scarce medicines containing 360 mg diltiazem, specifies the substitutable medicines that pharmacists are permitted to dispense in substitution for the scarce medicines, and specifies the circumstances in which they may do so.

The Instrument declares two registered medicines to be scarce medicines, being:

- Cardizem CD diltiazem hydrochloride 360 mg capsule bottle, registration number 75251 (this number relates to the entry of the medicine in the Australian Register of Therapeutic Goods (the Register)); and
- Vasocardol CD diltiazem hydrochloride 360 mg capsule bottle, registration number 75253.

The Instrument identifies two substitutable medicines, being:

- Cardizem CD diltiazem hydrochloride 180 mg capsule blister pack, registration number 46818; and
- Vasocardol CD diltiazem hydrochloride 180 mg capsule bottle, registration number 68922.



Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01305

Under the Instrument, either substitutable medicine may be substituted by a pharmacist for either of the scarce medicines.

**Background**

Medicine shortages occur for a number of reasons, ranging from shortages of raw materials to national disasters, logistical difficulties, manufacturing issues, or unexpected increases in demand.

When a medicine is unavailable, community pharmacists have limited scope to substitute another medicine without the prior approval of the prescribing doctor. A pharmacist may substitute a different brand of an equivalent dosage form and strength product, which may include an equivalent overseas-registered medicine approved for supply under section 19A of the Act. However, where there is no such equivalent available, the pharmacist cannot substitute a different medicine. If the pharmacist is unable to contact the prescriber to authorise a change to the prescription, the patient may be unable to obtain their medicine. This impedes timely availability of medicines and risks interruption to treatment, which can impact patient health and cause anxiety and stress for patients.

In 2020, an informal arrangement was implemented between the Commonwealth and the States and Territories to allow pharmacist substitution of medicines that are in shortage, with patient consent. However, this informal arrangement was implemented through State and Territory legislation, and some State and Territory legislation allows for such provision to be made for pharmacist substitution only during a public health emergency. A need therefore arose for a more consistent and responsive pharmacist substitution scheme to help alleviate the effects of medicine shortages; one that allows substitution arrangements to be in place consistently across all States and Territories more quickly, and which reflects that medicine shortages may occur in a range of circumstances, not only where there is a public health emergency.

The *Therapeutic Goods Amendment (2020 Measures No. 2) Act 2021* (the Amendment Act) amended the Act to introduce a pharmacist substitution scheme in Division 2C of Part 3-2 of the Act. This scheme was developed to help alleviate the effects of medicine shortages, by allowing substitution arrangements to be put in place quickly and consistently across Australia, and without being limited to circumstances where there is a public health emergency.

Under this scheme, section 30EK of the Act provides for the making of a legislative instrument declaring a serious scarcity of specified medicines and specifying the substitutable medicine and the circumstances in which substitution is permitted. Such an instrument operates in tandem with section 30EL of the Act, which provides that, where an instrument is in force under subsection 30EK(1) and a pharmacist is authorised to dispense the scarce medicine under a law of a State or Territory, a pharmacist may dispense the substitutable medicine to that person in the circumstances specified in the instrument, despite any law of a State or Territory prohibiting substitution.

**Purpose**

There is currently a national shortage of the scarce medicines, which are the only diltiazem 360 mg capsules available in Australia. The shortage is due to discontinuation of the medicines arising from manufacturing issues.

Medicines containing all strengths of diltiazem are indicated for use in patients for the treatment of hypertension and management of chronic stable angina where there is no evidence of vasospastic or unstable angina. Only the medicines containing 360 mg of diltiazem is in shortage.

The current shortage of the scarce medicines is having, and is anticipated to continue to have, a significant impact on the patients who take or need to take diltiazem 360 mg. If affected patients cannot access their usual dose, there is a risk they may use inappropriate alternatives or stop treatment entirely. Abrupt discontinuation of, or sudden interruption to, treatment may cause significant health



Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01305

concerns for affected patients, including worsening hypertension, severe chest pain, heart attack and stroke. This could potentially lead to patients seeking urgent medical care, increased hospital admissions and increased burden on the health system.

The specified substitutable medicines are medicines that are registered on the Register:

- Cardizem CD diltiazem hydrochloride 180 mg capsule blister pack, registration number 46818; and
- Vasocardol CD diltiazem hydrochloride 180 mg capsule bottle, registration number 68922.

The specified substitutable medicines contain the same active ingredient (diltiazem) and are in the same dosage form (capsules) as the scarce medicine. However, the substitutable medicines vary in strength, as they contain a lower dose of the active ingredient (i.e. 180 mg) as compared to the scarce medicine (i.e. 360 mg).

The making of the Instrument enables pharmacists to substitute the specified substitutable medicine for the relevant scarce medicine, without the patient affected by the unavailability of the scarce medicine needing to return to their prescriber for a new prescription. This means that patients who are prescribed the scarce medicine can access suitable treatment without delay, reducing the risk of interrupted treatment. This substitution is proposed to minimise the burden on health professionals and assist with timely access to medicine supply for patients.

The Instrument specifies a number of specific and general permitted circumstances that have the effect of confining the circumstances in which a pharmacist may substitute the substitutable medicine for the scarce medicine prescribed to a patient. These circumstances are designed to ensure that there are carefully determined safety-related parameters in place for patients in relation to the permitted substitution.

Certain *specific* permitted circumstances are specified, including that the pharmacist must have advised the patient, or person acting on behalf of the patient, of:

- the differences between the scarce medicine and the substitutable medicine;
- the number of dose units of substitutable medicine that must be taken by the patient in substitution for the prescribed dose of scarce medicine, based on the specified dose unit equivalence; and
- suitable instructions in relation to the administration of the substitutable medicine.

The *general* permitted circumstances specified in the Instrument include, for example, that 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, and that the prescriber has not indicated on the prescription for the scarce medicine that substitution is not permitted.

In accordance with subsection 30EK(2) of the Act, the rule-maker is satisfied in relation to each of the scarce medicines that the supply of the scarce medicine in Australia is not currently meeting, or that there is an imminent risk that supply of the scarce medicine in Australia will not likely meet, the demand for that medicine for all of the patients in Australia who take that medicine. The rule-maker is also satisfied that there is a significant risk of adverse health consequences for patients in Australia if those patients are unable to take the scarce medicine. There are no other matters prescribed by the regulations for the purposes of paragraph 30EK(2)(c).

In accordance with subsection 30EK(3) of the Act, diltiazem is included in Schedule 4 to the current Poisons Standard, and the scarce medicines, Cardizem CD diltiazem hydrochloride 360 mg capsule bottle, and Vasocardol CD diltiazem hydrochloride 360 mg capsule bottle, do not contain a substance in Schedule 8 to the current Poisons Standard.



Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01305

In accordance with subsection 30EK(5) of the Act, the Instrument specifies the period for which the Instrument remains in force, being until 1 October 2027, unless repealed earlier. This will give prescribers time to adapt to prescribing available alternatives to the discontinued medicines. If the shortage of the scarce medicine is resolved sooner, or if safety concerns with the substitutable medicines are identified, the Instrument may be revoked before its cessation date.

The Instrument will be automatically repealed at the start of 1 October 2027, unless repealed earlier.

**Incorporation by reference**

The Instrument incorporates by reference the *Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019* (TGO 101). TGO 101 is a disallowable legislative instrument which constitutes a standard for the purposes of section 10 of the Act, and sets out minimum requirements for therapeutic goods that are tablets, capsules or pills.

For the avoidance of doubt, in accordance with section 14 of the *Legislation Act 2003* (the Legislation Act), TGO 101 is incorporated as in force or existing from time to time.

TGO 101 is freely available on the Federal Register of Legislation at www.legislation.gov.au.

**Consultation**

The TGA has been working closely with stakeholders since the relevant provisions in the Amendment Act commenced in February 2021 and has developed the general permitted circumstances in consultation with these groups. Stakeholders included the Australian Medical Association, relevant clinical professional colleges and societies, sponsor peak bodies, wholesalers, state and territory Chief Pharmacists, and pharmacy and pharmacist peak bodies.

In September 2026, the TGA consulted with the:

- Royal Australian College of General Practitioners (RACGP)
- Royal Australasian College of Physicians (RACP)
- Cardiac Society of Australia and New Zealand (CSANZ)
- Australasian Society of Clinical and -Experimental Pharmacologists and Toxicologists (ASCEPT)
- Australian Medical Association
- Pharmacy Guild
- Pharmaceutical Society of Australia
- Advanced Pharmacy Australia
- Heart Foundation
- State and territory health departments or chief pharmacists.

Consultation was undertaken to ensure the substitution protocol and associated permitted circumstances are appropriate. The TGA received 10 responses, all of which were supportive of the proposed Instrument, and feedback was incorporated into the Instrument and associated public communication. The TGA has also consulted with the sponsor of the substitutable medicines to alert them to the potential change in demand.

**Other details**

Details of the Instrument are set out in **Attachment A**.

The Instrument is compatible with human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.



Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01305

The Instrument is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on 1 October 2026. The Instrument remains in force until 30 September 2027 and will be repealed at the start of 1 October 2027, unless it is repealed earlier.



Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01305

**Attachment A**

**Details of the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Diltiazem) Instrument 2026***

**Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Diltiazem) Instrument 2026* (the Instrument).

**Section 2 – Commencement**

This section provides that the Instrument commences on 1 October 2026.

**Section 3 – Authority**

This section provides that the legislative authority for making the Instrument is section 30EK of the *Therapeutic Goods Act 1989* (the Act).

**Section 4 – Definitions**

This section provides the definition of terms used in the Instrument. This section also notes that some expressions used in the Instrument, including 'medicine', 'pharmacist' and 'registration number', have the same meaning as in the Act.

**Section 5 – Declaration of serious scarcity of medicine**

This section provides a declaration that a serious scarcity of the medicine specified in column 2 of each item in the table in Schedule 1 exists across the whole of Australia.

**Section 6 – Substitution of scarce medicine by pharmacists**

This section provides that, for each item in the table in Schedule 1, a medicine specified in column 3 is a substitutable medicine that may be dispensed by a pharmacist in substitution for the scarce medicine specified in column 2, in the circumstances specified in column 5 of that item (the specific permitted circumstances) and in the table in Schedule 2 (the general permitted circumstances).

**Section 7 – Period instrument is in force**

This section provides that the Instrument remains in force until 30 September 2027.

**Section 8 – Repeals**

This section provides that, unless repealed earlier, the Instrument is repealed at the start of 1 October 2027.



Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01305

**Schedule 1—Scarce medicine, substitutable medicine, dose unit equivalence and specific permitted circumstances**

This Schedule specifies the scarce medicine, substitutable medicine and specific permitted circumstances for the purposes of sections 5 and 6 of the Instrument.

Columns 2 and 3 of item 1 in the table in Schedule 1 specify:

- the scarce medicine as being each of the following:
    - Cardizem CD diltiazem hydrochloride 360 mg capsule bottle (registration number 75251); and
    - Vasocardol CD diltiazem hydrochloride 360 mg capsule bottle (registration number 75253);
- the substitutable medicine as being any of the following:
    - Cardizem CD diltiazem hydrochloride 180 mg capsule blister pack, registration number 46818;
    - Vasocardol CD diltiazem hydrochloride 180 mg capsule bottle, registration number 68922.

Column 4 of item 1 in the table in Schedule 1 specifies the equivalent dose of the scarce medicine and the substitutable medicine for the purposes of the permitted circumstances in column 5. It specifies that two capsules of either substitutable medicine is equivalent to one capsule of either scarce medicine.

Column 5 of item 1 in the table in Schedule 1 sets out the specific permitted circumstances that apply in relation to the item. The specific permitted circumstances are that the pharmacist must have advised the patient, or person acting on behalf of the patient, of:

- the differences between the scarce medicine and the substitutable medicine.
- the number of dose units of substitutable medicine that must be taken by the patient in substitution for the prescribed dose of scarce medicine, based on the dose unit equivalence in column 4;
- suitable instructions in relation to the administration of the substitutable medicine.



Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01305

**Schedule 2—General permitted circumstances**

This Schedule specifies the general permitted circumstances in which a substitution of medicine may occur. For the purpose of section 6, substitution may only occur where these circumstances exist.

The general permitted circumstances prescribed are as follows:

(1) 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, i.e. there must be evidence of a prescription for the scarce medicine, which authorises the pharmacist to dispense the scarce medicine (if it were available) to the patient;

(2) the pharmacist does not have access to the scarce medicine, i.e. the pharmacist must only substitute a medicine if the scarce medicine is not available to the pharmacist;

(3) the prescriber has not indicated on the prescription for the scarce medicine that substitution is not permitted, i.e. if the prescriber has indicated on the prescription that substitution is not permitted, the pharmacist must not dispense the substitutable medicine as this may pose a significant safety risk to the patient. If a prescriber has indicated that substitution, even with a generic product, is not suitable, then the substitutable medicine must not be dispensed;

(4) the pharmacist has exercised professional judgement and determined that the patient is suitable to receive the substitutable medicine. This requires the pharmacist to exercise professional judgement in relation to the particular patient and their circumstances, to assess whether substitution is appropriate for the particular patient. For example, if the pharmacist is of the view that the patient may be sensitive to an excipient ingredient in the substitutable medicine, then the pharmacist must not dispense the substitutable medicine to the patient;

(5) 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. This is to ensure the pharmacist dispenses enough of the substitutable medicine to provide the patient with an equivalent treatment regimen (dosage and duration) as the scarce medicine;

(6) the patient, or person acting on behalf of the patient, has consented to receiving the substitutable medicine. If a person does not wish to receive the substitutable medicine, then the pharmacist must not dispense the substitutable medicine;

(7) the pharmacist makes a record of dispensing the substitutable medicine in substitution of the scarce medicine at the time of dispensing. This is to ensure that there is a record of the medicine that was actually dispensed to a patient, in case any safety concerns arise; and

(8) the pharmacist has an established procedure to notify the prescriber of the substitution at the time of, or as soon as practical after, dispensing the substitutable medicine. There are strong safety reasons for ensuring that the prescriber is aware of the particular medicine that has been dispensed to their patient. The prescriber would otherwise assume that the patient was dispensed the prescribed medicine and would not know about the substitution without notice of this from the dispensing pharmacist.



Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01305

**Attachment B**

## Statement of Compatibility with Human Rights

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

***Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Diltiazem) Instrument 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 legislative instrument**

Subsection 30EK(1) of the Act provides that the Minister may, by legislative instrument, declare that there is a serious scarcity of a specified medicine (the scarce medicine) across the whole or a specified part or parts of Australia, and specify the medicine (the substitutable medicine) that pharmacists are permitted to dispense in substitution for the scarce medicine and the circumstances in which that substitution is permitted.

Subsection 30EK(2) of the Act provides that the Minister may only make an instrument under subsection 30EK(1) if satisfied that the supply of the scarce medicine in Australia is not currently meeting the demand for that medicine for all of the patients in Australia who take that medicine, or that there is an imminent risk that supply of the scarce medicine in Australia will not, or will not be likely to, meet the demand for that medicine for all of the patients in Australia who take, or who may need to take, that medicine. In either case, the Minister must also be satisfied there is a significant risk of adverse health consequences for patients in Australia if they are not able to take the scarce medicine.

Subsection 30EK(3) of the Act provides that both the scarce medicine and the substitutable medicine must contain one or more substances included in Schedule 4 to the current Poisons Standard (i.e. prescription medicines) and must not contain any substances included in Schedule 8 to the current Poisons Standard (i.e. substances for which particular levels of control are required or recommended in order to avoid abuse, misuse or dependence).

The *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Diltiazem) Instrument 2026* (the Instrument) is a legislative instrument made under section 30EK(1) of the Act. It declares that there is a serious scarcity across Australia of the specified scarce medicines containing 360 mg diltiazem, specifies the substitutable medicines that pharmacists are permitted to dispense in substitution for the scarce medicines, and specifies the circumstances in which they may do so.

The Instrument declares two registered medicines to be scarce medicines, being:

- Cardizem CD diltiazem hydrochloride 360 mg capsule bottle, registration number 75251 (this number relates to the entry of the medicine in the Australian Register of Therapeutic Goods (the Register)); and
- Vasocardol CD diltiazem hydrochloride 360 mg capsule bottle, registration number 75253.

The Instrument identifies two substitutable medicines, being:

- Cardizem CD diltiazem hydrochloride 180 mg capsule blister pack, registration number 46818; and
- Vasocardol CD diltiazem hydrochloride 180 mg capsule bottle, registration number 68922.



Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01305

Under the Instrument, either substitutable medicine may be substituted by a pharmacist for either of the scarce medicines.

**Background**

Medicine shortages occur for a number of reasons, ranging from shortages of raw materials to national disasters, logistical difficulties, manufacturing issues, or unexpected increases in demand.

When a medicine is unavailable, community pharmacists have limited scope to substitute another medicine without the prior approval of the prescribing doctor. A pharmacist may substitute a different brand of an equivalent dosage form and strength product, which may include an equivalent overseas-registered medicine approved for supply under section 19A of the Act. However, where there is no such equivalent available, the pharmacist cannot substitute a different medicine. If the pharmacist is unable to contact the prescriber to authorise a change to the prescription, the patient may be unable to obtain their medicine. This impedes timely availability of medicines and risks interruption to treatment, which can impact patient health and cause anxiety and stress for patients.

In 2020, an informal arrangement was implemented between the Commonwealth and the States and Territories to allow pharmacist substitution of medicines that are in shortage, with patient consent. However, this informal arrangement was implemented through State and Territory legislation, and some State and Territory legislation allows for such provision to be made for pharmacist substitution only during a public health emergency. A need therefore arose for a more consistent and responsive pharmacist substitution scheme to help alleviate the effects of medicine shortages; one that allows substitution arrangements to be in place consistently across all States and Territories more quickly, and which reflects that medicine shortages may occur in a range of circumstances, not only where there is a public health emergency.

The *Therapeutic Goods Amendment (2020 Measures No. 2) Act 2021* (the Amendment Act) amended the Act to introduce a pharmacist substitution scheme in Division 2C of Part 3-2 of the Act. This scheme was developed to help alleviate the effects of medicine shortages, by allowing substitution arrangements to be put in place quickly and consistently across Australia, and without being limited to circumstances where there is a public health emergency.

Under this scheme, section 30EK of the Act provides for the making of a legislative instrument declaring a serious scarcity of specified medicines and specifying the substitutable medicine and the circumstances in which substitution is permitted. Such an instrument operates in tandem with section 30EL of the Act, which provides that, where an instrument is in force under subsection 30EK(1) and a pharmacist is authorised to dispense the scarce medicine under a law of a State or Territory, a pharmacist may dispense the substitutable medicine to that person in the circumstances specified in the instrument, despite any law of a State or Territory prohibiting substitution.

**Purpose**

There is currently a national shortage of the scarce medicines, which are the only diltiazem 360 mg capsules available in Australia. The shortage is due to discontinuation of the medicines arising from manufacturing issues.

Medicines containing all strengths of diltiazem are indicated for use in patients for the treatment of hypertension and management of chronic stable angina where there is no evidence of vasospastic or unstable angina. Only the medicines containing 360 mg of diltiazem is in shortage.

The current shortage of the scarce medicines is having, and is anticipated to continue to have, a significant impact on the patients who take or need to take diltiazem 360 mg. If affected patients cannot access their usual dose, there is a risk they may use inappropriate alternatives or stop treatment entirely. Abrupt discontinuation of, or sudden interruption to, treatment may cause significant health



Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01305

concerns for affected patients, including worsening hypertension, severe chest pain, heart attack and stroke. This could potentially lead to patients seeking urgent medical care, increased hospital admissions and increased burden on the health system.

The specified substitutable medicines are medicines that are registered on the Register:

- Cardizem CD diltiazem hydrochloride 180 mg capsule blister pack, registration number 46818; and
- Vasocardol CD diltiazem hydrochloride 180 mg capsule bottle, registration number 68922.

The specified substitutable medicines contain the same active ingredient (diltiazem) and are in the same dosage form (capsules) as the scarce medicine. However, the substitutable medicines vary in strength, as they contain a lower dose of the active ingredient (i.e. 180 mg) as compared to the scarce medicine (i.e. 360 mg).

The making of the Instrument enables pharmacists to substitute the specified substitutable medicine for the relevant scarce medicine, without the patient affected by the unavailability of the scarce medicine needing to return to their prescriber for a new prescription. This means that patients who are prescribed the scarce medicine can access suitable treatment without delay, reducing the risk of interrupted treatment. This substitution is proposed to minimise the burden on health professionals and assist with timely access to medicine supply for patients.

The Instrument specifies a number of specific and general permitted circumstances that have the effect of confining the circumstances in which a pharmacist may substitute the substitutable medicine for the scarce medicine prescribed to a patient. These circumstances are designed to ensure that there are carefully determined safety-related parameters in place for patients in relation to the permitted substitution.

Certain *specific* permitted circumstances are specified, including that the pharmacist must have advised the patient, or person acting on behalf of the patient, of:

- the differences between the scarce medicine and the substitutable medicine;
- the number of dose units of substitutable medicine that must be taken by the patient in substitution for the prescribed dose of scarce medicine, based on the specified dose unit equivalence; and
- suitable instructions in relation to the administration of the substitutable medicine.

The *general* permitted circumstances specified in the Instrument include, for example, that 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, and that the prescriber has not indicated on the prescription for the scarce medicine that substitution is not permitted.

In accordance with subsection 30EK(2) of the Act, the rule-maker is satisfied in relation to each of the scarce medicines that the supply of the scarce medicine in Australia is not currently meeting, or that there is an imminent risk that supply of the scarce medicine in Australia will not likely meet, the demand for that medicine for all of the patients in Australia who take that medicine. The rule-maker is also satisfied that there is a significant risk of adverse health consequences for patients in Australia if those patients are unable to take the scarce medicine. There are no other matters prescribed by the regulations for the purposes of paragraph 30EK(2)(c).

In accordance with subsection 30EK(3) of the Act, diltiazem is included in Schedule 4 to the current Poisons Standard, and the scarce medicines, Cardizem CD diltiazem hydrochloride 360 mg capsule bottle, and Vasocardol CD diltiazem hydrochloride 360 mg capsule bottle, do not contain a substance in Schedule 8 to the current Poisons Standard.



Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01305

In accordance with subsection 30EK(5) of the Act, the Instrument specifies the period for which the Instrument remains in force, being until 1 October 2027, unless repealed earlier. This will give prescribers time to adapt to prescribing available alternatives to the discontinued medicines. If the shortage of the scarce medicine is resolved sooner, or if safety concerns with the substitutable medicines are identified, the Instrument may be revoked before its cessation date.

The Instrument will be automatically repealed at the start of 1 October 2027, unless repealed earlier.

**Human rights implications**

The Instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (the ICESCR). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)* (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a 'fundamental human right indispensable for the exercise of other human rights', and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The Instrument takes positive steps to promote the right to health by facilitating improved access to the substitutable medicine, and to ameliorate the effects of the limited availability or unavailability of the scarce medicine across the Australian market. By enabling pharmacists to substitute these important medicines, the Instrument will support the right to health through helping Australian patients avoid the suffering that may otherwise occur due to an interruption in treatment for their condition.

**Conclusion**

The Instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and otherwise does not raise any other human rights issues.



Authorised Version Explanatory Statement registered 28/09/2026 to F2026L01305