



Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Cefalexin) Instrument 2022

I, Elspeth Kay, as delegate of the Minister for Health and Aged Care, make the following instrument.

Dated 20 December 2022

Elspeth Kay
Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health and Aged Care

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1 Name

This instrument is the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Cefalexin) Instrument 2022*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	21 December 2022.	21 December 2022

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 30EK of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

- (a) medicine;
- (b) Register;
- (c) registered goods.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

capsule has the same meaning as in TGO 101.

pharmacist has the same meaning as in subsection 30EK(6) of the Act.

prescriber means the person who:

- (a) is authorised under a law of a State or Territory to prescribe medicine; and
- (b) prescribed the scarce medicine for the patient.

registered medicine means a medicine that is included in the part of the Register for goods known as registered goods.

scarce medicine has the meaning given by section 5.

substitutable medicine has the meaning given by section 6.

TGO 101 means the *Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019*.

Note: TGO 101 is a legislative instrument published on the Federal Register of Legislation at www.legislation.gov.au.

5 Declaration of a serious scarcity

For paragraph 30EK(1)(a) of the Act, a serious scarcity of the medicine specified in column 2 of each item in the tables in Part 1 and Part 2 of Schedule 1 (the *scarce medicine*) across the whole of Australia is declared.

6 Substitution of scarce medicine by pharmacists

For paragraph 30EK(1)(b) of the Act, in relation to each item mentioned in the tables in Part 1 and Part 2 of Schedule 1, each medicine specified in column 3 (the *substitutable medicine*) is permitted to be dispensed by a pharmacist in substitution for the scarce medicine specified in column 2, in the circumstances specified in:

- (a) column 5 of that item (the *specific permitted circumstances*); and
- (b) the table in Schedule 2 (the *general permitted circumstances*).

Note: Substitution is only permitted where both the specific permitted circumstances and the general permitted circumstances exist.

7 Period instrument in force

This instrument remains in force until 31 July 2023.

8 Repeals

Unless repealed earlier, this instrument is repealed at the start of 1 August 2023.

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

Note: See sections 5 and 6.

Part 1—Scarce medicine: cefalexin in liquid or suspension preparations

Scarce medicine, substitutable medicine, dose unit equivalence and specific permitted circumstances				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Scarce medicine	Substitutable medicine	Dose unit equivalence	Specific permitted circumstances
1	<p>a registered medicine that:</p> <p>(a) contains cefalexin 125 mg/5 mL in a 100 mL oral liquid or suspension; and</p> <p>(b) is manufactured in the dosage form of a powder for oral liquid or suspension, as relevant</p>	<p>a medicine that:</p> <p>(a) contains cefalexin 250 mg/5 mL in a 100 mL oral liquid or suspension; and</p> <p>(b) is manufactured in the dosage form of a powder for oral liquid or suspension, as relevant</p>	<p>250 mg of cefalexin is equivalent to 5 mL of the substitutable medicine</p>	<p>the pharmacist has:</p> <p>(a) advised the patient, or person acting on behalf of the patient, of the number of dose units in millilitres 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 specified in column 4; and</p> <p>(b) ensured that the correct dose of substitutable medicine is written in millilitres on the dispensing label; and</p> <p>(c) if multiple bottles of substitutable medicine are dispensed—ensured that the patient’s treatment course will be completed prior to the expiry of each bottle; and</p> <p>(d) ensured the patient, or person acting on behalf of the patient, has access to information to support them in administering the substitutable medicine</p>

Scarce medicine, substitutable medicine, dose unit equivalence and specific permitted circumstances				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Scarce medicine	Substitutable medicine	Dose unit equivalence	Specific permitted circumstances
2	<p>a registered medicine that:</p> <p>(a) contains cefalexin 125 mg/5 mL in a 100 mL oral liquid or suspension; and</p> <p>(b) is manufactured in the dosage form of a powder for oral liquid or suspension, as relevant</p>	<p>a medicine that:</p> <p>(a) contains 250 mg cefalexin; and</p> <p>(b) is manufactured in the dosage form of a capsule</p>	<p>250 mg of cefalexin is equivalent to one capsule of the substitutable medicine</p>	<p>the pharmacist has:</p> <p>(a) ensured that the patient can take the substitutable medicine in a capsule dosage form; and</p> <p>(b) only substituted the substitutable medicine for the scarce medicine where the prescribed dose of scarce medicine is divisible by 250 mg; and</p> <p>(c) advised the patient, or person acting on behalf of the patient, of 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 specified in column 4; and</p> <p>(d) ensured that the correct number of dose units of substitutable medicine that must be taken by the patient in substitution for the prescribed dose of scarce medicine is written on the dispensing label; and</p> <p>(e) ensured that the patient, or person acting on behalf of the patient, has access to information to support them in administering the</p>

Scarce medicine, substitutable medicine, dose unit equivalence and specific permitted circumstances				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Scarce medicine	Substitutable medicine	Dose unit equivalence	Specific permitted circumstances
				substitutable medicine
3	a registered medicine that: (a) contains cefalexin 250 mg/5 mL in a 100 mL oral liquid or suspension; and (b) is manufactured in the dosage form of a powder for oral liquid or suspension, as relevant	a medicine that: (a) contains cefalexin 125 mg/5 mL in a 100 mL oral liquid or suspension; and (b) is manufactured in the dosage form of a powder for oral liquid or suspension, as relevant	250 mg of cefalexin is equivalent to 10 mL of the substitutable medicine	the pharmacist has: (a) advised the patient, or person acting on behalf of the patient, of the number of dose units in millilitres 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 specified in column 4; and (b) ensured that the correct dose of substitutable medicine is written in millilitres on the dispensing label; and (c) if multiple bottles of substitutable medicine are dispensed—ensured that the patient's treatment course will be completed prior to the expiry of each bottle; and (d) ensured the patient, or person acting on behalf of the patient, has access to information to support them in administering the substitutable medicine
4	a registered medicine that: (a) contains cefalexin 250 mg/5 mL in a 100 mL oral liquid or suspension; and (b) is manufactured in the dosage form of	a medicine that: (a) contains 250 mg cefalexin; and (b) is manufactured in the dosage form of a capsule	250 mg of cefalexin is equivalent to one capsule of the substitutable medicine	the pharmacist has: (a) ensured that the patient can take the substitutable medicine in a capsule dosage form; and (b) only substituted the substitutable medicine

Scarce medicine, substitutable medicine, dose unit equivalence and specific permitted circumstances				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Scarce medicine	Substitutable medicine	Dose unit equivalence	Specific permitted circumstances
	a powder for oral liquid or suspension, as relevant			<p>for the scarce medicine where the prescribed dose of scarce medicine is divisible by 250 mg; and</p> <p>(c) advised the patient, or person acting on behalf of the patient, of 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 specified in column 4; and</p> <p>(d) ensured that the correct number of dose units of substitutable medicine that must be taken by the patient in substitution for the prescribed dose of scarce medicine is written on the dispensing label; and</p> <p>(e) ensured that the patient, or person acting on behalf of the patient, has access to information to support them in administering the substitutable medicine</p>

Part 2—Scarce medicine: cefalexin in capsule dosage form

Scarce medicine, substitutable medicine, dose unit equivalence and specific permitted circumstances				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Scarce medicine	Substitutable medicine	Dose unit equivalence	Specific permitted circumstances
1	a registered medicine that: (a) contains 500 mg cefalexin; and (b) is manufactured in the dosage form of a capsule	a medicine that: (a) contains 250 mg cefalexin; and (b) is manufactured in the dosage form of a capsule	one capsule of the scarce medicine is equivalent to two capsules of the substitutable medicine	the pharmacist has: (a) advised the patient, or person acting on behalf of the patient, of 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 specified in column 4; and (b) ensured that the correct number of dose units of substitutable medicine that must be taken by the patient in substitution for the prescribed dose of scarce medicine is written on the dispensing label; and (c) ensured that the patient, or person acting on behalf of the patient, has access to information to support them in administering the substitutable medicine

Schedule 2—General permitted circumstances

Note: See section 6.

General permitted circumstances	
Column 1	Column 2
Item	Circumstances
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
2	the pharmacist does not have access to the scarce medicine
3	the prescriber has not indicated on the prescription for the scarce medicine that substitution is not permitted
4	the pharmacist has exercised professional judgement and determined that the patient is suitable to receive the substitutable medicine
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
6	the patient, or person acting on behalf of the patient, has consented to receiving 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
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
