



Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Phenoxymethylpenicillin) Instrument 2023

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

Dated 14 April 2023

Nicholas Henderson
Acting First 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) (Phenoxymethylpenicillin) Instrument 2023*.

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	17 April 2023.	17 April 2023

Note: This table relates only to the provisions of this instrument as originally made.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;
- (d) registration number.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

capsule has the same meaning as in TGO 101.

Penicillin V means the active ingredient phenoxymethylpenicillin.

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.

scarce medicine has the meaning given by section 5.

substitutable medicine has the meaning given by section 6.

tablet has the same meaning as in TGO 101.

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 30 September 2023.

8 Repeals

Unless repealed earlier, this instrument is repealed at the start of 1 October 2023.

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

Note: See sections 5 and 6.

Part 1—Substitutable medicine: phenoxymethylpenicillin in liquid 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	PHENOXYMETHYL PENICILLIN- AFT Penicillin V (as potassium salt) 125mg/5ml powder for oral liquid bottle, registration number 159753	each of the following medicines: (a) a medicine that contains Penicillin V 150mg/5mL in a 100mL oral suspension; (b) a medicine that contains Penicillin V 250mg/5mL in a 100mL oral liquid and is in the dosage form of a powder for oral liquid	125mg of Penicillin V is equivalent to the following volumes of each substitutable medicine: (a) 4.2mL of Penicillin V 150mg/5mL oral suspension; (b) 2.5mL of Penicillin V 250mg/5mL oral liquid	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 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 in millilitres; and (c) ensured the patient,

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
				or person acting on behalf of the patient, has access to information to support them in administering the substitutable medicine; and (d) 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
2	CILICAINE V Penicillin V (as benzathine) 150mg/5mL oral liquid, suspension bottle, registration number 151598	each of the following medicines: (a) a medicine that contains Penicillin V 125mg/5mL in a 100mL oral liquid and is in the dosage form of a powder for oral liquid; (b) a medicine that contains Penicillin V 250mg/5mL in a 100mL oral liquid and is in the dosage form of a powder for oral liquid	150mg of Penicillin V is equivalent to the following volumes of each substitutable medicine: (a) 6mL of Penicillin V 125mg/5mL oral liquid; (b) 3mL of Penicillin V 250mg/5mL oral liquid	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 number of dose units of substitutable medicine that must be taken by the patient in substitution for the prescribed dose of scarce medicine is

Scarce medicine, substitutable medicine, dose unit equivalence and specific permitted circumstances				
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				written on the dispensing label in millilitres; and
				(c) ensured the patient, or person acting on behalf of the patient, has access to information to support them in administering the substitutable medicine; and
				(d) 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
3	PHENOXYMETH YLPENICILLIN-AFT Penicillin V (as potassium salt) 250mg/5ml powder for oral liquid bottle, registration number 159754	each of the following medicines: (a) a medicine that contains Penicillin V 125mg/5mL in a 100mL oral liquid and is in the dosage form of a powder for oral liquid; (b) a medicine that contains Penicillin V 150mg/5mL in a 100mL oral suspension	250mg of Penicillin V is equivalent to the following volumes of each substitutable medicine: (a) 10mL of Penicillin V 125mg/5mL oral liquid; (b) 8.3mL of Penicillin V 150mg/5mL oral suspension	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 number of dose units of substitutable medicine that must

Scarce medicine, substitutable medicine, dose unit equivalence and specific permitted circumstances				
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Item	Scarce medicine	Substitutable medicine	Dose unit equivalence	Specific permitted circumstances
				be taken by the patient in substitution for the prescribed dose of scarce medicine is written on the dispensing label in millilitres; and (c) ensured the patient, or person acting on behalf of the patient, has access to information to support them in administering the substitutable medicine; and (d) 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

Part 2—Substitutable medicine: phenoxymethylpenicillin in tablet or capsule dosage forms

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	PHENOXYMETHYL PENICILLIN- AFT Penicillin V (as potassium salt) 125mg/5ml powder for oral liquid bottle, registration number 159753	each of the following medicines: (a) a medicine that contains 250mg Penicillin V and is in the dosage form of a capsule; (b) a medicine that contains 250mg Penicillin V and is in the dosage form of a tablet	250mg of Penicillin V is equivalent to each of the following: (a) one 250mg Penicillin V capsule; (b) one 250mg Penicillin V tablet	the pharmacist has: (a) ensured that the patient can take the substitutable medicine in a capsule or tablet dosage form, as relevant; and (b) ensured the prescribed dose of scarce medicine is divisible by 250mg; and (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 (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

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
				medicine is written on the dispensing label; and (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
2	CILICAINE V Penicillin V (as benzathine) 150mg/5mL oral liquid, suspension bottle, registration number 151598	each of the following medicines: (a) a medicine that contains 250mg Penicillin V and is in the dosage form of a capsule; (b) a medicine that contains 250mg Penicillin V and is in the dosage form of a tablet	250mg of Penicillin V is equivalent to each of the following: (a) one 250mg Penicillin V capsule; (b) one 250mg Penicillin V tablet	the pharmacist has: (a) ensured that the patient can take the substitutable medicine in a capsule or tablet dosage form, as relevant; and (b) ensured the prescribed dose of scarce medicine is divisible by 250mg; and (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

Scarce medicine, substitutable medicine, dose unit equivalence and specific permitted circumstances				
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Item	Scarce medicine	Substitutable medicine	Dose unit equivalence	Specific permitted circumstances
				(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
				(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
3	PHENOXYMETH YLPENICILLIN-AFT Penicillin V (as potassium salt) 250mg/5ml powder for oral liquid bottle, registration number 159754	each of the following medicines: (a) a medicine that contains 250mg Penicillin V and is in the dosage form of a capsule; (b) a medicine that contains 250mg Penicillin V and is in the dosage form of a tablet	250mg of Penicillin V is equivalent to each of the following: (a) one 250mg Penicillin V capsule; (b) one 250mg Penicillin V tablet	the pharmacist has: (a) ensured that the patient can take the substitutable medicine in a capsule or tablet dosage form, as relevant; and (b) ensured the prescribed dose of scarce medicine is divisible by 250mg; and (c) advised the patient, or person acting on behalf of the patient, of the number of dose units of substitutable

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
				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 (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 (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

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
