Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Metformin) Instrument 2025

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

Dated 26 May 2025

Nicholas Henderson
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health, Disability and Ageing

Contents

1 Name

This instrument is the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Metformin) Instrument 2025.*

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	28 May 2025.	28 May 2025

Note: This table relates only to the provisions of this instrument as originally made.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) pharmacist;
(c) Register;
(d) registered goods;
(e) registration number.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

immediate-release means, in relation to a tablet, a coated or uncoated tablet for which the rate, place or time of release of the active ingredient in the gastrointestinal tract has not been modified.

modified-release means, in relation to a tablet, a coated or uncoated tablet which contains special excipients or which is prepared by special procedures, or both, designed to modify the rate, the place or the time at which the active ingredient is, or active ingredients are, released.

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.

5 Declaration of 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 table in 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 in the table in Schedule 1, the 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 August 2025.

8 Repeals

Unless repealed earlier, this instrument is repealed at the start of 1 September 2025.

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

Note: See sections 5 and 6.

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	each of the following: (a) FORMET 1000 metformin hydrochloride 1000 mg tablet bottle, registration number 91112; (b) FORMET 1000 metformin hydrochloride 1000 mg tablet blister pack, registration number 91113; (c) DIAFORMIN VIATRIS metformin hydrochloride 1000 mg film-coated tablet blister pack, registration number 206735; (d) METFORMIN GH metformin hydrochloride 1000 mg tablet blister pack, registration	a registered medicine, or a medicine subject to an approval under section 19A of the Act, that is manufactured in the dosage form of a tablet, and contains either: (a) 1000 mg of metformin as the only active ingredient; or (b) 500 mg of metformin as the only active ingredient	one tablet of scarce medicine is equivalent to: (a) one 1000 mg tablet of substitutable medicine; or (b) two 500 mg tablets of substitutable medicine	all of the following: (a) the prescribed dose of the scarce medicine must not be more than 2 g of metformin a day; (b) when substituting with 500 mg immediate-release tablets of the substitutable medicine—the pharmacist does not have access to 1000 mg immediate-release tablets of the substitutable medicine; (c) when substituting with modified-release tablets of substitutable medicine—the pharmacist does not have access to immediate-release tablets of substitutable medicine; (d) the pharmacist has advised the patient, or person acting on behalf of the patient: (i) of the number of dose units of

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**
	number 284975; (e) METFORMIN SANDOZ metformin hydrochloride 1000 mg tablet blister pack, registration number 292865; (f) DIAFORMIN 1000 metformin hydrochloride 1000 mg tablet blister pack, registration number 82207			substitutable medicine that must be administered to the patient in substitution for the prescribed dose of scarce medicine, based on the dose unit equivalence specified in column 4; and (ii) of the differences between the scarce medicine and the substitutable medicine; and (iii) of suitable instructions for administering the substitutable medicine; (e) where the substitutable medicine is a modified-release tablet—the pharmacist has advised the patient, or person acting on behalf of the patient, that dosing is limited to once daily

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