Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Gliclazide) Instrument 2024

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

Dated 27 February 2024

Nicholas Henderson
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name

This instrument is the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Gliclazide) Instrument 2024.*

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	29 February 2024.	29 February 2024

Note: This table relates only to the provisions of this instrument as originally made.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.*

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.

tablet has the same meaning as in 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 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, 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 2024.

8 Repeals

Unless repealed earlier, this instrument is repealed at the start of 1 August 2024.

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 medicines: (a) APO-GLICLAZIDE MR 30mg tablets blister pack, registration number 151303; (b) GLICLAZIDE MR VIATRIS gliclazide 30mg modified release tablet blister pack, registration number 295541; (c) PHARMACOR GLICLAZIDE MR gliclazide 30mg modified release tablet blister pack, registration number 316934	a registered medicine that: (a) contains 60mg gliclazide as the only active ingredient; and (b) is manufactured in the dosage form of a modified release tablet	half a tablet of substitutable medicine is equivalent to one tablet of scarce medicine	the pharmacist has advised the patient, or person acting on behalf of the patient: (a) 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) that cutting a tablet of substitutable medicine in half is required to obtain the correct dose of the substitutable medicine; and (c) that to maintain the modified release properties of the substitutable medicine, a tablet should only be halved and swallowed, and not crushed or chewed; and (d) of suitable instructions in relation to the

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**
				administration of 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