



Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Insulin Isophane Human) Instrument 2024

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

Dated 11 December 2024

Avinash Clarke
Acting First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name	1
2 Commencement.....	1
3 Authority	1
4 Definitions	1
5 Declaration of serious scarcity	2
6 Substitution of scarce medicine by pharmacists.....	2
7 Period instrument in force	2
8 Repeals	2
Schedule 1—Scarce medicine, substitutable medicine, dose unit equivalence and specific permitted circumstances	3
Schedule 2—General permitted circumstances	5

1 Name

This instrument is the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Insulin Isophane Human) 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	16 December 2024.	16 December 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Note: This table relates only to the provisions of this instrument as originally made.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) nurse practitioner;
- (c) pharmacist;
- (d) registration number.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

credentialed diabetes educator means a person who is:

- (a) a diabetes educator, and
- (b) credentialed by the Australian Diabetes Educators' Association Limited (ABN 65008 656 522).

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.

suitably qualified health practitioner means a health practitioner who is one of the following:

- (a) a general practitioner;
- (b) a nurse practitioner;
- (c) a pharmacist;
- (d) an endocrinologist.

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 28 February 2026.

8 Repeals

Unless repealed earlier, this instrument is repealed at the start of 1 March 2026.

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	PROTAPHANE INNOLET human insulin (rys) 100 IU/mL injection multidose cartridge, registration number 169633	PROTAPHANE PENFILL human insulin (rys) 100 IU/mL injection multidose cartridge, registration number 169635	one 3 mL (300 IU) cartridge of the substitutable medicine is equivalent to one 3 mL (300 IU) pre-filled cartridge of the scarce medicine	the pharmacist has: (a) ensured the patient, or person acting on behalf of the patient, has, or is given, a suitable insulin delivery system to administer the substitutable medicine; and (b) advised the patient, or person acting on behalf of the patient: (i) of suitable instructions for safely and effectively administering the substitutable medicine, including using the insulin delivery system; or (ii) where the pharmacist is unable to provide suitable instructions—to obtain suitable instructions for administering the substitutable medicine, including using the insulin delivery system,

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
				<p>from the prescriber, a suitably qualified health practitioner or a credentialed diabetes educator; 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 administered to 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) advised the patient, or person acting on behalf of the patient, of the differences between the scarce medicine and the substitutable medicine</p>

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
