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

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

Dated 13 November 2024

Andrew Simpson
Acting 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) (Estradiol) 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	19 November 2024.	19 November 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Note: This table relates only to the provisions of this instrument as originally made.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;
(b) registration number.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

generic product has the same meaning as in the *Therapeutic Goods Regulations 1990.*

patch means transdermal drug delivery system.

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.

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 January 2026.

8 Repeals

Unless repealed earlier, this instrument is repealed at the start of 1 February 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	each of the following: (a) ESTRADERM MX 25 estradiol 25 microgram/ 24 hours transdermal drug delivery system sachet, registration number 67089; (b) ESTRADOT 25 estradiol 25 microgram transdermal drug delivery system sachet, registration number 338056	a registered medicine, or a medicine subject to an approval under section 19A of the Act, that: (a) contains estradiol as the only active ingredient; and (b) is manufactured in the dosage form of a patch; and (c) releases 25 micrograms of estradiol per day	one patch of the scarce medicine is equivalent to one patch of the substitutable medicine	the pharmacist has advised the patient, or person acting on behalf of the patient, of: (a) 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 (b) suitable instructions for administering the substitutable medicine
2	each of the following: (a) ESTRADERM MX 50 estradiol 50 microgram/ 24 hours transdermal drug delivery system sachet, registration number 56658; (b) ESTRADOT 50 estradiol 50 microgram transdermal	either of the following: (a) a registered medicine, or a medicine subject to an approval under section 19A of the Act, that: (i) contains estradiol as the only active ingredient; and (ii) is manufacture	one patch of the scarce medicine is equivalent to: (a) one patch of the substitutable medicine in paragraph (a) in column 3; or (b) two patches of the substitutable medicine in paragraph (b) in column 3	all of the following: (a) when substituting with the substitutable medicine in paragraph (b) in column 3—the pharmacist: (i) does not have access to the substitutable medicine in paragraph (a) of column 3; and

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**
	drug delivery system sachet, registration number 338058	d in the dosage form of a patch; and (iii) releases 50 micrograms of estradiol per day; (b) a registered medicine, or a medicine subject to an approval under section 19A of the Act, that: (i) contains estradiol as the only active ingredient; and (ii) is manufactured in the dosage form of a patch; and (iii) releases 25 micrograms of estradiol per day		(ii) dispenses patches that are of the same brand; (b) the pharmacist has advised the patient, or person acting on behalf of the patient, of: (i) 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 (ii) suitable instructions for administering the substitutable medicine
3	each of the following: (a) ESTRADERM MX 75 estradiol 75 microgram/ 24 hr transdermal drug delivery system sachet, registration number 76117;	either of the following: (a) a registered medicine, or a medicine subject to an approval under section 19A of the Act, that: (i) contains estradiol as the only active	one patch of the scarce medicine is equivalent to: (a) one patch of the substitutable medicine in paragraph (a) in column 3; or (b) two patches of the substitutable	all of the following: (a) when substituting with the substitutable medicine in paragraph (b) of column 3—the pharmacist: (i) does not have access to the substitutable medicine in

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**
	(b) ESTRADOT 75 estradiol 75 microgram transdermal drug delivery system, registration number 338059	ingredient; and (ii) is manufactured in the dosage form of a patch; and (iii) releases 75 micrograms of estradiol per day; (b) a registered medicine, or a medicine subject to an approval under section 19A of the Act, that: (i) contains estradiol as the only active ingredient; and (ii) is manufactured in the dosage form of a patch; and (iii) releases 37.5 micrograms of estradiol per day	medicine in paragraph (b) in column 3	paragraph (a) of column 3; and (ii) dispenses patches that are of the same brand; (b) the pharmacist has advised the patient, or person acting on behalf of the patient, of: (i) 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 (ii) suitable instructions for administering the substitutable medicine
4	each of the following: (a) ESTRADERM MX 100 estradiol 100 microgram /24 hours transdermal drug delivery system sachet,	either of the following: (a) a registered medicine, or a medicine subject to an approval under section 19A of the Act, that: (i) contains estradiol as	one patch of the scarce medicine is equivalent to: (a) one patch of the substitutable medicine in paragraph (a) in column 3; or	all of the following: (a) when substituting with the substitutable medicine in paragraph (b) of column 3—the pharmacist:

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**
	registration number 67090; (b) ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system, registration number 338060	the only active ingredient; and (ii) is manufactured in the dosage form of a patch; and (iii) releases 100 micrograms of estradiol per day; (b) a registered medicine, or a medicine subject to an approval under section 19A of the Act, that: (i) contains estradiol as the only active ingredient; and (ii) is manufactured in the dosage form of a patch; and (iii) releases 50 micrograms of estradiol per day	(b) two patches of the substitutable medicine in paragraph (b) in column 3	(i) does not have access to the substitutable medicine in paragraph (a) of column 3; and (ii) dispenses patches that are of the same brand; (b) the pharmacist has advised the patient, or person acting on behalf of the patient, of: (i) 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 (ii) suitable instructions for 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