Government of **Western Australia**
Department of **Health**

Structured Administration and Supply Arrangement (SASA)

TITLE: **Serious shortage medicines substitution by registered pharmacists**

1. **Authority:**

   Issued by the Chief Executive Officer of Health under Part 6 of the Medicines and Poisons Regulations 2016.

2. **Scope:**

   This SASA authorises a registered pharmacist to substitute a Schedule 4 medicine, prescribed on a current and valid prescription, issued by an authorised prescriber, for supply of an alternative Schedule 4 medicine, during a serious shortage, subject to the criteria and conditions below.

3. **Criteria:**

   This SASA authorises the actions specified in the table below.

Practitioner:	Registered pharmacist
Practice setting:	Presentation by a patient of a current, valid prescription for Schedule 4 medicines, which are the subject of a serious shortage, as listed in Appendix 1.
Approved activity:	Supply
Approved medicines:	Alternative Schedule 4 medicine(s) listed as in Appendix 1.
Medical conditions:	Substitute supply of alternative Schedule 4 medicine(s) during a serious medicines shortage.

4. **Conditions:**

   The supply of approved medicines under this SASA is subject to the conditions that:

   a) The patient presents the pharmacist with a current, valid prescription for a Schedule 4 medicine, which is subject to a serious shortage, during the applicable dates, as listed in Appendix 1.

   b) The patient agrees to the substitution of another medicine.

   c) The substituted Schedule 4 medicine, strength and dose, is supplied in accordance with Appendix 1.

   d) The total quantity of the substituted medicines supplied is equivalent to the number of days of treatment specified on the original prescription for the medicines that are unavailable.

e) Only one standard supply quantity of the substitute medicines is supplied on an occasion, without the authority of the original prescriber.

f) Before making the substitute supply, the pharmacist must:

   i) where practicable, make reasonable attempts to contact the original prescriber;

   ii) be satisfied that the supply is required urgently and it is impractical for the patient to return to the prescriber for a prescription;

   iii) make a professional judgment that the substitution is safe and suitable in relation to the specific patient circumstances;

   iv) counsel the patient regarding the substitution and new dosage instructions; and

   v) affix labels to the packaging that meet Part 9 of the Medicines and Poisons Regulations 2016 and includes correct dosage instructions for the substituted medicine.

g) In addition to the usual dispensing records required under Regulation 23 of the Medicines and Poisons Regulations 2016, the pharmacist:

   i) make notation in the patient's clinical (dispensing) record that a substitution has been made; and

   ii) clearly mark the original prescription and the repeat form issued (if any) indicating the substitution and the name(s), form(s), strength(s) and quantities of the medicines(s) substituted.

5. **References:**

a. *Shortage of Estradot (estradiol) hormone replacement therapy patches (multiple strengths).* Therapeutic Goods Administration*. 26 August 2020.* Available at: https://www.tga.gov.au/alert/shortage-estradot-estradiol-hormone-replacement-therapy-patches-multiple-strengths

b. *Shortage of Estradot (estradiol) 25 and 75.* Therapeutic Goods Administration. *18 December 2020.* Available at: https://www.tga.gov.au/alert/shortage-estradot-estradiol-25-and-75

6. **Issued by:**

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Position:	CHIEF HEALTH OFFICER
Date:	15 January 2021

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Date: 15/01/2021

APPENDIX 1

Approved Medicines

Registered pharmacists may substitute the supply of a Schedule 4 medicine in accordance with this SASA where:

a) the prescription presented is for an unavailable medicine;

b) during the dates specified; and

c) the alternative medicine is substituted;

as outlined in the tables below.

Dates	15 January 2021 to 30 June 2021
Unavailable medicine	**Estradot 25®** Estradiol 25mcg transdermal drug delivery system sachet One patch twice a week
Substitute medicine to be supplied – Option 1	**Estraderm MX 25®** Estradiol 25mcg/24 hours (0.75 mg) transdermal drug delivery system sachet One patch **twice** a week
Substitute medicine to be supplied – Option 2	**Climara 25®** Estradiol 25mcg/day transdermal drug delivery system sachet One patch **once** a week

Notes

- The patch size and dose interval varies between brands.
- The patch must not be cut or torn.
- Total number supplied under this protocol must be equivalent to the number of days supplied on the original prescription.
  - If dispensing Climara 25® as the substitute medicine, only half the number of patches specified in the original prescription for Estradot 25® will be required.

Dates	15 January 2021 to 30 June 2021
Unavailable medicine	**Estradot 75®** Estradiol 75mcg transdermal drug delivery system sachet One patch twice a week
Substitute medicine to be supplied	**Climara 75®** Estradiol 75mcg/day transdermal drug delivery system sachet One patch **once** a week.
Notes • The patch size and dose interval varies between brands. • The patch must not be cut or torn. • Total number supplied under this protocol must be equivalent to the number of days supplied on the original prescription: only half the number of patches specified in the original prescription for Estradot 75® will be required.	

The pharmacist may, in their professional judgement, determine that the patient is not suitable to receive the substitute medicine, for example, due to known previous hypersensitivity or severe adverse reactions to excipients, or known previous intolerance to the alternative formulation.