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

Structured Administration and Supply Arrangement (SASA)

TITLE: **Serious scarcity substitution instrument for 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 scarcity 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 scarcity, 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 medicine scarcity.

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 scarcity, 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 medicine 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 urgently required 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 (if applicable) 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. *Shortages of tocilizumab (Actemra) medicines*. Therapeutic Goods Administration. 6 August 2021. Available at: https://www.tga.gov.au/alert/shortages-tocilizumab-actemra-medicines

b. *Tocilizumab (Actemra) Serious Scarcity Substitution Instrument*. Therapeutic Goods Administration.6 August 2021. Available at: https://www.tga.gov.au/alert/tocilizumab-actemra-serious-scarcity-substitution-instrument

c. *Estradiol valerate (Progynova) Serious Scarcity Substitution Instrument*. Therapeutic Goods Administration. 12 August 2021. Available at: https://www.tga.gov.au/alert/substitution-instrument-address-shortage-progynova-estradiol-valerate-tablets-multiple-strengths

6. **Issued by:**

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Position:	CHIEF HEALTH OFFICER
Date:	2 September 2021

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Date: 02/09/2021

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 table~~s~~ below.

Dates	6 August 2021 to 31 December 2021	
Unavailable medicine	**ACTEMRA®** tocilizumab 162 mg/0.9 mL solution for injection pre-filled syringe	**ACTEMRA®** tocilizumab 162 mg/0.9 mL solution for injection pre-filled pen, ACTPen Autoinjector
Substitute medicine to be supplied	**ACTEMRA®** tocilizumab 162 mg/0.9 mL solution for injection pre-filled pen, ACTPen Autoinjector	**ACTEMRA®** tocilizumab 162 mg/0.9 mL solution for injection pre-filled syringe

Notes

Both Actemra® products are in short supply.

Specific permitted circumstances

All of the following:

a) the patient is at least 18 years of age;

b) the pharmacist has advised the patient or person acting on behalf of the patient:

(i) to obtain instructions from the prescriber, or a general practitioner or rheumatology nurse, in relation to the administration of the substitutable medicine; and

(ii) 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:

- one pre-filled syringe of the substitutable medicine containing tocilizumab 162 mg/0.9 mL solution is equivalent to one pre-filled pen of the scarce medicine containing tocilizumab 162 mg/0.9 mL solution.
- one pre-filled pen of the substitutable medicine containing tocilizumab 162 mg/0.9 mL solution is equivalent to one pre-filled syringe of the scarce medicine containing tocilizumab 162 mg/0.9 mL solution.

Dates	12 August 2021 to 1 May 2022	
Unavailable medicine	**PROGYNOVA 1 mg** Estradiol valerate (as hemihydrate) 1 mg tablet	**PROGYNOVA 2 mg** Estradiol valerate (as hemihydrate) 2 mg tablet
Substitute medicine to be supplied Option 1	**ESTROFEM 1 mg** Estradiol (as hemihydrate) 1 mg tablet One tablet is equivalent to one tablet of Progynova 1 mg	**ESTROFEM 2 mg** Estradiol (as hemihydrate) 2 mg tablet One tablet is equivalent to one tablet of Progynova 2 mg
Substitute medicine to be supplied Option 2	**ZUMENON 2 mg** Estradiol (as hemihydrate) 2 mg tablet Half a tablet is equivalent to one tablet of Progynova 1 mg	**ZUMENON 2 mg** Estradiol (as hemihydrate) 2 mg tablet One tablet is equivalent to one tablet of Progynova 2 mg
Notes Both Progynova 1mg and Progynova 2 mg tablets are in short supply.		
Specific permitted circumstances All of the following: The pharmacist has advised the patient, or the person acting on behalf of the patient of: a) The number of dose units of the substitute medicine that is equivalent to the prescribed dose of the scarce medicine and b) Where cutting of the tablet is required to obtain the correct dose of the substitute medicine, the instructions for cutting the tablet.		

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.