

# THE SOUTH AUSTRALIAN GOVERNMENT GAZETTE

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# STATE GOVERNMENT INSTRUMENTS

#### CONTROLLED SUBSTANCES (POISONS) REGULATIONS 2011

Community Pharmacy Urinary Tract Infection Services Scheme under Regulation 21(2)(h)

I, CHRIS PICTON, Minister for Health and Wellbeing, hereby determine the Community Pharmacy Urinary Tract Infection Services Scheme set out in this notice to be a scheme for the purposes of Regulation 21(2)(h) of the Controlled Substances (Poisons) Regulations 2011:

# Medicines that may be sold or supplied without a prescription by a pharmacist under this Scheme:

- 1. The following Schedule 4 medicines may be sold or supplied by a pharmacist without a prescription:
  - a. trimethoprim; or
  - b. nitrofurantoin, where trimethoprim is not appropriate for the patient or not available; or
  - c. cefalexin, where trimethoprim and nitrofurantoin are not appropriate for the patient or not available.

## Requirements with respect to the Sale or Supply of the Schedule 4 medicines to which this Scheme applies:

- A pharmacist must not sell or supply the medicines in a quantity that exceeds the smallest available size of the manufacturer's pack of the medicine.
- 3. The medicines are only sold or supplied by a pharmacist to eligible patients and in accordance with the SA Community Pharmacy Urinary Tract Infection (UTI) Services UTI Management Protocol (UTI Management Protocol) and relevant professional practice standards and guidelines, including the professional practice standards and guidelines referred to in the UTI Management Protocol.
- 4. The supply, packaging and labelling of the approved medicines is in accordance with the *Controlled Substances Act (1984)* and the *Controlled Substances (Poisons) Regulations 2011*.

#### Patient eligibility:

- 5. Eligible patients include women aged 18 to 65 years with an anatomical female urinary tract:
  - a. Who are deemed to be likely experiencing an acute uncomplicated urinary tract infection, after assessment by a pharmacist;
  - b. Who are at low risk of complications, as assessed by a pharmacist; and
  - c. Who meet inclusion criteria in accordance with the UTI Management Protocol and relevant professional practice standards and guidelines, including the professional practice standards and guidelines referred to in the UTI Protocol.

#### Pharmacist requirements:

- 6. The pharmacist providing services must have an unconditional general registration with the Australian Health Practitioner Regulation Agency (Ahpra).
- 7. The pharmacist must comply with all relevant legislation, Ahpra & the Pharmacy Board of Australia's Code of Conduct, and the expected standards of ethical behaviour of pharmacists towards individuals, the community and society.
- 8. Prior to providing services, the pharmacist must have successfully completed the training set out in paragraph 9 of this scheme, and must maintain eligibility to provide services, including any ongoing training.

# Pharmacist training requirements:

- 9. Prior to providing services, pharmacists must have successfully completed one or more of the competency-based training programs on managing urinary tract infections specified in the SA Community Pharmacy UTI Services UTI Management Protocol, delivered through a higher education institution accredited by the Tertiary Education Quality and Standards Agency or an accredited continuing professional development program, that meets the Australian Pharmacy Council's Standards for Continuing Professional Development Activities.
- 10. Training programs must include learning objectives on:
  - a. Classification and epidemiology of urinary tract infections.
  - Clinical features, assessment and differential diagnosis, including conditions with similar symptoms and risk factors for complicated UTIs.
  - c. Pharmacological and non-pharmacological management of UTIs.
  - d. Evidence and role of over-the-counter products for UTIs.
  - e. Antimicrobial resistance management and stewardship.
  - f. The importance of referring a patient to a GP or other appropriate health service if risk factors for complicated UTI are present or a pharmacist is not confident that an uncomplicated UTI is a likely diagnosis.
  - g. The importance of ensuring privacy and confidentiality for patients in pharmacy.
- 11. Pharmacists must complete cultural safety and gender diversity training relevant to their place of practice, reflect on their competency and provide the service in ways that are inclusive, culturally safe, sensitive, and responsive.

## Pharmacy requirements:

- 12. Only pharmacies registered by the Pharmacy Regulation Authority of South Australia (PRASA) under the *Health Practitioner Regulation National Law (South Australia) Act 2010* may participate in the scheme.
- 13. The pharmacy must have an area suitable to maintain confidentiality of the consultation, i.e. have a screened or private consulting area that:
  - a. Ensures patients' privacy and confidentiality, including visual and auditory privacy
  - b. Has sufficient space to allow the presence of the patient, a carer if required, the pharmacist, and relevant documentation.

## Clinical documentation and communication requirements:

14. The pharmacist must make a clinical record and a record in a pharmacy dispensing system regarding the supply of any antibiotics under these services.

- 15. The pharmacist is required, to make and keep (at the pharmacy where the patient consultation occurred) a comprehensive clinical record of the consultation and of any treatment provided, in accordance with relevant legislation and professional responsibilities. The record must include:
  - a. sufficient information to identify the patient
  - b. the name of the pharmacist who undertook the consultation and their healthcare identifier number (HPI-I)
  - c. the date of the consultation
  - d. information relevant to the patient's diagnosis and treatment (for example, patient's medical history, adverse drug reactions)
  - e. any clinical opinion reached, and actions taken by the pharmacist
  - f. details of any medication supplied for the patient (generic name, form, strength and quantity)
  - g. any information or advice given by the pharmacist to the patient in relation to any proposed treatment
  - h. any consent given by a patient to the consultation, treatment proposed, sharing information with their medical practitioner.
- 16. Where a patient has a My Health Record, the pharmacist must ensure the details of the medicine supply are uploaded to My Health Record, unless otherwise requested by the patient.
- 17. The pharmacist must offer a record of the treatment and consultation to the patient. This may include a copy of the checklist completed by the pharmacist during the consultation. The patient may choose to share this with their GP or other health professionals.
- 18. Following consent by the patient, the pharmacist may share a record of the supply and consultation with the patient's usual treating medical practitioner or medical practice, where the patient has one.
- 19. Pharmacists must, at the request of the Minister for Health and Wellbeing, provide data on the scheme periodically (for monitoring and evaluation purposes).

## Consultation fees

- 20. Pharmacists may charge a consultation fee for the service, in addition to the cost of any medicine that is supplied.
- 21. Pharmacists should ensure that the patient understands the costs involved when offering the service.

# Commencement of Scheme

22. This Scheme commences on 1 March 2024.

The SA Community Pharmacy Urinary Tract Infection (UTI) Services UTI Management Protocol means the document of that name published by the Department (as amended from time to time).

Dated: 1 February 2024

HON CHRIS PICTON MP Minister for Health and Wellbeing

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