POISONS AND THERAPEUTIC GOODS ACT 1966

Section 10 Poisons and Therapeutic Goods Act 1966

Clauses 170 and 171 of the Poisons and Therapeutic Goods Regulation 2008

AUTHORITY

I, Dr Kerry Chant, Chief Health Officer, a duly appointed delegate of the Secretary, NSW Health, pursuant to clauses 53, 170, and 171 of the Poisons and Therapeutic Goods Regulation 2008 for the purpose of section 10 of the Poisons and Therapeutic Goods Act 1966, hereby:

1. revoke the instrument of *Authority – Supply of specified restricted substances by pharmacists* signed 28 May 2024; and
2. make this instrument.

Dr Kerry Chant

Chief Health Officer

Dated: 5/6/24

Authority – Supply of specified restricted substances by pharmacists

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1) Authorisation

This instrument authorises an 'approved pharmacist' to supply to an 'applicable patient' a restricted substance listed in clause 2 otherwise than on prescription subject to the conditions in clause 3 of this instrument.

2) Restricted substance to which this instrument applies

This instrument applies to oral forms of:

a. trimethoprim
b. nitrofurantoin
c. cefalexin.

3) Conditions — Limitation on supply

An approved pharmacist may supply the restricted substance listed in clause 2, subject to the conditions that:

a. The pharmacist must only supply nitrofurantoin if trimethoprim is unavailable or inappropriate for treatment of the particular patient.

b. The pharmacist must only supply cefalexin if both trimethoprim and nitrofurantoin are unavailable or inappropriate for treatment of the particular patient.

c. The pharmacist must not supply a medicine specified in clause 2 in a quantity that exceeds the smallest available size of the manufacturer's pack of the medicine.

d. The pharmacist acts in accordance with any practice standards approved by the Chief Health Officer, including in relation to any limitations on the supply of cefalexin, trimethoprim or nitrofurantoin to a patient based on their age or other factor, and circumstances where a patient must be referred to a general practitioner.

e. The patient and pharmacist must both be physically present at the approved pharmacy premises, for consultation to occur.

f. The pharmacist must make and keep a secure electronic clinical record of the consultation for 7 years (at the pharmacy where the patient consultation occurred) that contains:

- sufficient information to identify the patient
- the date of the treatment
- the name of the pharmacist who undertook the consultation
- any information known to the pharmacist that is relevant to the patient's diagnosis or treatment (for example, information concerning the patient's medical history)
- any clinical opinion reached by the pharmacist
- actions taken by the pharmacist
- particulars of any medication supplied for the patient (such as form, strength and amount)
- notes as to information or advice given to the patient in relation to any treatment proposed by the pharmacist who is treating the patient
- any consent given by a patient to the treatment proposed.

g. The pharmacist must share a record of the consultation with the patient's usual treating medical practitioner or medical practice, where the patient has one, following consent by the patient. This must be shared within a week following the consultation.[1]

h. The pharmacist must comply with the AHPRA & National Boards Code of Conduct; and the expected standards of ethical behaviour of pharmacists towards individuals, the community and society.

4) Publication

This instrument will be published on the NSW Health website.

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[1] Communication with the patient's usual treating medical practitioner or medical practice should ensure patient confidentiality is maintained. Use of a secure digital messaging platform is considered best practice.

5) Definitions

In this instrument:

- An 'applicable patient' means a female patient 18 years of age or over and up to and including aged 65 years.
- An 'approved pharmacist' means a pharmacist holding general registration under the *Health Practitioner Regulation National Law* and who is employed or engaged in an 'approved pharmacy' who has successfully completed the following training:
    - Australasian College of Pharmacy Uncomplicated Cystitis Treatment – Pharmacist Training; or
    - Pharmaceutical Society of Australia Managing uncomplicated cystitis; and
    - Any additional training module(s) that have been approved by the Chief Health Officer (as listed on the NSW Health website).
- An 'approved pharmacy' means a pharmacy or class of pharmacies which:
    - offers applicable patients the services specified in this authorisation at all opening hours of the pharmacy, when an approved pharmacist is present;
    - maintains up-to-date service availability listings via Healthdirect Australia (as detailed on the NSW Health website); and
    - has a service room, consulting room, or area consistent with the following:
        - the room or area is not to be used as a dispensary, storeroom, staff room or retail area,
        - fully enclosed and provides adequate privacy (a divider or curtain in a dispensary, storeroom, staff room or retail area is not acceptable),
        - has adequate lighting,
        - is maintained at a comfortable ambient temperature,
        - has a hand sanitisation facility,
        - has ready access to a hand washing facility, and
        - has sufficient floor area, clear of equipment and furniture, to accommodate the person receiving the consultation and an accompanying person, and to allow the pharmacist adequate space to manoeuvre.
- A 'pharmacy' has the same meaning as in the Health Practitioner Regulation National Law.

6) Commencement

This authority commences on publication.

7) Cancellation

This authority is cancelled on 31 May 2025, unless earlier cancelled.