POISONS AND THERAPEUTIC GOODS ACT 1966

Section 10 Poisons and Therapeutic Goods Act 1966

Clauses 53, 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 restricted substances by pharmacists* signed 5 September 2023; and

2. Make this instrument.

Dr Kerry Chant

Chief Health Officer

Dated: 23/9/24

Authority – Supply of 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 listing in clause 2 otherwise than on prescription subject to the conditions in clause 3 of this instrument.

2) Restricted substances to which this instrument applies:

This instrument applies to single or combined oral forms of:

a. ethinyloestadiol (40µg or less)

b. levonorgestrel

c. norethisterone

d. drospirenone (single ingredient preparations only)

Conditions — Limitation on supply

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

a. The supply to the applicable patient must be primarily for the purpose of contraception.

b. The patient must have been treated with the restricted substance referred to in clause 2 by a medical practitioner or nurse practitioner for the past 24 months and the use has been continuous.

c. The pharmacist must ensure that the applicable patient has not been supplied a restricted substance listed in clause 2 by the pharmacist or has, to the pharmacist's knowledge, been supplied by any other pharmacist acting under this authority for a period exceeding 12 months.

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 substances listed in clause 2 to a patient based on their age or other factor, and circumstances where a patient must be referred to a general practitioner.

e. The pharmacist must make and keep a 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 consultation
    - the name of the pharmacist who undertook the consultation and their Healthcare Provider Identifier Individual number
    - 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, with particular consideration of UKMEC 3 and 4 conditions)[1]
    - any clinical opinion reached by the pharmacist
    - actions and management plan taken by the pharmacist
    - particulars of any medication supplied for the patient (such as form, strength and quantity)
    - 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 consultation, supply of medication and treatment proposed
    - any referrals made to a medical practitioner or other healthcare professional.

f. The pharmacist must share a record of the consultation and supply 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.[2]

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[1] The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) Contraception Clinical Guideline (1991, updated August 2024): https://ranzcog.edu.au/wp-content/uploads/Contraception-Clinical-Guideline.pdf

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

g. 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.

3) Publication

This instrument will be published on the NSW Health website.

4) Definitions

In this instrument:

- An 'applicable patient' means a female patient 18 years of age or over and up to and including aged 49 years who has been supplied or prescribed the oral contraceptive pill by a medical practitioner or nurse practitioner for the previous 24 months and use has been continuous.
- An 'approved pharmacist' means a pharmacist holding general registration with the Australian Health Practitioner Regulation Agency (AHPRA), with no conditions on their registration, and who is employed or engaged in an 'approved pharmacy' who has successfully completed:
    - Australasian College of Pharmacy Oral Contraceptives: a comprehensive training course for pharmacists; or
    - Pharmaceutical Society of Australia NSW – Contraception Essentials; and
    - Any training module(s) that have been approved by the Chief Health Officer.
- An 'approved pharmacy' means a pharmacy or class of pharmacies approved in writing by the Chief Health Officer which:
    - offers applicable patients the services specified in this authorisation at all opening hours of the pharmacy, when an approved pharmacist is present; and
    - maintains up-to-date service availability listings via Healthdirect Australia (as detailed on the NSW Health website); and
    - has a clearly designated consulting room for confidential conversations consistent with the following:
        - the room or area is not to be used as a dispensary, storeroom, staff room or retail area,
        - is 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.

5) Commencement

This authority commences on publication.

6) Cancellation

This authority is cancelled on 30 September 2025, unless earlier cancelled.