NSW GOVERNMENT | Health

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 make this instrument.

Dr Kerry Chant

Chief Health Officer

Dated: 5/9/23

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 for the purposes of the 'clinical trial'.

2) Restricted substance to which this instrument applies

This instrument applies to single or combined oral forms of:

a. ethinyloestradiol (40µg or less)
b. levonorgestrel
c. norethisterone
d. drospirenone (single ingredient preparations only)

3) 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 oral 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 complies with the 'Management Protocols', including the requirement that the pharmacist makes a record in MedAdvisor pharmacy software, or an approved system by the Ministry of Health, regarding the supply.

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 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.

f. The pharmacist shares a record of the supply with the patient's usual treating medical practitioner or medical practice, where the patient has one, following consent by the patient.

g. The pharmacist must consent to participate in the clinical trial and its evaluation, including by sharing records of applicable patients with the University of Newcastle.

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.

5) Definitions

In this instrument:

- An 'applicable patient' means a female patient 18 years of age or over and up to and including aged 35 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) and who is employed or engaged in an 'approved pharmacy' who has successfully completed:
    - Australasian College of Pharmacy Continuation of Oral Contraception Course; or
    - Pharmaceutical Society of Australia NSW - Contraception Essentials; and
    - Training module(s) that have been approved by the Chief Health Officer for the purposes of the clinical trial.
- 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; 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,
        - 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.
- 'Management protocols' means the protocols established for use by pharmacists in the clinical trial.
- The 'clinical trial' means the trial put in place by the University of Newcastle on behalf of the Ministry of Health regarding the supply of specified contraceptive medication by community pharmacists without a prescription.
- 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 30 September 2024, unless earlier cancelled.