POISONS AND THERAPEUTIC GOODS ACT 1966
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 section 10(4)(d) of the Poisons and Therapeutic Goods Act 1966 and clauses 170, and 171 for the purpose of clause 53 of the Poisons and Therapeutic Goods Regulation 2008, hereby:

1. Revoke the instrument of *Authority – Supply of restricted substances by pharmacists* signed 23 September 2024; and

2. Make this instrument.

Dr Kerry Chant

Chief Health Officer

(Delegation Number PH380, PH381, PH427)

Dated: 30 January 2025

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 for the continuation of hormonal contraception 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 to an applicable patient, subject to the conditions that:

a. The pharmacist must only supply a medicine indicate in clause 2 for the continuation of hormonal contraception.

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

c. 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.

d. 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.

e. The pharmacist acts in accordance with NSW Pharmacist Practice Standards for Hormonal Contraception approved by the Chief Health Officer and published on the NSW Health Website, 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 medical practitioner or other healthcare professional.

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

g. The name of the pharmacist providing the consultation as shown in the Register of Pharmacists maintained by Australian Health Practitioner Regulation Agency (AHPRA), must be displayed at or near the consultation room.

h. Pharmacists must make a full clinical record of the consultation using secure digital software. Records must be stored securely for minimum seven (7) years and must contain:
    - 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
    - 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

[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

- 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.

i. The pharmacist must seek the patient's consent to share a record of the consultation and any subsequent consultations (including adverse events) with the patient's usual treating medical practitioner or medical practice, where the patient has one, following consent by the patient. If the patient consents to the disclosure, the record must be shared within a week following the consultation.[2]

j. The pharmacist must comply with the AHPRA & Pharmacy Board 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 under the *Health Practitioner Regulation National Law (NSW)* and who:
    - is employed or engaged in an 'approved pharmacy',
    - has successfully completed the following training options:

1. Training Pathway 1:

<table>
<tr><td>Australasian College of Pharmacy Oral Contraceptives: a comprehensive training course for pharmacists (NSW);</td><td>OR</td><td>Pharmaceutical Society of Australia NSW – Contraception Essentials;</td></tr>
<tr><td colspan="3">AND</td></tr>
<tr><td colspan="3">Any additional training module(s) that have been approved by the Chief Health Officer (as listed on the NSW Health website).</td></tr>
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OR

[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.

2. Training Pathway 2:

The Queensland University of Technology's Safe prescribing and quality use of medicines course	**OR**	James Cook University's Extended community practice pharmacists course (subject PC6300).
AND		
James Cook University's Extended community practice pharmacists course (subjects PC6100 and PC6200).		

- Pharmacists who complete Training Pathway 2 must provide NSW Health with their full name, contact details, pharmacist registration number, intended services and location of services via the form at: https://www.health.nsw.gov.au/pharmaceutical/Pages/expanded-services-application.aspx.

- 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:
    - is not to be used for any other purpose (such 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 28 February 2026, unless earlier cancelled.