

# 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 make this instrument.

Dr Kerry Chant

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**Chief Health Officer** 

(Delegation Number PH380, PH381, PH427)

**Dated:** 30/01/2025

Authority - Supply of specified restricted substances by pharmacists

#### 1) Authorisation

This instrument authorises an approved pharmacist to supply to an applicable patient a restricted substance listed in clause 2 for the treatment of Gastro-oesophageal Reflux and Gastro-oesophageal Reflux Disease 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:

- Famotidine
- Nizatidine
- Esomeprazole
- Lansoprazole
- Omeprazole
- Pantoprazole
- Rabeprazole

### 3) Conditions — Limitation on supply

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

- a. The pharmacist must only supply a medicine indicated in clause 2 for the treatment of Gastro-oesophageal Reflux and/or Gastro-oesophageal Reflux Disease.
- b. The pharmacist must not supply a medicine indicated in clause 2 in a quantity that exceeds the duration of treatment specified in the Practice Standard except in the circumstances described in clause 3(c) of this instrument.
- c. If the smallest available size of the manufacturer's pack of the medicine exceeds the quantity specified in the Practice Standard, the pharmacist may supply the medicine in the smallest available size.
- d. Despite clause 3(c), the pharmacist must not supply a medicine indicated in clause 2 of this instrument in a quantity which would result in supply for a period that is longer than 12 weeks.
- e. The pharmacist acts in accordance with the NSW Pharmacist Practice Standards for Gastro-Oesophageal Reflux And Gastro-Oesophageal Reflux Disease approved by the Chief Health Officer and published on the NSW Health website, including in relation to any limitations on the supply of medicines indicated 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 pharmacist must provide NSW Health with their full name, contact details, pharmacist registration number, intended services and location of services via the form at: <a href="https://www.health.nsw.gov.au/pharmaceutical/Pages/expanded-services-application.aspx">https://www.health.nsw.gov.au/pharmaceutical/Pages/expanded-services-application.aspx</a>.
- g. The patient and pharmacist must both be physically present at the approved pharmacy premises, for consultation with the patient to occur prior to supply.
- h. 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.
- i. Pharmacists must make a full clinical record of the consultation using secure digital software. Records must be stored securely for a minimum of 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)
  - any clinical opinion reached by the pharmacist
  - actions and management plan taken by the pharmacist
  - particulars of any medication supplied for the patient (including the name, form, strength and quantity of the medication)
  - 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.
- j. 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. If the patient consents to the disclosure, the record must be shared within a week following the consultation.<sup>1</sup>
- k. The pharmacist must comply with the AHPRA & Pharmacy Board of Australia 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 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 (NSW) and who:
  - is employed or engaged in an 'approved pharmacy',
  - has successfully completed the following training options:

Prescribing training	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 only).
AND			
Clinical practice training	James Cook University's Extended community practice pharmacists course (subjects PC6100 and PC6200 only).		

and

- has provided NSW Health with their full name, contact details, pharmacist registration number, intended services and location of services via the form at: <a href="https://www.health.nsw.gov.au/pharmaceutical/Pages/expanded-services-application.aspx">https://www.health.nsw.gov.au/pharmaceutical/Pages/expanded-services-application.aspx</a>.
- An 'approved pharmacy' means a pharmacy which:
  - o offers applicable patients the services specified in this authorisation when an approved pharmacist is present;
  - maintains up-to-date service availability listings via Healthdirect Australia (as detailed on the NSW Health website); and

<sup>&</sup>lt;sup>1</sup> 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.

- o has a consulting room which:
  - is not used for any other purpose (such 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 applicable patient receiving the consultation and an accompanying person, and to allow the pharmacist adequate space to manoeuvre.
- A 'pharmacy' has the same meaning as in Schedule 5F of the Health Practitioner Regulation National Law (NSW).

## 6) Commencement

This authority commences on publication.

#### 7) Cancellation

This authority is cancelled on 28 February 2026, unless earlier cancelled.