



New South Wales

Poisons and Therapeutic Goods Amendment (Restricted Substances) Regulation 2020

under the

Poisons and Therapeutic Goods Act 1966

Her Excellency the Governor, with the advice of the Executive Council, has made the following Regulation under the *Poisons and Therapeutic Goods Act 1966*.

BRAD HAZZARD, MP
Minister for Health and Medical Research

Explanatory note

The objects of this Regulation are—

- (a) to require special authorisation to prescribe, supply or administer hydroxychloroquine, and
- (b) to enable pharmacists to supply certain medicines requiring prescriptions in different ways than specified in prescriptions if those medicines are in short supply during the COVID-19 pandemic.

This Regulation is made under the *Poisons and Therapeutic Goods Act 1966*, including sections 17 and 45C (the general regulation-making power).

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1 Name of Regulation

This Regulation is the *Poisons and Therapeutic Goods Amendment (Restricted Substances) Regulation 2020*.

2 Commencement

This Regulation commences on the day on which it is published on the NSW legislation website.

Schedule 1 Amendment of Poisons and Therapeutic Goods Regulation 2008

[1] **Clauses 37(1), 52(1) and 60(1)**

Insert in alphabetical order—

hydroxychloroquine

[2] **Clause 42A**

Insert after clause 42—

42A Special provisions for supply of restricted substances during COVID-19 pandemic

- (1) If the Secretary is satisfied that there is a shortage of a restricted substance or class of restricted substances for supply to patients by pharmacists, the Secretary may, by order published in the Gazette (an *authorisation order*), authorise any of following—
 - (a) the supply of the substance or class of substances (a *short supply medicine*) in accordance with this clause,
 - (b) the supply of another substance (a *substitute medicine*) in accordance with this clause instead of a short supply medicine.
- (2) An authorisation order may be made subject to any conditions the Secretary specifies in the order, including (without limitation) conditions concerning the supply of a substitute medicine.
- (3) A pharmacist supplying a short supply medicine or substitute medicine is taken to supply the substance in accordance with the prescription despite anything to the contrary in the prescription dosage details if—
 - (a) the form of supply is one permitted by subclause (4), and
 - (b) the supply complies with the conditions (if any) specified in the authorisation order for the medicine.
- (4) Each of the following forms of supply is permitted for subclause (3)(a)—
 - (a) supplying a different quantity of a short supply medicine with a different strength than specified by the prescription dosage details with appropriate instructions to the patient about the correct dosage,
 - (b) supplying a short supply medicine with a different formulation or preparation than specified by the prescription dosage details with appropriate instructions to the patient about the correct dosage,
 - (c) supplying a substitute medicine instead of a short supply medicine with appropriate instructions to the patient about the correct dosage.

Examples.

- 1 An example of a supply covered by paragraph (a) is supplying 60 × 20mg tablets of the short supply medicine at a dose of 2 tablets each day instead supplying 30 × 40mg tablets at a dose of 1 tablet each day.
- 2 Examples of supplies covered by paragraph (b) are—
 - (a) supplying the short supply medicine as tablets instead of capsules, or
 - (b) supplying the short supply medicine in liquid form instead of tablets or capsules, or
 - (c) supplying the short supply medicine with a different rate of release.
- (5) For subclause (4), appropriate instructions about the correct dosage are instructions sufficient to enable the patient to achieve the same, or

substantially same, result as taking the short supply medicine in accordance with the prescription dosage details.

- (6) This clause applies despite anything to the contrary in another provision of this Regulation (including clauses 35 and 39).
- (7) This clause is repealed on the day that is 12 months after the commencement of this clause.
- (8) In this clause—
 - prescription* includes a medication chart prescription.
 - prescription dosage details* means—
 - (a) any details concerning the name, form, strength or quantity of the substance to be supplied included in the prescription, and
 - (b) if the strength of the substance is not included in a prescription because it is readily apparent—the strength at which it is ordinarily supplied.