



New South Wales

Poisons Amendment (Miscellaneous) Regulation 1996

under the
Poisons Act 1966

HIS Excellency the Governor, with the advice of the Executive Council, has made the following Regulation under the *Poisons Act 1966*.

Andrew Refshauge
Deputy Premier and Minister for Health

Explanatory note

The object of this Regulation is to amend certain provisions of the *Poisons Regulation 1994*:

- (a) to remove certain restrictions on the labelling of certain poisons as teratogenic or carcinogenic hazards, and
- (b) to remove certain restrictions on the prescription and supply of the substance “nystatin”, and
- (c) to tighten controls on the supply of Schedule 7 substances to scientifically qualified persons in charge of laboratories, and
- (d) to alter the requirements relating to the identification of authorities that are required to prescribe certain restricted substances, and
- (e) to modify the application of provisions concerning the supply of restricted substances in hospitals, and
- (f) to provide for the Director-General to approve the manner in which directions to administer a restricted substance, or a drug of addiction, may be given, and

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- (g) to allow drugs of addiction to be supplied by a pharmacist on the written requisition of a nurse in charge of a hospital ward as well as on the authorisation of a medical practitioner, dentist or veterinary surgeon, and
- (h) to provide for the supply of certain substances on the authorisation of a nurse in charge of a hospital ward, as well as on the authorisation of a medical practitioner or dentist, and
- (i) to modify the factors to be taken into account in the issue of a licence to supply Schedule 2 substances, and
- (j) to remove certain residential centres from the category of residential centres for disabled persons that are affected by the *Poisons Regulation 1994*, and
- (k) to remove certain alkyl homologues of tetrahydrocannabinol from the restrictions otherwise applicable to hallucinogens, and
- (l) to make revisions of a minor nature to clarify the application of certain provisions.

This Regulation is made under the *Poisons Act 1966*, including section 45C (the general regulation making power).

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1 Name of Regulation

This Regulation is the *Poisons Amendment (Miscellaneous) Regulation 1996*.

2 Commencement

This Regulation commences On 31 August 1996.

3 Amendment of the Poisons Regulation 1994

The *Poisons Regulation 1994* is amended as set out in Schedule 1.

4 Notes

The explanatory note does not form part of this Regulation.

**Schedule 1 Amendment of the Poisons
Regulation 1994**

(Clause 3)

[1] Clause 4 Packaging and labelling .generally

Insert “, and any quantity of a substance to which clause 25 applies supplied by a pharmacist on prescription or otherwise,” after “on prescription” in clause 4 (3).

[2] Clause 5

Omit the clause. Insert instead:

5 Misleading labelling of substances as poisons

A dealer must not supply any substance in a container that has a label that states or implies that the substance is a poison, unless the substance is a poison.

[3] Clause 13 Certain Schedule 3 substances

Omit “nystatin” from clause 13 (1).

**[4] Clause 20 Schedule 7 substances to be supplied and used only
under an authority**

Insert “for use in that laboratory or facility” after “facility” in clause 20 (4) (c).

**[5] Clause 25 Supply of certain Schedule 3 substances to be
recorded**

Omit “nystatin” from clause 25 (1).

[6] Clause 28

Omit the clause. Insert instead:

28 Misleading labelling of substances as restricted substances

A dealer must not supply any substance in a container that has a label that states or implies that the substance is a restricted substance, unless the substance is such a substance.

[7] Clause 39 Authority required to prescribe certain restricted substances

Omit clause 39 (4) (a). Insert instead:

- (a) in the case of a prescription that is issued in accordance with an authority under Part 7 that was granted to a particular person (by means of an instrument in writing given to the person), must be endorsed with the reference number shown on the authority, or

[8] Clause 49 Supply by pharmacists

Omit clause 49 (b). Insert instead:

- (b) on the written authorisation of a medical practitioner or dentist, where that authorisation is made on a patient's medication chart, or
- (c) on the written requisition of a medical practitioner, a dentist or the nurse in charge of the ward in which the substance is to be used or stored.

[9] Clause 51 Administration by persons employed at a hospital

Omit clause 51 (2). Insert instead:

- (2) Such a direction:
 - (a) must be given in writing or in some other manner approved by the Director-General, or
 - (b) in an emergency, may be given verbally, by telephone or by facsimile, or in any other manner approved by the Director-General.

[10] Clause 73

Omit the clause. Insert instead:

73 Misleading labelling of substances as drugs of addiction

A dealer must not supply any substance in a container that has a label that states or implies that the substance is a drug of addiction, unless the substance is such a drug.

[11] Clause 74 Packages to be sealed so that broken seal is readily distinguishable

Insert after clause 74 (2) (b):

- (b1) by a pharmacist employed at a hospital, on the written requisition of a medical practitioner, a dentist or the nurse in charge of the ward in which the drug is to be used or stored, or

[12] Clauses 77 and 77A

Omit the clause. Insert instead:

77 Responsibility for storage in hospitals

- (1) The chief pharmacist of a hospital is responsible for the storage of all drugs of addiction at a hospital other than those that have been supplied to a ward.
- (2) In the case of a hospital for which there is no pharmacist, the responsibilities of a chief pharmacist under this clause are instead the responsibilities of:
 - (a) the chief nurse of the hospital, or
 - (b) the medical superintendent of the hospital,as the chief executive officer of the hospital may determine.
- (3) The nurse in charge of a hospital ward is responsible for the storage of all drugs of addiction in the ward.

77A Storage in hospital wards

- (1) Drugs of addiction that are kept in a hospital ward must be stored apart from all other goods (other than prescribed restricted substances) in a separate room, safe, cupboard or other receptacle securely attached to a part of the ward and kept securely locked when not in immediate use.
- (2) The nurse in charge of a hospital ward must ensure that:
 - (a) the room, safe, cupboard or receptacle is kept securely locked when not in immediate use, and
 - (b) the key:
 - (i) is kept in the possession of a nurse whenever it is in the ward, and
 - (ii) is removed from the ward whenever there is no nurse in the ward.
- (3) The requirements of subclause (2) are satisfied if the key is kept on the hospital premises, in a separately locked safe to which only a nurse has access.

[13] Clause 78 Storage in pharmacies

Insert “to which only a pharmacist has access” after “safe” in clause 78 (4).

[14] Clause 78 (5)

Insert after clause 78 (4):

- (5) This clause applies to a hospital pharmacy as well as to a retail pharmacy.

[15] Clause 80 Prescriptions may only be issued for certain purposes

Omit clause 80 (2). Insert instead:

- (2) A dentist must not issue a prescription for a drug of addiction otherwise than for the dental treatment (for a period not exceeding one month’s continuous treatment) of a patient and must endorse any such prescription with the words “FOR DENTAL TREATMENT ONLY”.

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- (2A) If the patient is in a hospital, the dentist may issue a prescription for any drug of addiction.
- (2B) If the patient is not in a hospital, the dentist may issue a prescription only for a drug of addiction included in the list entitled "Preparations which may be Prescribed by Participating Dental Practitioners for Dental Treatment Only", as in force from time to time, being the list shown in the Schedule of Pharmaceutical Benefits for Approved Pharmacists and Medical Practitioners issued by the Department of Health and Family Services of the Commonwealth.

[16] Clause 100 Administration by persons employed at a hospital

Omit clause 100 (2). Insert instead:

- (2) Such a direction:
 - (a) must be given in writing or in some other manner approved by the Director-General, or
 - (b) in an emergency, may be given verbally, by telephone or by facsimile, or in any other manner approved by the Director-General.

[17] Clause 104 Possession of drugs of addiction by retail pharmacists

Insert after clause 104 (1):

- (1A) A retail pharmacist must not supply a drug of addiction to the chief nurse of a private hospital or nursing home unless the drug is supplied in accordance with a written order signed by the chief nurse.
- (1B) The chief nurse must not sign an order for any quantity of a drug of addiction if the quantity of that drug that will be in the possession of the chief nurse as a result of the order being filled will be in excess of the maximum quantity allowed by clause 105.

[18] Clause 117 Ward registers to be kept

Omit “drug register” wherever occurring.
Insert instead “ward register”.

[19] Clause 118 Entries in ward registers

Omit “drug register for that ward”;
Insert instead “ward register”.

[20] Clause 124

Omit clause 124. Insert instead:

124 Destruction of unusable drugs of addiction in public hospital wards

- (1) The nurse in charge of a ward in a public hospital having responsibility for a drug of addiction that becomes unusable must immediately notify the chief pharmacist of the hospital of the fact and of the circumstances under which the drug became unusable.
- (2) A pharmacist employed in a public hospital:
 - (a) may (but only in the presence of a nurse) destroy the drug of addiction, and
 - (b) in that event, must record the fact of the destruction of the drug in the ward register.
- (3) The entry must be dated and signed by the pharmacist and countersigned by the nurse who witnessed the destruction of the drug.
- (4) In the case of a public hospital for which there is no pharmacist, the functions of a chief pharmacist or pharmacist under this clause are instead the functions of:
 - (a) the chief nurse of the hospital, or
 - (b) the medical superintendent of the hospital,as the chief executive officer of the hospital may determine.

[21] Clause 138 Consideration of applications

Omit clause 138 (2) and (3). Insert instead:

(2) A licence may not be granted or renewed unless:

- (a) in the case of premises the subject of an existing licence issued before 7 April 1989 that is in force, the Director-General is satisfied that the premises to which the application relates are at least 6.5 kilometres (measured along the shortest practicable route) from the premises of the nearest retail pharmacist, or
- (b) in any other case, the Director-General is satisfied that the premises to which the application relates are at least 20 kilometres (measured along the shortest practicable route) from the premises of the nearest retail pharmacist.

[22] Clause 147 Authorities

Insert after clause 147 (1):

(1A) The Director-General may require a person seeking an authority to furnish such information as is necessary to enable the Director-General to determine the granting of the authority.

[23] Clause 151 Director-General may restrict authorisations conferred by this Regulation

Omit “of any other person” from clause 151 (2) (d).

Insert instead “of that or any other person”.

[24] Clause 160 Transitional

Insert “prescribe,” after “possess,” in clause 160 (4).

[25] Appendix A Labelling of therapeutic substances

Omit the item headed “Warning: therapeutic substances for internal use”.

Insert instead:

Warning: therapeutic substances for internal use

The label on a container of a therapeutic substance specified in Appendix F to the Uniform Standard (being a therapeutic substance that is intended for internal use) must bear the warning specified in that Appendix in respect of that substance.

The label on a container of a therapeutic substance specified in Appendix K to the Uniform Standard (being a therapeutic substance that is supplied on prescription and is intended for internal use in humans) must bear Warning Statement 39 or 40 specified in Part 1 of Appendix F to that Standard. The warning must be immediately preceded by a symbol in the form of an open equilateral triangle at least 4.5 millimetres high in bold print, coloured red.

[26] Appendix F Residential centres for disabled persons

Omit the following matter:

John Williams Centre, Warringah

Pennant Hills Hostel, Pennant Hills

York Road Cottages, Bondi Junction

[27] Appendix G Forms

Omit “*(as defined below)*” from Form 1.

[28] Dictionary

Omit paragraph (e) of the definition of **hallucinogen**.

Insert instead:

- (e) tetrahydrocannabinols and their alkyl homologues (except dronabinol (delta-9 tetrahydrocannabinol) when prepared and packed for therapeutic use, and nabilone).

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[29] Dictionary

Omit the definitions of *nurse* and *pharmacist*.

Insert instead:

nurse means a person who is a registered nurse within the meaning of the *Nurses Act 1991*.

pharmacist includes a pharmacy trainee working under the direct personal supervision of a pharmacist.