New South Wales

Poisons and Therapeutic Goods Amendment (Miscellaneous) Regulation 1999

under the

Poisons and Therapeutic Goods Act 1966

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

CRAIG KNOWLES, M.P.,

Minister for Health

Explanatory note

This Regulation makes the following miscellaneous amendments to the *Poisons and Therapeutic Goods Regulation 1994* (the Regulation):

(a) it inserts a standard provision to the effect that notes in the text of the Regulation do not form part of the Regulation—item [1],

(b) it removes the requirement that a prescription issued for the supply of nicotine in a form that is included in Schedule 3 to the Poisons List (for example, in the form of transdermal patches) comply with the requirements for prescriptions for restricted substances, and also removes the obligation on a pharmacist who supplies nicotine in that form to record certain details of the supply—item [2],

(c) it adds to the list of restricted substances that a person must not prescribe, administer or supply unless the person is the holder of an authority under Part 7 of the Regulation to do so, and makes it clear that such an authority is required in relation to the prescription of the substance isotretinoin only when it is to be prescribed for oral use—items [4] and [3],

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[12]

(d) it removes the prohibition on a pharmacist's supplying a restricted substance more than once on a ''repeat'' prescription issued in another State or Territory—item [5],

(e) it removes the requirement that a medical practitioner or dentist who, otherwise than in writing, directs the administration of a restricted substance or a drug of addiction to a patient in a hospital sign an entry in the patient's medical history confirming the direction within 24 hours after giving it and prescribes, instead, the follow-up steps that are to be taken if the direction is given (in an emergency) verbally or by telephone or by another method approved by the Director-General of the Department of Health (the Director-General)—items [6], [7], [13] and [14],

(f) it removes the requirement that, before a medical practitioner can prescribe or supply certain drugs of addiction for continuous therapeutic use for a period of up to 12 months by a person who (in the opinion of the practitioner) requires the drugs for the relief of pain associated with cancer, a cancer specialist or other medical practitioner approved by the Director-General make the diagnosis of cancer and estimate the person's life expectancy to be 12 months or less and allows, instead, the medical practitioner prescribing or supplying the drug to make the estimation of life expectancy—items [9] and [11],

(g) it permits a medical practitioner to prescribe or supply the drug fentanyl in the form of transdermal patches in the circumstances referred to in paragraph (f)—items [10] and [12],

(h) it inserts a note drawing attention to the fact that the information required to be shown on a label ''on'' a container of a therapeutic substance may be shown by markings on the container itself rather than on something attached or affixed to the container, and specifies that the information must be in the English language and in durable characters—items [16] and [17],

(i) it prescribes an alternative form of wording for labels for preparations that are not to be taken internally—item [18],

(j) it adds the substance ketamine to the list of substances that are prescribed for the purposes of section 16 (Offences relating to prescribed restricted substances) of the *Poisons and Therapeutic Goods Act 1966* (the Act), and prescribes the amount of 2.0 grams of that substance for the purposes of section 18A (Evidentiary provisions) of the Act—item [19],

(k) it prescribes the carrying out of first aid by the holders of certain first aid certificates for the purposes of paragraph (d) of the definition of ***supply by wholesale*** in section 4 (1) of the Act (thus authorising the supply in wholesale quantities of certain substances for the purpose of that activity)—item [20],

(l) it amends the definition of ***hallucinogen*** so as to exclude from its ambit tetrahdyrocannabinols and their alkyl homologues in hemp seed oil in certain circumstances—item [21],

(m) it makes consequential amendments—items [8] and [15].

This Regulation is made under the *Poisons and Therapeutic Goods Act 1966*, and, in particular, under section 45C (the general regulation-making power) and the sections mentioned above.

Poisons and Therapeutic Goods Amendment (Miscellaneous) Regulation 1999

1 Name of Regulation

This Regulation is the *Poisons and Therapeutic Goods Amendment (Miscellaneous) Regulation 1999*.

2 Commencement

This Regulation commences on 1 October 1999.

3 Amendment of Poisons and Therapeutic Goods Regulation 1994

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

4 Notes

The explanatory note does not form part of this Regulation.

Schedule 1 Amendments

(Clause 3)

[1] Clause 3A

Insert after clause 3:

3A Notes

Notes in the text of this Regulation do not form part of the Regulation.

[2] Clauses 13 and 25

Omit ''nicotine'' wherever occurring in clauses 13 (1) and 25 (1).

[3] Clauses 39 (1), 53 (1) and 55 (1)

Insert ''for oral use'' after ''isotretinoin'' wherever occurring.

[4] Clauses 39 (1), 53 (1) and 55 (1)

Insert in alphabetical order ''follitropin beta'', ''luteinising hormone'' and ''tretinoin for oral use''.

[5] Clause 41 Prescriptions may be filled only if in proper form

Insert ''(a) or (b)'' after ''subclause (2)'' in clause 41 (3).

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

Omit clause 51 (2) and (3). Insert instead:

(2) Such a direction:

(a) must be given in writing (otherwise than by facsimile) or in any other manner approved by the Director-General for the purposes of this paragraph, or

(b) in an emergency, may be given:

(i) by facsimile, or

(ii) verbally, by telephone or in any other manner approved by the Director-General for the purposes of this subparagraph.

(3) A medical practitioner or a dentist who gives a direction under subclause (2) (b) (ii) must:

(a) as soon as is practicable (and in any case within the next 24 hours) either:

(i) sign an entry in the patient's medical history confirming that he or she has given the direction, or

(ii) confirm the direction by facsimile, and

(b) attend to review the patient as soon as he or she considers it appropriate in the circumstances of the case.

[7] Clause 51 (4A)

Insert after clause 51 (4):

(4A) A medical practitioner or a dentist who, by facsimile, gives or confirms a direction for the administration of a restricted substance to a patient must attend to review the patient as soon as he or she considers it appropriate in the circumstances of the case.

[8] Clause 51 (5)

Omit ''and (4)''. Insert instead '', (4) and (4A)''.

[9] Clause 86 Exceptions to section 28 (a) and (b)—prescription

Omit clause 86 (2). Insert instead:

(2) A medical practitioner is authorised to issue a prescription for a drug of addiction for a person as referred to in section 28 (a) or (b) of the Act for continuous therapeutic use by that person for a period of up to 12 months without an authority under section 29 of the Act if:

(a) the medical practitioner is of the opinion that the person requires the drug for the relief of pain associated with cancer, and

(b) a medical practitioner (whether or not the medical practitioner referred to in paragraph (a)) whose qualifications in the diagnosis and treatment of cancer are recognised by the National Specialist Qualification Advisory Committee of Australia, or who is approved by the Director-General for the purposes of this paragraph, has made the diagnosis of cancer, and

(c) either the medical practitioner referred to in paragraph (a) or a medical practitioner referred to in paragraph (b) has estimated the person's life expectancy to be 12 months or less.

[10] Clause 86 (3)

Omit ''fentanyl (all forms)''.
Insert instead ''fentanyl (all forms, except transdermal patches)''.

[11] Clause 94 Exceptions to section 28 (a) and (b)—supply

Omit clause 94 (2). Insert instead:

(2) A medical practitioner is authorised to supply a drug of addiction for a person as referred to in section 28 (a) or (b) of the Act for continuous therapeutic use by that person for a period of up to 12 months without an authority under section 29 of the Act if:

(a) the medical practitioner is of the opinion that the person requires the drug for the relief of pain associated with cancer, and

(b) a medical practitioner (whether or not the medical practitioner referred to in paragraph (a)) whose qualifications in the diagnosis and treatment of cancer are recognised by the National Specialist Qualification Advisory Committee of Australia, or who is approved by the Director-General for the purposes of this paragraph, has made the diagnosis of cancer, and

(c) either the medical practitioner referred to in paragraph (a) or a medical practitioner referred to in paragraph (b) has estimated the person's life expectancy to be 12 months or less.

[12] Clause 94 (3)

Omit ''fentanyl (all forms)''.
Insert instead ''fentanyl (all forms, except transdermal patches)''.

[13] Clause 100 Administration by persons employed by a hospital

Omit clause 100 (2) and (3). Insert instead:

(2) Such a direction:

(a) must be given in writing (otherwise than by facsimile) or in any other manner approved by the Director-General for the purposes of this paragraph, or

(b) in an emergency, may be given:

(i) by facsimile, or

(ii) verbally, by telephone or in any other manner approved by the Director-General for the purposes of this subparagraph.

(3) A medical practitioner or a dentist who gives a direction under subclause (2) (b) (ii) must:

(a) as soon as is practicable (and in any case within the next 24 hours) either:

(i) sign an entry in the patient's medical history confirming that he or she has given the direction, or

(ii) confirm the direction by facsimile, and

(b) attend to review the patient as soon as he or she considers it appropriate in the circumstances of the case.

[14] Clause 100 (4A)

Insert after clause 100 (4):

(4A) A medical practitioner or a dentist who, by facsimile, gives or confirms a direction for the administration of a drug of addiction to a patient must also attend to review the patient as soon as he or she considers it appropriate in the circumstances of the case.

[15] Clause 100 (5)

Omit ''and (4)''. Insert instead '', (4) and (4A)''.

[16] Appendix A Labelling of therapeutic substances

Insert before clause 1:

Note. Although this Appendix refers to labels ''on'' a container, the information required by this Appendix may be shown by tags, brands, marks or statements in writing on the container itself (rather than on something affixed or attached to the container). See the definition of ***label*** in section 4 (1) of the Act.

[17] Appendix A, clause 1

Insert before the matter in clause 1:

(1) All details, words and other information that a label on a container of a therapeutic substance must carry must be in the English language (although it may also be in another language).

(2) All symbols, numbers and words on a label must be in durable characters.

[18] Appendix A, clause 1

Insert '', or the words 'FOR EXTERNAL USE ONLY','' after '' 'POISON' '' in clause 1 (3) (e).

[19] Appendix D Prescribed restricted substances

Insert in alphabetical order:

Ketamine..... 2.0 grams

[20] Appendix E Supply by wholesale

Insert after clause 16:

17 General first aid

A person who holds a current occupational first-aid certificate approved by the WorkCover Authority (as referred to in clause 8 (4) of the *Occupational Health and Safety (First Aid) Regulation 1989*) is authorised to be in possession of methoxyflurane and nitrous oxide in connection with the carrying out of first aid.

[21] Dictionary

Omit paragraph (e) in the definition of ***hallucinogen***.
Insert instead:

(e) tetrahydrocannabinols and their alkyl homologues except:

(i) dronabinol (delta-9 tetrahydrocannabinol) when prepared and packed for therapeutic use, and nabilone,

(ii) in hemp seed oil (being the oil obtained by cold expression from the ripened fruits or seeds of cannabis sativa) containing 50 mg/kg or less of tetrahydrocannabinols, when labelled ''Not for internal use'' or ''Not to be taken'', or

(iii) in products for purposes other than internal use containing 50 mg/kg or less of tetrahydrocannabinols.

BY AUTHORITY