HE306

POISONS ACT 1964

POISONS AMENDMENT REGULATIONS (No. 2) 1994

Made by the Lieutenant-Governor and deputy of the Governor in Executive Council.

Citation

1. These regulations may be cited as the *Poisons Amendment Regulations (No. 2) 1994.*

Principal regulations

2. In these regulations the *Poisons Regulations 1965** are referred to as the principal regulations.

[**Reprinted as at 7 January 1993. For amendments to 10 May 1994 see Gazettes of 28 May, 25 June, 9 July, 1 October, 12 November and 31 December 1993.*]

Regulation 2 amended

3. Regulation 2 of the principal regulations is amended—

(a) by deleting the definitions of "approved name", "internal use" and "SUSDP"; and

(b) by inserting, in the appropriate alphabetical positions, the following definitions—

"

"director of nursing" means a registered nurse appointed—

(a) to be in charge of a hospital; or

(b) to a remote area nursing post;

"distributor" means a person who imports, sells or otherwise supplies a poison or hazardous substance;

"dosage unit" means an individual dose of a poison and includes a tablet, capsule, cachet, single dose powder, or a single dose sachet of powders or granules;

"external" in relation to the use of a poison or hazardous substance, means application in the ears, eyes or nose, or to a body surface other than in the mouth, rectum, vagina, urethra or other body orifice;

"immediate container" includes any form of container in which a poison or hazardous substance is directly packed, but does not include any such container intended for consumption or any immediate wrapper;

"immediate wrapper" means metal foil, plastic foil, waxed paper, or any other such material not intended for consumption, when used as the first wrapper for a dosage unit or dressing;

"manufacturer" means a person who manufactures, produces, or packs a poison or hazardous substance;

"remote area nursing post" means a remote area site designated as a remote area nursing post by the Commissioner of Health under regulation 11;

"SUSDP" means the STANDARD FOR THE UNIFORM SCHEDULING OF DRUGS AND POISONS NO. 8 issued by the National Health and Medical Research Council and published by the Australian Government Publishing Service, Canberra;

".

Regulation 11 inserted

4. After regulation 10A of the principal regulations the following regulation is inserted—

"

Commissioner of Health may designate remote area nursing posts

11. (1) The Commissioner of Health may, in writing, designate a remote area site to be a remote area nursing post for the purposes of these regulations.

(2) The Commissioner of Health may amend or withdraw a designation under subregulation (1), in writing, at any time.

".

Regulation 16 amended

5. Regulation 16 of the principal regulations is amended by deleting "16 years" and substituting the following—

" 15 years ".

Regulation 19 amended

6. Regulation 19 of the principal regulations is amended by inserting after subregulation (2) the following subregulation—

"

(2a) For the purposes of this regulation, the interpretation provisions of Part 1 of the SUSDP shall be used to interpret Part 2 of the SUSDP as adopted by this regulation.

".

Regulation 21 amended

7. Regulation 21 (1) of the principal regulations is repealed and the following subregulation substituted—

" (1) Notwithstanding regulation 19, a medicine or preparation containing any poison or hazardous substance dispensed or supplied in the course of the professional practice of—

(a) a pharmaceutical chemist, medical practitioner, registered nurse at a remote area nursing post, or dentist, for human internal use shall comply with that regulation if it is labelled in the English language with—

(i) the words "Keep out of reach of children";

(ii) the name and strength or amount of each poison in the preparation, or the trade name and strength of the preparation (unless the trade name also uniquely identifies the strength, in which case only the trade name need be given);

(iii) the name of the patient;

(iv) a date of dispensing or supply, and a number identifying the prescription or supply which corresponds to—

(I) the entry in the Prescription Book referred to in regulation 36 (3) (c), in the case of a pharmaceutical chemist; or

(II) the patient's records, in the case of a medical practitioner, registered nurse at a remote area nursing post, or dentist;

(v) the name and address of the pharmacy, or medical or dental surgery, or remote area nursing post, from which it is supplied;

(vi) the instructions given on the prescription, if dispensed by a pharmaceutical chemist, or directions for use, if supplied by a medical practitioner, registered nurse at a remote area nursing post, pharmaceutical chemist or dentist; and

(vii) the total quantity contained;

(b) a pharmaceutical chemist, medical practitioner, registered nurse at a remote area nursing post or dentist, for human external use shall comply with that regulation if it is labelled in accordance with paragraph (a), together with the words "Not to be taken";

(c) a pharmaceutical chemist or veterinary surgeon, for use on any animal shall comply with that regulation if it is labelled in the English language with—

(i) the words "Keep out of reach of children";

(ii) the name and strength or amount of each poison in the preparation, or the trade name and strength of the preparation (unless the trade name also uniquely identifies the strength, in which case only the trade name need be given);

(iii) the owner's surname and the species of animal;

(iv) instructions for the use of that medicine or preparation;

(v) a date of dispensing, and a number identifying the prescription or supply which corresponds to—

(I) the entry in the Prescription Book referred to in regulation 36 (3) (c), in the case of a pharmaceutical chemist; or

(II) the patient's records, in the case of a veterinary surgeon;

(vi) the name and address of the pharmacy or veterinary practice, from which it is supplied;

(vii) the words "For veterinary use only" or "For animal treatment only", together with the words "For external use only" if the medicine or preparation is not prepared for internal use; and

(viii) the total quantity contained.

".

Regulation 21A amended

8. Regulation 21A of the principal regulations is amended by inserting after subregation (2) the following subregulations—

"

(3) A statement set out in subregulation (1) shall be in letters not less than 1.5mm in height and in a colour which provides a distinct contrast to the background colour of the container or label on which the statement appears.

(4) In this regulation—

"height" means the height of capital letters or lower case letters having an ascender or a descender.

".

Regulations 27AA and 27A repealed

9. Regulations 27AA and 27A of the principal regulations are repealed.

Regulation 33B amended

10. Regulation 33B of the principal regulations is amended—

(a) by inserting after the regulation designation "33B." the subregulation designation "(1)"; and

(b) by inserting the following subregulation—

"

(2a) For the purposes of this regulation the interpretation provisions of Part 1 of the SUSDP shall be used to interpret Appendix P of the SUSDP.

".

Heading amended

11. After regulation 34D of the principal regulations, the Division heading is amended by deleting "*Second and Third*".

Regulation 36 amended

12. Regulation 36 of the principal regulations is amended—

(a) in subregulation (1)—

(i) after paragraph (b) by deleting "or";

(ii) at the end of paragraph (c) (ii) by deleting the full stop and substituting the following—

" ; or "; and

(iii) by inserting the following paragraph—

"

(d) he or she is a registered nurse working at a remote area nursing post and he or she supplies a drug, not being a psychoactive drug—

(i) in accordance with regulation 36 (1) (c) (i);

(ii) for the treatment of an acute medical condition in compliance with the written standing orders of a medical practitioner which have been approved in writing by the Commissioner of Health; or

(iii) for the treatment of an acute medical condition in compliance with oral instructions of a medical practitioner for that particular patient.

";

(b) in subregulation (3) by deleting subparagraph (c) (i) and substituting the following subparagraph—

"

(i) for the purposes of this paragraph—

(I) handwritten records in a bound book with sequentially numbered pages;

(II) computer records on disk or tape that can be displayed and from which printed copies of the records can be produced on demand;

(III) microfilm, microfiche, or any other photographic systems in logical sequence and retrievable form;

(IV) client record cards, which include the details set out in a prescription; or

(V) alternative recording methods which have been specifically and individually approved in writing by the Commissioner of Health for the purposes of this paragraph,

are deemed to be the Prescription Book;

";

and

(c) by inserting after subregulation (3) the following subregulation—

"

(4) The following conditions shall be observed by persons supplying Fourth Schedule drugs under subregulation (1) (d)—

(a) the supply shall be recorded in the client record cards of the remote area nursing post and the record cards kept for a minimum of 2 years following the last entry in those records; and

(b) the drugs shall be labelled in accordance with regulation 21(1) (a) or 21(1) (b).

".

Regulation 38B repealed

13. Regulation 38B of the principal regulations is repealed.

Regulation 38C repealed and a regulation substituted

14. Regulation 38C of the principal regulations is repealed and the following regulation is substituted—

"

Clomiphene and Cyclofenil

38C. Clomiphene or cyclofenil or a substance containing clomiphene or cyclofenil and other substances specifically prepared to stimulate ovulation shall not be supplied except—

(a) by wholesale dealing;

(b) on the prescription or order of a medical practitioner specialising in gynaecology or obstetrics;

(c) on the prescription or order of a medical practitioner authorized in writing by the Commissioner of Health; or

(d) for the purpose of medical or scientific research, including veterinary trials under the direction of a veterinary surgeon.

".

Regulation 38H amended

15. Regulation 38H (c) of the principal regulations is amended by inserting after "meat," the following—

" edible offal, ".

Regulation 38J amended

16. The Table to regulation 38J of the principal regulations is amended by inserting, in the appropriate alphabetical positions, the following—

" atipamezole "; and " medetomidine ".

Regulations 38M and 38N inserted

17. After regulation 38L of the principal regulations the following regulations are inserted—

"

Clozapine

38M. Clozapine or a substance containing clozapine shall not be supplied except—

(a) by wholesale dealing;

(b) on the prescription or order of a medical practitioner specialising in psychiatry; or

(c) on the prescription or order of a medical practitioner authorized in writing by the Commissioner of Health, for the treatment of a patient in a hospital.

Nitrofuran derivatives

38N. The Fourth Schedule nitrofuran derivatives listed in the Table to this regulation, or a substance containing any of those drugs, shall not be supplied except—

(a) by wholesale dealing;

(b) on the prescription or order of a medical practitioner for human use or in accordance with regulation 36 (1) (c); or

(c) on the prescription of a veterinary surgeon for use in the feeding or the treatment of an animal not used for meat, edible offal, egg or milk production.

Table

NITROFURAN DERIVATIVES

Furazolidone
Nifursol
Nitrofuran
Nitrofurantoin
Nitrofurazone.

".

Regulation 41C inserted

18. After regulation 41B of the principal regulations the following regulation is inserted—

"

Access to Seventh Schedule poisons

41C. A substance referred to in the Seventh Schedule shall not be stored for retail sale in any area or in any manner that allows physical access to that substance by any person other than—

(a) the owner of the business carried on on the premises where it is stored;

(b) a person employed on the premises where it is stored; or

(c) a person authorized to purchase Seventh Schedule substances by notice given under section 24 of the Act.

".

Regulation 44A amended

19. Regulation 44A (4) of the principal regulations is amended in paragraph (b) by deleting "quality" and substituting the following—

" quantity ".

Regulation 51F amended

20. Regulation 51F of the principal regulations is amended—

(a) in subregulation (1) by inserting after "30 days" the following—

"

, or for periods that in the aggregate over the preceding 12 months exceed 30 days, or for a course of treatment exceeding 30 days,

";

and

(b) in subregulation (2) by inserting after "30 days" the following—

"

, or for periods that in the aggregate over the preceding 12 months exceed 30 days, or for a course of treatment exceeding 30 days,

".

Regulation 56 amended

21. Regulation 56 (3) of the principal regulations is amended by deleting paragraph (a) and substituting the following paragraphs—

"

(a) to a pharmaceutical chemist who is in possession of a drug or drugs of addiction in an amount that is less than or equal to the amount prescribed by regulation 56A for the purposes of his or her profession or employment who stores the drug in a safe—

(i) of a type that was prescribed by regulation 56A (2) or (3); and

(ii) that was in place and used by him or her,

immediately before the commencement of the *Poisons Amendment Regulations (No. 2) 1993;*

(aa) to a pharmaceutical chemist who is in possession of a drug or drugs of addiction in an amount that is greater than the amount prescribed by regulation 56A for the purposes of his or her profession or employment who stores the drug in a safe—

(i) of a type that was prescribed by regulation 56A (2) or (3); and

(ii) that was in place and used by him or her,

immediately before the commencement of the *Poisons Amendment Regulations (No. 2) 1993,* if that safe complies with the additional security requirements prescribed by clause 2 of Appendix M;

".

Appendix A amended

22. Appendix A to the principal regulations is amended—

(a) in Form 4A in paragraphs (c) and (d) by deleting "16" wherever it occurs and substituting in each case the following—

" 15 ";

(b) in Form 5A in paragraphs (c) and (d) by deleting "16" wherever it occurs and substituting in each case the following—

" 15 ";

(c) in Form 6A in paragraphs (c) and (d) by deleting "16" wherever it occurs and substituting in each case the following—

" 15 "; and

(d) in Form 10 by deleting

"

1. The (a) approved name of the drug .....

(b) generic name of the drug .....

"

and substituting the following—

"

1. The generic name of the drug .....

".

Appendix M amended

23. Appendix M to the principal regulations is amended—

(a) in clause 1 (b) (iii) by deleting "that is at least 25 millimetres thick"; and

(b) in clause 2—

(i) in subclause (2) by deleting

" or

(b) the device's alarm control panel. "

and substituting the following—

"

(b) the detection device; or

(c) the device's alarm control panel.

";

and

(ii) in subclause (3) (b) by inserting after "installed" the following—

"

in compliance with the Australian Standard having the designation AS 2201.1-1986 and entitled "Intruder alarm systems Part 1: Systems installed in client's premises", and

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By Command of the Lieutenant-Governor and deputy of the Governor,

Dated 21 June 1994.

D. G. BLIGHT, Clerk of the Council.