

Queensland

Health (Drugs and Poisons) Amendment Regulation (No. 1) 2011

Subordinate Legislation 2011 No. 4

made under the

Health Act 1937

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1 Short title

This regulation may be cited as the *Health (Drugs and Poisons) Amendment Regulation (No. 1) 2011.*

2 Regulation amended

insert—

This regulation amends the *Health* (*Drugs and Poisons*) *Regulation 1996*.

3 Amendment of s 4 (Meaning of *manufacture*)

(1) Section 4(1)(a), after paragraph (a)—

`Example—

mix 2 substances that are not a controlled drug, restricted drug or a poison to produce a controlled drug, restricted drug or a poison'.

(2) Section 4(4), from 'written'—

omit, insert—

'certified written policy, about packing or repacking controlled or restricted drugs or poisons, published by the department.'.

4 Insertion of new s 5A

After section 5—

insert—

'5A Meaning of supervision and personal supervision

- '(1) **Supervision**, by a person of another person, includes supervision using any technology that allows reasonably contemporaneous and continuous communication between the persons.
- '(2) **Personal supervision**, by a person (the **supervisor**) of another person, includes supervision using any technology that allows reasonably contemporaneous and continuous communication between the persons, and allows reasonably contemporaneous

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and continuous observation by the supervisor of actions taken by the other person.

Example—videoconferencing'.

5 Amendment of s 9A (Classification of new drugs and poisons)

Section 9A(2)(b) and editor's note omit. insert—

'(b) the Secretary to the Department in which the *Therapeutic Goods Act 1989* (Cwlth) is administered, or the Secretary's delegate, decides the new drug or poison is not to be included in a schedule.'.

6 Amendment of s 10 (Packaging of controlled or restricted drugs or poisons)

Section 10(2), 'under a certification'—

omit, insert—

'in a way certified'.

7 Amendment of s 15 (Suitability of person to hold endorsement)

Section 15(1)—

insert-

'(e) whether the person engages, or has engaged, in conduct that risks, or is likely to risk, a controlled drug, a restricted drug or a poison being used for a purpose that is unlawful under a law of a State or the Commonwealth.'.

8 Amendment of s 24 (Procedure for suspension or cancellation of endorsement)

Section 24(5)—

omit, insert—

- '(5) If the chief executive decides to suspend or cancel the endorsement, the notice must—
 - (a) be a QCAT information notice for the decision; and
 - (b) state the day before which the endorsement holder is not permitted to apply to the chief executive under section 26A.
- '(5A) The day mentioned in subsection (5)(b) must be a day the chief executive believes is reasonable having regard to the grounds for the suspension or cancellation.'.

9 Amendment of s 25 (Urgent suspension or cancellation of endorsement)

Section 25(4)— *omit, insert*—

- '(4) The notice must—
 - (a) be a QCAT information notice for the decision; and
 - (b) state the day before which the endorsement holder is not permitted to apply to the chief executive under section 26A.
- '(4A) The day mentioned in subsection (4)(b) must be a day the chief executive believes is reasonable having regard to the grounds for the suspension or cancellation.'.

10 Amendment of s 43 (Controlled drug manufacturer licence)

Section 43(b)—

omit, insert—

- '(b) is taken to hold the following licences—
 - (i) a controlled drug wholesaler licence;
 - (ii) a restricted drug wholesaler licence;
 - (ii) a poison wholesaler licence.'.

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11 Amendment of s 45 (Offence to manufacture controlled drugs without licence)

Section 45(c)—
omit, insert—

'(c) is a State analyst, or a trainee State analyst under the supervision of a State analyst, who manufactures the controlled drug for the analyst's, or trainee's, official duties; or'.

12 Amendment of s 48 (General conditions that apply to controlled drug wholesaler licence)

(1) Section 48(2), 'A controlled'—

omit, insert—

'Subject to subsection (3), a controlled'.

(2) Section 48—

insert—

'(3) Subsection (2) does not apply to a controlled drug wholesaler to the extent the wholesaler carries on business under the wholesaler's licence in a way that does not require the wholesaler to store, handle or transport a controlled drug.'.

13 Insertion of new s 50A

Chapter 2, part 1, division 4—
insert—

'50A Discrepancy to be immediately reported to chief executive

- '(1) This section applies if a licensee—
 - (a) finds an discrepancy between—
 - (i) the quantity or volume of a class of controlled drug held by the licensee; and
 - (ii) the balance shown in the licensee's controlled drugs register for the drug; or

- (b) knows, or reasonably suspects, a controlled drug has been lost, misappropriated or stolen.
- '(2) The licensee must immediately give the chief executive written notice about the discrepancy, loss, misappropriation or theft.

Maximum penalty—40 penalty units.'.

14 Amendment of s 51 (Endorsement needed for controlled drugs)

Section 51(2)—
omit, insert—

'(2) A person must not obtain a controlled drug unless the person is, under this regulation, endorsed to obtain the drug.

Maximum penalty—80 penalty units.'.

15 Omission of s 53 (Approved dispenser)

Section 53—
omit.

16 Amendment of s 58 (Doctors)

Section 58—

insert—

'(2) A doctor is authorised to obtain, possess or use a controlled drug, other than a regulated controlled drug, for a genuine research or teaching purpose.'.

17 Amendment of s 58B (Hospital pharmaceutical assistants)

Section 58B, 'in the hospital'—
omit.

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18 Replacement of s 59 (Hospitals)

Section 59—

omit, insert—

'59 Hospitals

- The persons authorised to do an authorised thing at a hospital are—
 - (a) the medical superintendent of the hospital; and
 - (b) a doctor nominated by the medical superintendent; and
 - (c) if there is a pharmacist in charge of the hospital's dispensary—
 - (i) the pharmacist in charge; and
 - (ii) a pharmacist nominated in writing by the pharmacist in charge.
- '(2) Subsection (3) applies if none of the persons mentioned in subsection (1) are present at the hospital.
- '(3) The director of nursing of the hospital is authorised to do an authorised thing.
- '(4) If subsection (2) applies and the director of nursing is not present at the hospital, the registered nurse in charge of the hospital is authorised to do an authorised thing.
- '(5) In this section—do an authorised thing, at a hospital, means—
 - (a) obtain a controlled drug for use at the hospital; or
 - (b) possess a controlled drug at the hospital; or
 - (c) issue a controlled drug for treatment of the hospital's patients.'.

19 Amendment of s 64 (Pharmacists)

Section 64(2)—

omit, insert—

- '(2) A pharmacist is authorised to obtain, possess or use a controlled drug, other than a regulated controlled drug, for a genuine research or teaching purpose.
- '(3) A trainee pharmacist is authorised to do, under a pharmacist's direction and personal supervision, anything a pharmacist is authorised to do under subsection (1).'.

20 Amendment of s 70 (State analysts)

Section 70—

insert—

- '(2) A trainee State analyst under the personal supervision of a State analyst is authorised to—
 - (a) obtain or manufacture a controlled drug; or
 - (b) possess a controlled drug at the place where the trainee is performing official duties; or
 - (c) use a controlled drug for official purposes or destroy it.'.

21 Insertion of new s 70AA

After section 70—

insert—

'70AA State forensic and scientific service facilities

- '(1) To the extent necessary to perform the person's official duties, the person in charge of a forensic and scientific facility operated by the State is authorised to—
 - (a) possess a controlled drug; or
 - (b) destroy a controlled drug.
- '(2) The person in charge may delegate the authority to an appropriately qualified officer of the department.
- '(3) In this section—

appropriately qualified, for an officer of the department, includes having the qualifications, experience or standing appropriate to the exercise of the authority.'.

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22 Amendment of s 71 (Veterinary surgeons)

Section 71—

insert—

'(2) A veterinary surgeon is authorised to obtain, possess or use a controlled drug, other than a regulated controlled drug, for a genuine research or teaching purpose.'.

23 Amendment of s 74 (When endorsement is not needed)

(1) Section 74(2), 'Also, a'—

omit, insert—

'Α'.

(2) Section 74—

insert—

- '(3) A person does not need an endorsement to administer, dispense, issue, manufacture, obtain, possess, prescribe, supply or use a controlled drug for a clinical trial approved by—
 - (a) the Therapeutic Goods Administration; or
 - (b) a human research ethics committee registered by the Australian Health Ethics Committee established under the *National Health and Medical Research Council Act* 1992 (Cwlth).'.

24 Amendment of s 77 (Approved drug—dronabinol (*delta*-9-tetrahydrocannabinol))

Section 77, 'A person'—

omit, insert—

'Subject to section 74(3), a person'.

25 Amendment of s 78 (Specified condition drugs—amphetamine, dexamphetamine, methylamphetamine, methylphenidate, phenmetrazine)

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Section 78(1), 'A person'—

omit, insert—

'Subject to section 74(3), a person'.
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Amendment of s 80 (Restrictions on making prescriptions)

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Section 80(1), from 'the prescriber' to 'code'—

omit, insert—

'the code is certified'.
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27 Amendment of s 82 (Conditions of dispensing)

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Section 82(2)(f), '1 year'—

omit, insert—

'6 months'.
```

28 Amendment of s 83 (Dispensing generic drugs)

(1) Section 83(1), from '(the generic drug)'—
 omit, insert—
 'or without a brand name (both the generic drug).'.

(2) Section 83(2) and (3)— *omit, insert*—

- '(2) A dispenser may dispense the generic drug in place of the specified drug if the drug is dispensed at a public sector hospital.
- Also, a dispenser may dispense the generic drug in place of the specified drug at a place other than a public sector hospital if—

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- (a) the specified drug and the generic drug are both drugs to which a pharmaceutical benefit applies under the National Health Act; and
- (b) the prescriber did not indicate on the prescription that only the specified drug was to be dispensed; and
- (c) either—
 - (i) both of the following apply—
 - (A) the schedule of pharmaceutical benefits, issued by the Commonwealth department within which the National Health Act is administered, states the specified drug and the generic drug are equivalent;
 - (B) a determination is in force for the generic drug under the National Health Act, section 85(6); or
 - (ii) if the dispenser is a pharmacist, the pharmacist has, using a relevant process under the pharmacist's quality standard for dispensing controlled drugs, confirmed the specified drug and the generic drug are equivalent; and
- (d) it is lawful to dispense the generic drug on prescription; and
- (e) the person to whom it is dispensed asks for, or agrees to, the dispensing of the generic drug in place of the specified drug.
- '(4) If a generic drug is dispensed, the dispenser must enter, in the prescription—
 - (a) the brand name of the generic drug; or
 - (b) if the generic drug does not have a brand name, the name of the manufacturer of the drug.

Maximum penalty—20 penalty units.'.

29 Amendment of s 85 (Labelling dispensed and supplied medicines)

(1) Section 85(3)(c)—

omit, insert—

- '(c) the name and address of—
 - (i) the person selling the dispensed or supplied medicine; or
 - (ii) the business from which the dispensed or supplied medicine is sold; and'.
- (2) Section 85—

insert—

- '(3A) However, the warnings mentioned in subsection (1) or (3)(i) need not be printed or written on the label if the warning—
 - (a) appears on the dispensed or supplied medicine's container; and
 - (b) is clearly visible after the label is attached to the container.'
 - (3) Section 85(4)(b), after 'name', second mention—

insert—

', if any,'.

30 Insertion of new s 85A

After section 85—

insert—

'85A Sale of controlled drug after expiry date

'A person must not sell a controlled drug after the expiry date for the drug stated on the container for the drug or a label attached to the container.

Maximum penalty—60 penalty units.'.

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31 Amendment of s 88 (Stock to be checked)

Section 88(1), '7 days or more'—

omit, insert—

'more than 7 days'.

32 Amendment of s 94 (Unlawful possession of controlled drugs)

Section 94(2) and editor's note— *omit.*

Amendment of s 110 (Responsibility for checking accuracy of records at institutions)

(1) Section 110(1)(b), 'at least once a week'—

omit, insert

'at reasonable intervals'.

(2) Section 110(2)— *omit, insert*—

- '(2) The person who checks the stock of controlled drugs and inspects the records (the *checker*) must—
 - (a) write the date and results of the inspection on the record; and
 - (b) immediately report any of the following to the institution's medical superintendent or, if there is no medical superintendent, the chief executive—
 - (i) a contravention of this regulation;
 - (ii) an apparently excessive use of a controlled drug;
 - (iii) any discrepancy between the controlled drug in stock and the drugs the records indicate should be in stock; and
 - (c) if the checker knows, or reasonably suspects, a controlled drug has been lost, misappropriated or stolen,

immediately give the chief executive written notice about the loss, misappropriation or theft.

Maximum penalty—40 penalty units.'.

(3) Section 110(3)—

insert—

'reasonable interval means an interval of not more than 1 month that is reasonably necessary to carry out the check and inspection under subsection (1)(b).'.

(4) Section 110(3)—
renumber as section 110(4).

(5) Section 110—

insert-

'(3) The checker for an institution must be the responsible person for the institution or a doctor, pharmacist, registered nurse or hospital pharmaceutical assistant nominated in writing by the responsible person.'.

34 Amendment of s 112 (Records—ambulance officers, indigenous health workers and rural and isolated practice endorsed nurses

(1) Section 112, heading, after 'workers'—

insert—

', midwives'.

(2) Section 112(1) and (3), after 'worker'—

insert—

', midwife'.

(3) Section 112(2)—

omit, insert—

'(2) The ambulance officer, indigenous health worker, midwife or rural and isolated practice endorsed nurse must—

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- (a) use a separate record book or a separate part of the record book for each class of controlled drug; and
- (b) enter in the book—
 - (i) for an ambulance officer—full details of each transaction involving a controlled drug administered, obtained or used by the officer; or
 - (ii) for an indigenous health worker—full details of each transaction involving a controlled drug administered, obtained or used by the worker; or
 - (iii) for a midwife—full details of each transaction involving a controlled drug administered, obtained, supplied or used by the midwife; or
 - (iv) for a nurse—full details of each transaction involving a controlled drug administered, obtained, supplied or used by the nurse; and
- (c) make the entry as soon as possible after the controlled drug is administered, obtained, supplied or used by the officer, worker, midwife or nurse, but no later than the day after it is administered, obtained, supplied or used.

Maximum penalty—40 penalty units.'.

(4) Section 112(3)(d) and (f), after 'worker's'—

insert—

', midwife's'.

Amendment of s 113 (Record keeping for certain nursing practices and Queensland Ambulance Service stations)

Section 113(4)—

insert—

'(d) if the person knows, or reasonably suspects, a controlled drug has been lost, misappropriated or stolen, the person's knowledge, or reasonable suspicion, of the loss, misappropriation or theft.'.

36 Replacement of s 116A (Discrepancy to be immediately reported to chief executive)

Section 116A—
omit, insert—

'116A Discrepancy to be immediately reported to chief executive

- '(1) This section applies to a person who, under this division, is required to keep a record book, keep records or ensure records are kept, about transactions in controlled drugs and who—
 - (a) finds a discrepancy between the quantity or volume of a class of controlled drug kept by the person and the balance shown in the person's records for the drug; or
 - (b) knows, or reasonably suspects, a controlled drug has been lost, misappropriated or stolen.
- '(2) The person must immediately give the chief executive a written notice about the discrepancy, loss, misappropriation or theft.

Maximum penalty—40 penalty units.

'(3) If a person is punishable under this section, and also under section 113(4)(c), the person may be prosecuted and convicted under either section 113(4) or this section but not both.'.

37 Amendment of s 118 (Storage of controlled drugs at institutions)

Section 118(2)(c)—

omit, insert—

'(c) ensure the key or combination to, or other way used to personally access, the receptacle or secure place can not be used by a person who is not authorised to possess a controlled drug at the institution.'.

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38 Amendment of s 119 (Storage of controlled drugs generally)

Section 119(2)(b)—
omit, insert—

'(b) ensure the key or combination to, or other way used to personally access, the receptacle or secure place can not be used by a person who is not authorised to possess a controlled drug at the place.'.

39 Amendment of s 122 (Approval needed for treating drug dependent person with controlled drugs)

(1) Section 122, heading, 'drug dependent person'—

omit, insert—

'certain drug dependent persons'.

- (2) Section 122(10)—

 renumber as section 122(11).
- (3) Section 122—
 insert—
- '(10) This section does not apply to a relevant practitioner treating a drug dependent person as an inpatient in a hospital.'.

40 Amendment of s 137 (Restricted drug manufacturer licence)

Section 137(b) and (c)—
omit. insert—

- '(b) is taken to hold the following licences—
 - (i) a restricted drug wholesaler licence;
 - (ii) a poison manufacturer licence;
 - (ii) a poison wholesaler licence.'.

41 Amendment of s 139 (Offence to manufacture restricted drug without licence)

Section 139(b)—

omit, insert—

'(b) is a State analyst, or a trainee State analyst under the supervision of a State analyst, who manufactures the restricted drug for the analyst's, or trainee's, official duties: or'.

42 Amendment of s 142 (General conditions that apply to restricted drug wholesaler licence)

(1) Section 142(3) 'A restricted'—

omit, insert—

'Subject to subsection (4), a restricted'.

(2) Section 142—

insert—

'(4) Subsection (3) does not apply to a restricted drug wholesaler to the extent the wholesaler carries on business under the wholesaler's licence in a way that does not require the wholesaler to store, handle or transport a restricted drug.'.

43 Insertion of new s 144A

After section 144—

insert—

'144A Certain losses etc. to be immediately reported to chief executive

'If a licensee knows, or reasonably suspects that any of the following has been lost, misappropriated or stolen, the licensee must immediately give the chief executive a written notice about the loss, misappropriation or theft—

- (a) a restricted drug that is an anabolic steroidal agent;
- (b) a regulated restricted drug;

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(c) S4 pseudoephedrine.

Maximum penalty—40 penalty units.'.

44 Amendment of s 146 (Endorsement needed for restricted drugs)

- (1) Section 146(2)—
 omit. insert—
- '(2) A person must not obtain a restricted drug unless the person is, under this regulation, endorsed to obtain the drug.

 Maximum penalty—60 penalty units.'.
- (2) Section 146(6), 'Subsection (7)'—

 omit, insert—

 'Subsection (9)'.
- (3) Section 146(5), (6) and (7)—
 renumber as section 146(7), (8) and (9).
- (4) Section 146—
 insert—
- '(5) Subsection (6) applies to a person who may, under an endorsement, administer, dispense, issue, obtain, possess, prescribe or sell a restricted drug, or write a written instruction, or give an oral instruction, for a restricted drug.
- '(6) The person must not destroy a restricted drug unless the person is endorsed to destroy the drug.

Maximum penalty—60 penalty units.'.

45 Amendment of s 147 (Wholesale representative licence)

Section 147(1)(a), from 'for—'

omit, insert—

'for displaying or giving, as samples, to dentists, doctors, pharmacists or veterinary surgeons; and'.

Amendment of s 148 (Wholesale representative may obtain restricted drugs)

Section 148, from 'for—' omit, insert—

'for displaying or giving, as samples, to dentists, doctors, pharmacists or veterinary surgeons.'.

47 Amendment of s 149 (Storage etc. of samples)

Section 149(2), (4)(b)(ii) and (5)(a), after 'doctor'—

insert—

', pharmacist'.

48 Amendment of s 153 (Giving samples)

Section 153, after 'doctor'—
insert—
', pharmacist'.

49 Omission of s 156 (Approved dispensers)

Section 156—
omit.

50 Amendment of s 158A (Dental hygienists)

(1) Section 158A(1)—

insert—

- '(e) articaine.'.
- (2) Section 158A(3) and (4), 'to (d)'— *omit, insert*—

 'to (e)'.

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51 Amendment of s 158B (Dental therapists)

(1) Section 158B(1)—

insert-

- '(g) articaine.'.
- (2) Section 158B(3), 'to (f)'— *omit, insert*—

 'to (g)'.

52 Amendment of s 158C (Oral health therapists)

(1) Section 158C(1)—

insert—

- '(g) articaine.'.
- (2) Section 158C(3), 'to (f)' *omit, insert*—

 'to (g)'.

53 Amendment of s 161 (Doctors)

Section 161—

insert—

'(2) A doctor is authorised to obtain, possess or use a restricted drug, other than a regulated restricted drug, for a genuine research or teaching purpose.'.

54 Amendment of s 163A (Hospital pharmaceutical assistants)

Section 163A, 'in the hospital'— *omit*.

55 Replacement of s 164 (Hospitals)

Section 164—

omit, insert-

'164 Hospitals

- '(1) The persons authorised to do an authorised thing at a hospital are—
 - (a) the medical superintendent of the hospital; and
 - (b) a doctor nominated by the medical superintendent; and
 - (c) if there is a pharmacist in charge of the hospital's dispensary—
 - (i) the pharmacist in charge; and
 - (ii) a pharmacist nominated in writing by the pharmacist in charge.
- '(2) Subsection (3) applies if none of the persons mentioned in subsection (1) are present at the hospital.
- '(3) The director of nursing of the hospital is authorised to do an authorised thing.
- '(4) If subsection (2) applies and the director of nursing is not present at the hospital, the registered nurse in charge of the hospital is authorised to do an authorised thing.
- '(5) An employee of a hospital who is an adult (an *adult employee*) may, to the extent necessary to carry out the employee's duties at the hospital, and only under a medical gas protocol—
 - (a) possess a restricted medical gas; or
 - (b) issue a restricted medical gas for treatment of the hospital's patients.
- '(6) In this section—

do an authorised thing, at a hospital, means—

- (a) obtain a restricted drug for use at the hospital; or
- (b) possess a restricted drug at the hospital; or
- (c) issue a restricted drug for treatment of the hospital's patients.

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medical gas protocol means a certified document published by the department stating—

- (a) the qualifications an adult employee must have to possess or issue a restricted medical gas; and
- (b) the circumstances in which, and the conditions under which, an adult employee may possess or issue a restricted medical gas.

restricted medical gas means a gas that is a restricted drug ordinarily used for a medical purpose in a hospital.'.

56 Insertion of new s 167A

After section 167—
insert—

'167A Eligible midwives

- '(1) To the extent necessary to practise midwifery, an endorsed eligible midwife is authorised to prescribe a restricted drug.
- '(2) In this section—

endorsed eligible midwife means a midwife whose registration is endorsed under the Health Practitioner Regulation National Law (Queensland), section 94 as being qualified to prescribe scheduled medicines required for midwifery practice.'

57 Amendment of s 170 (Optometrists)

```
Section 170(1)(a)—

insert—

'(vi) 4% or less of lignocaine; or'.
```

58 Insertion of new s 170A

After section 170—
insert—

'170A Orthopists

- '(1) To the extent necessary to practise orthoptics, an orthoptist who has the relevant qualifications is authorised to—
 - (a) obtain a restricted drug; and
 - (b) possess a restricted drug; and
 - (c) administer a restricted drug under a drug therapy protocol.
- '(2) In this section—

relevant qualifications means the qualifications required under a drug therapy protocol to administer a restricted drug.'.

59 Amendment of s 171 (Pharmacists)

(1) Section 171(1)—

insert—

- '(f) destroy, or otherwise dispose of, a restricted drug in a way that poses no risk, or only a negligible risk, of a person gaining access to the drug.'.
- (2) Section 171(2)—

omit, insert—

- '(2) A trainee pharmacist is authorised to do, under a pharmacist's direction and personal supervision, anything a pharmacist is authorised to do under subsection (1).'.
- (3) Section 171—

insert—

'(4) A pharmacist is authorised to obtain, possess or use a restricted drug, other than a regulated restricted drug, for a genuine research or teaching purpose.'.

60 Amendment of s 175 (Registered nurses)

(1) Section 175(2A), 'or nurse practitioner'—

omit, insert—

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', nurse practitioner or physician's assistant'.

(2) Section 175(3), from 'to administer'—

omit, insert—

'to-

- (a) obtain a vaccine or other restricted drug; or
- (b) administer a vaccine or other restricted drug under a drug therapy protocol.'.

61 Amendment of s 179 (State analysts)

Section 179—

insert—

- '(2) A trainee State analyst under the personal supervision of a State analyst is authorised to—
 - (a) obtain or manufacture a restricted drug; or
 - (b) possess a restricted drug at the place where the trainee is performing official duties; or
 - (c) use a restricted drug for official purposes or destroy it.'.

62 Insertion of new s 179AAA

After section 179—

insert—

'179AAA State forensic and scientific service facilities

- '(1) To the extent necessary to perform the person's official duties, the person in charge of a forensic and scientific facility operated by the State is authorised to—
 - (a) possess a restricted drug; or
 - (b) destroy a restricted drug.
- '(2) The person in charge may delegate the authority to an appropriately qualified officer of the department.
- '(3) In this section—

appropriately qualified, for an officer of the department, includes having the qualifications, experience or standing appropriate to the exercise of the authority.'.

63 Amendment of s 180 (Veterinary surgeons)

Section 180—

insert—

'(2) A veterinary surgeon is authorised to obtain, possess or use a restricted drug, other than a regulated restricted drug, for a genuine research or teaching purpose.'.

Amendment of s 183 (When endorsement is not needed)

Section 183—

insert—

- '(3) Further, a person does not need an endorsement to administer, dispense, issue, manufacture, obtain, possess, prescribe, supply or use a restricted drug for a clinical trial approved by—
 - (a) the Therapeutic Goods Administration; or
 - (b) a human research ethics committee registered by the Australian Health Ethics Committee established under the *National Health and Medical Research Council Act* 1992 (Cwlth).'.

Amendment of s 186 (Acitretin, etretinate, isotretinoin and tretinoin)

(1) Section 186(1)—

insert—

- '(c) is either—
 - (i) a registrar in dermatology working directly under the supervision of a specialist health practitioner in the specialty of dermatology; or

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- (ii) a registrar training to be a specialist physician working directly under the supervision of a specialist physician.'.
- (2) Section 186(2)(a), from 'clinical'—

omit, insert—

'a clinical trial approved by—

- (i) the Therapeutic Goods Administration; or
- (ii) a human research ethics committee registered by the Australian Health Ethics Committee established under the *National Health and Medical Research Council Act 1992* (Cwlth); or'.
- (3) Section 186(4)— *omit.*

66 Amendment of s 188A (Bosentan)

Section 188A—

insert—

'(c) is a registrar in cardiology, rheumatology or respiratory and sleep medicine working directly under the supervision of a specialist health practitioner in the specialty of cardiology, rheumatology or respiratory and sleep medicine.'.

67 Amendment of s 188B (Teriparatide)

(1) Section 188B(c)—

renumber as section 188B(d).

(2) Section 188B—

insert—

- '(c) is either—
 - (i) a registrar in endocrinology, geriatric medicine or rheumatology working directly under the supervision of a specialist health practitioner in the

- specialty of endocrinology, geriatric medicine or rheumatology; or
- (ii) a registrar training to be a specialist physician working directly under the supervision of a specialist physician; or'.

Amendment of s 189 (Exemptions for some acts involving certain regulated restricted drugs)

- (1) Section 189(2)—
 renumber as section 189(4).
- (2) Section 189—
 insert—
- '(2) Also, this part does not prevent either of the following from being carried out under the supervision of a relevant specialist or registrar under this part—
 - (a) a doctor or nurse practitioner administering, or giving an oral or written instruction to administer, a section 189 drug to a person who is an inpatient in a hospital (the *inpatient*);
 - (b) a nurse administering a section 189 drug to an inpatient in a hospital under an oral or written instruction mentioned in paragraph (a).
- '(3) Subsection (2) applies only if the inpatient was receiving treatment with the section 189 drug immediately before becoming an inpatient in the hospital.'.

69 Amendment of s 190 (Prescribing restricted drugs)

(1) Section 190(2)(h), 'if' to 'assistant', first mention—
omit, insert—

'if a prescriber, other than a veterinary surgeon,'.

(2) Section 190(2)(i), 'if' to 'surgeon'—

omit, insert—

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'if a prescriber'.

(3) Section 190—

insert—

- '(5A) Despite subsection (5), the prescriber may use another certified way to indicate the prescriber's approval of the particulars in the prescription, if the prescription—
 - (a) is generated by a computer; and
 - (b) is to be dispensed at a pharmacy operated by the State.'.
 - (4) Section 190(6)(b), 'the approved'—

omit, insert—

'a certified'.

(5) Section 190(7)— *omit.*

70 Amendment of s 191 (Restrictions on making prescriptions)

Section 191(1), from 'the prescriber' to 'code'—

omit, insert—

'the code is certified'.

71 Amendment of s 195 (Dispensing generic drugs)

(1) Section 195(1), from '(the *generic drug*)'— *omit, insert*—

'or without a brand name (both the generic drug).'.

(2) Section 195(2) and (3) omit. insert—

'(2) A dispenser may dispense the generic drug in place of the specified drug if the drug is dispensed at a public sector hospital.

- Also, a dispenser may dispense the generic drug in place of the specified drug at a place other than a public sector hospital if—
 - (a) the specified drug and the generic drug are both drugs to which a pharmaceutical benefit applies under the National Health Act; and
 - (b) the prescriber did not indicate on the prescription that only the specified drug was to be dispensed; and
 - (c) either—
 - (i) both of the following apply—
 - (A) the schedule of pharmaceutical benefits, issued by the Commonwealth department within which the National Health Act is administered, states the specified drug and the generic drug are equivalent;
 - (B) a determination is in force for the generic drug under the National Health Act, section 85(6); or
 - (ii) if the dispenser is a pharmacist, the pharmacist has, using a relevant process under the pharmacist's quality standard for dispensing restricted drugs, confirmed the specified drug and the generic drug are equivalent; and
 - (d) it is lawful to dispense the generic drug on prescription; and
 - (e) the person to whom it is dispensed asks for, or agrees to, the dispensing of the generic drug in place of the specified drug.
- '(4) If a generic drug is dispensed, the dispenser must enter, in the prescription—
 - (a) the brand name of the generic drug; or
 - (b) if the generic drug does not have a brand name, the name of the manufacturer of the drug.

Maximum penalty—20 penalty units.'.

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72 Amendment of s 197 (Dealing with prescriptions)

Section 197(3) and (4)—

omit, insert—

- '(3) Subsection (4) applies if a dispenser is asked to dispense a section 197 restricted drug for a person—
 - (a) more frequently than appears to be reasonably necessary; or
 - (b) in a greater quantity or volume than appears to be reasonably necessary.
- '(4) The dispenser must immediately give the chief executive a written notice about—
 - (a) the circumstances in which the dispenser has been asked to dispense the section 197 restricted drug; and
 - (b) the quantity or volume of the section 197 restricted drug dispensed; and
 - (c) when it has been dispensed for the person.

Maximum penalty—40 penalty units.

'(5) In this section—

section 197 restricted drug means—

- (a) restricted drug of dependency; or
- (b) an anabolic steroidal agent that is a restricted drug.'.

73 Amendment of s 198 (Labelling dispensed medicines)

(1) Section 198(3)(c)—

omit, insert—

- '(c) the name and address of—
 - (i) the person selling the dispensed or supplied medicine; or
 - (ii) the business from which the dispensed or supplied medicine is sold; and'.
- (2) Section 198(4)(b), after 'name', second mention—

insert—

', if any,'.

(3) Section 198—

insert—

- '(6) However, the warnings mentioned in subsection (1) and the words mentioned in subsection (3)(i)(i) or (ii) need not be printed or written on the label if the warning—
 - (a) appears on the dispensed or supplied medicine's container; and
 - (b) is clearly visible after the label is attached to the container.'

74 Insertion of new s 198A

After section 198—

insert—

'198A Sale of restricted drug after expiry date

'A person must not sell a restricted drug after the expiry date for the drug stated on the container for the drug or a label attached to the container.

Maximum penalty—60 penalty units.'.

75 Amendment of s 203 (Dealing with purchase orders)

(1) Section 203(1), from 'must'—

omit, insert—

'must write on the front of the order—

- (a) the date the drug is sold; and
- (b) the name and address of the dispensary at or from which the drug is sold.

Maximum penalty—40 penalty units.'.

(2) Section 203(5)—

omit.

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(3) Section 203(6)—

renumber as section 203(5).

76 Amendment of s 204 (Unlawful possession of restricted drugs)

Section 204(2) and editor's note— *omit.*

77 Amendment of s 207 (Records of restricted drugs supplied to be kept)

Section 207(3)(d) and (e)—
omit. insert—

- '(d) the directions for use stated in the instruction on which, or the drug therapy protocol under which, the restricted drug is supplied; and
- (e) for an instruction, the name of the person who gave the instruction; and'.

78 Amendment of s 213 (Approval needed for treating drug dependent person with restricted drugs of dependency)

(1) Section 213, heading, 'drug dependent person'—

omit, insert—

'certain drug dependent persons'.

(2) Section 213(9)—

renumber as section 213(10).

(3) Section 213—
insert—

'(9) This section does not apply to a relevant practitioner treating a drug dependent person as an inpatient in a hospital.'.

79 Amendment of s 227 (Offence to manufacture S2, S3 or S7 poisons without licence)

Section 227(b)—
omit, insert—

'(b) is a State analyst, or a trainee State analyst under the supervision of a State analyst, who manufactures the poison for the analyst's, or trainee's, official duties; or'.

80 Amendment of ss 231 and 232

Sections 231 and 232, 'and S7'—
omit.

Amendment of s 240A (Obtaining, possession or use of strychnine)

Section 240A—

insert—

- '(1A) However, a responsible adult authorised by a person who holds a strychnine permit (the *permit holder*) may possess or use strychnine under the permit but only—
 - (a) in accordance with the conditions of the permit; and
 - (b) under the supervision of the permit holder.
- '(1B) Without limiting subsection (1A)(a), the responsible adult must possess or use the strychnine in accordance with the conditions stated in section 242(2).'.

82 Amendment of s 242 (Permit conditions)

(1) Section 242(1)—

omit, insert—

'(1) A person who is the holder of a strychnine permit, or a responsible adult authorised under section 240A(1A) (each a *person in possession*), must keep either the permit or a copy

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of the permit with the person while the person possesses strychnine under the permit.

Maximum penalty—20 penalty units.'.

(2) Section 242(2), 'holder of a strychnine permit'—

omit, insert—

'person in possession'.

(3) Section 242(2)(b), 'holder's'—

omit, insert—

'person's'.

83 Amendment of s 243 (Endorsement needed for S2, S3 or S7 poison)

(1) Section 243(4), 'Subsection (5)'—

omit, insert—

'Subsection (6)'.

- (2) Section 243(3), (4) and (5) renumber as section 243(4), (5) and (6).
- (3) Section 243—
 insert—
- '(3) A person who may, under an endorsement, administer, dispense, issue, prescribe or sell an S2, S3 or S7 poison, or write a written instruction or give an oral instruction for an S2, S3 or S7 poison, must not destroy an S2, S3 or S7 poison unless the person is endorsed to destroy the poison.

Maximum penalty—40 penalty units.'.

84 Omission of s 245 (Approved dispensers)

Section 245—
omit.

85 Replacement of ss 248 to 248B

Sections 248, 248A and 248B—

omit, insert—

'248 Dental hygienists

'To the extent necessary to perform a dental hygienist's functions as a dental hygienist, a dental hygienist is authorised to administer the following S2 and S3 poisons—

- (a) fluorides in preparations for topical human therapeutic
- (b) lignocaine when in preparations for topical human therapeutic use (other than eye drops) that contain not more than 10% lignocaine;
- (c) silver salts;
- (d) adrenalin of a strength of not more than 0.1%, if administered by a pre-loaded device for the management of anaphylaxis.

Example for paragraph (d)—an EpiPen.

'248A Dental therapists

- '(1) To the extent necessary to perform a dental therapist's functions as a dental therapist, a dental therapist is authorised to administer the following S2 and S3 poisons—
 - (a) ether;
 - (b) fluorides;
 - (c) lignocaine when in preparations for topical human therapeutic use (other than eye drops) that contain not more than 10% lignocaine;
 - (d) phenol;
 - (e) ferric sulphate;
 - (f) adrenalin of a strength of not more than 0.1%, if administered by a pre-loaded device for the management of anaphylaxis.

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Example for paragraph (f)—an EpiPen.

- '(2) Subsection (3) applies to a person (a *trainee*) who is undergoing a course of training, the successful completion of which will qualify the trainee to practise as a dental therapist.
- '(3) To the extent necessary to undergo the course of training, the trainee is authorised to administer the S2 and S3 poisons mentioned in subsection (1).

'248B Oral health therapists

- f(1) To the extent necessary to perform an oral health therapist's functions as an oral health therapist, an oral health therapist is authorised to administer the following S2 and S3 poisons—
 - (a) lignocaine when in preparations for topical human therapeutic use (other than eye drops) that contain not more than 10% lignocaine;
 - (b) silver salts;
 - (c) ether;
 - (d) fluorides;
 - (e) phenol;
 - (f) ferric sulphate;
 - (g) adrenalin of a strength of not more than 0.1%, if administered by a pre-loaded device for the management of anaphylaxis.

Example for paragraph (g)—an EpiPen.

- '(2) Subsection (3) applies to a person (a *trainee*) who is undergoing a course of training, the successful completion of which will qualify the trainee to practise as an oral health therapist.
- '(3) To the extent necessary to undergo the course of training, the trainee is authorised to administer the S2 and S3 poisons mentioned in subsection (1).'.

Amendment of s 252A (Hospital pharmaceutical assistants)

Section 252A, 'in the hospital'— *omit*.

87 Insertion of new s 256AA

After section 256—

insert—

'256AA Orthopists

- '(1) To the extent necessary to practise orthoptics, an orthoptist who has the relevant qualifications is authorised to administer an S2 or S3 poison under a drug therapy protocol.
- '(2) In this section—

relevant qualifications means the qualifications required under a drug therapy protocol to administer an S2 or S3 poison.'.

88 Amendment of s 257 (Pharmacists)

Section 257(1)—

omit, insert—

- '(1) To the extent necessary to practise pharmacy, a pharmacist is authorised to—
 - (a) dispense or sell, other than by wholesale, an S2, S3 or S7 poison at a dispensary; or
 - (b) destroy, or otherwise dispose of, an S2 or S3 poison in a way that poses no risk, or only a negligible risk, of a person gaining access to the poison.'.

89 Amendment of s 258 (Pharmacy assistants)

(1) Section 258, 'adult'—

omit.

(2) Section 258—

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insert—

'(2) For subsection (1), a competent employee must be an employee who is 16 years or more.'.

90 Amendment of s 265 (State analysts)

Section 265—

insert—

- '(2) A trainee State analyst, under the personal supervision of a State analyst, is authorised to—
 - (a) manufacture an S2, S3 or S7 poison; or
 - (b) use an S2, S3 or S7 poison or destroy it.'.

91 Amendment of s 267A (Wholesale representatives)

Section 267A, after 'doctor'—

insert-

', pharmacist'.

92 Amendment of s 270 (When endorsement is not needed)

(1) Section 270(2), 'Also, a'—

omit, insert—

'Α'.

(2) Section 270—

insert—

- '(4) A person does not need an endorsement to administer, dispense, manufacture, obtain, possess, prescribe, supply or use a controlled drug for a clinical trial approved by—
 - (a) the Therapeutic Goods Administration; or
 - (b) a human research ethics committee registered by the Australian Health Ethics Committee established under the *National Health and Medical Research Council Act* 1992 (Cwlth).'.

93 Amendment of s 271 (Prohibition on dispensing etc. regulated poisons)

(1) Section 271(1), 'not dispense'—*omit, insert*—'not destroy, dispense'.

(2) Section 271(1)(g)—

omit, insert—

- '(g) is a State analyst, or a trainee State analyst under the supervision of a State analyst, who manufactures, possesses, uses or destroys the regulated poison while performing the analyst's, or trainee's, official duties; or
- (h) is the person in charge of a forensic and scientific facility operated by the State, or a person nominated in writing by the person in charge, who possesses or destroys a regulated poison while performing the person's official duties.'.

94 Omission of s 273 (Prohibition on possession etc. of certain poisons)

Section 273—
omit.

omit, insert—

95 Amendment of s 275 (Dispensing generic poisons)

(1) Section 275(1), from '(the *generic poison*)'—

'or without a brand name (both the *generic poison*).'.

(2) Section 275(2) and (3)— *omit, insert*—

'(2) A dispenser may dispense the generic poison in place of the specified poison if the poison is dispensed at a public sector hospital.

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- '(3) Also, a dispenser may dispense the generic poison in place of the specified poison at a place other than a public sector hospital if—
 - (a) the specified poison and the generic poison are both poisons to which a pharmaceutical benefit applies under the National Health Act; and
 - (b) the prescriber did not indicate on the prescription that only the specified poison was to be dispensed; and
 - (c) either—
 - (i) both of the following apply—
 - (A) the schedule of pharmaceutical benefits, issued by the Commonwealth department within which the National Health Act is administered, states the specified poison and the generic poison are equivalent;
 - (B) a determination is in force for the generic poison under the National Health Act, section 85(6); or
 - (ii) if the dispenser is a pharmacist, the pharmacist has, using a relevant process under the pharmacist's quality standard for dispensing a poison, confirmed the specified drug and the generic drug are equivalent; and
 - (d) it is lawful to dispense the generic poison on prescription; and
 - (e) the person to whom it is dispensed asks for, or agrees to, the dispensing of the generic poison in place of the specified poison.
- '(4) If a generic poison is dispensed, the dispenser must enter, in the prescription—
 - (a) the brand name of the generic poison; or
 - (b) if the generic poison does not have a brand name, the name of the manufacturer of the poison.

Maximum penalty—20 penalty units.'.

96 Insertion of new s 276A

After section 276—

insert—

'276A Sale of S2 or S3 poison after expiry date

'A person must not sell an S2 or S3 poison after the expiry date for the poison stated on the container for the poison or a label attached to the container.

Maximum penalty—60 penalty units.'.

97 Insertion of new s 285B

Chapter 4, part 8

insert—

'285B Certain losses etc. immediately reported to chief executive

'If a person who sells a poison that is S3 pseudoephedrine knows, or reasonably suspects, that any of the poison that is S3 pseudoephedrine has been lost, misappropriated or stolen, the person must immediately give the chief executive a written notice about the loss, misappropriation or theft.

Maximum penalty—40 penalty units.'.

98 Amendment of s 286 (Prohibition on dispensing or supplying poisons to child under 16)

Section 286—

insert—

- '(4) Subsection (5) applies to—
 - (a) a supplier who may supply a poison under subsection (1) or (2), other than a veterinary surgeon; or
 - (b) a registered nurse who may supply an S3 poison under subsection (3).
- '(5) Despite subsections (1), (2) or (3), the supplier or registered nurse may supply the following S3 poisons to a child who is 14 years or more if the supplier or registered nurse is

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reasonably satisfied the child has a therapeutic need for the poison—

- (a) salbutamol;
- (b) terbutaline.'.

99 Amendment of s 297 (Colouring of grain baits)

Section 297, from 'way' to 'executive'—

omit, insert—

'certified way'.

100 Amendment of s 298 (Vaporisers and other devices)

Section 298(2)(b), 'by the chief executive'— *omit.*

101 Amendment of appendix 3 (Who must sign certain purchase orders for controlled or restricted drugs)

(1) Appendix 3, part 1, item 8, column 2, entry for the hospital's medical superintendent, after 'superintendent'—

insert-

'or, in the medical superintendent's absence, a doctor nominated in writing by the medical superintendent'.

(2) Appendix 3, part 1, item 8, column 2, entry for the pharmacist in charge of the hospital's dispensary, after 'dispensary'—

insert—

'or, in the pharmacist's absence, a pharmacist nominated in writing by the pharmacist in charge'.

(3) Appendix 3, part 2, item 9, column 2, entry for the hospital's medical superintendent, after 'superintendent'—

insert—

'or, in the medical superintendent's absence, a doctor nominated in writing by the medical superintendent'.

(4) Appendix 3, part 2, item 9, column 2, entry for the pharmacist in charge of the hospital's dispensary, after 'dispensary'—

insert-

'or, in the pharmacist's absence, a pharmacist nominated in writing by the pharmacist in charge'.

102 Amendment of appendix 4 (Computer-generated paper prescriptions)

(1) Appendix 4, section 2, 'The'—

omit, insert—

'Subject to subsection (2), the'.

(2) Appendix 4, section 2—

insert—

- '(2) The computer program may allow a certified person, or a certified class of persons to generate a prescription of the type mentioned in section 190(5A).'.
- (3) Appendix 4, section 4(1)(d), from 'printed'—

omit, insert—

'or section 190(2)(a) printed on the form.'.

103 Amendment of appendix 7 (Regulated poisons)

(1) Appendix 7, item 1—

insert—

'hydrocyanic acid and cyanide' and 'strychnine'.

(2) Appendix 7, item 4, entries for hydrocyanic acid and cyanide, and strychnine—

omit.

104 Amendment of appendix 8 (Restricted drugs of dependency)

Appendix 8, entry for benzodiazepines, 'barbiturates'—

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omit, insert—
'benzodiazepines'.

105 Amendment of appendix 9 (Dictionary)

- (1) Appendix 9, definitions certification, National Drugs and Poisons Schedule Committee and restricted drug—
 omit.
- (2) Appendix 9—

insert—

'certified means approved by the chief executive.

orthoptist means a person whose name is recorded in the Register of Orthoptists kept by the Australian Orthoptists Registration Body Pty Ltd ACN 095 117 678.

personal supervision see section 5A.

restricted drug means an S4 substance.

supervision see section 5A.

trainee State analyst means a person who is undergoing a course of training, the successful completion of which will qualify the trainee for appointment as a State analyst.'.

(3) Appendix 9, definition acceptable form of identification, before 'document'—

insert—

'current'.

(4) Appendix 9, definition *acceptable form of identification*, after paragraph (b)—

insert—

'Example of document—

driver licence'.

(5) Appendix 9, definition *administer*, from 'means'— *omit*, *insert*—

'means—

- (a) give a person a single treatment dose of the drug or poison, to be taken by the person immediately; or
- (b) cause an animal to take a single treatment dose of the drug or poison immediately.'.
- (6) Appendix 9, definition dispensed medicine—

insert—

- '(aa) supplied for human therapeutic use by a dentist who may supply the medicine while practising dentistry; or'.
- (7) Appendix 9, definition *drug therapy protocol*, 'document certified by the chief executive and'—

omit, insert-

'certified document'.

- (8) Appendix 9, definition *endorsement*, paragraph (c)— *omit*.
- (9) Appendix 9, definition *immunisation program*, paragraph (a), 'a district health service'—

omit, insert—

'the department'.

(10) Appendix 9, definition *ocular therapeutics protocol*, 'document certified by the chief executive and'—

omit, insert—

'certified document'.

- (11) Appendix 9, definitions *paramedic 3*, *paramedic 3* (*ECP*) and *paramedic 4*, 'by the chief executive'— *omit*.
- (12) Appendix 9, definition standard, 'Drugs'—

omit, insert—

'Medicines'.

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ENDNOTES

- 1 Made by the Governor in Council on 27 January 2011.
- 2 Notified in the gazette on 28 January 2011.
- 3 Laid before the Legislative Assembly on . . .
- 4 The administering agency is the Department of Health.

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