

Queensland



Subordinate Legislation 2003 No. 255

Health Act 1937

**HEALTH (DRUGS AND POISONS)
AMENDMENT REGULATION (No. 2) 2003**

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1 Short title

This regulation may be cited as the *Health (Drugs and Poisons) Amendment Regulation (No. 2) 2003*.

2 Regulation amended

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

3 Insertion of new ch 1, pt 5, div 2A

After section 20—

insert—

‘Division 2A—Applications for operating approvals

‘20A Purpose of division

‘This division states the requirements, in addition to the requirements in division 2, that apply to an application for an operating approval.

‘20B Who may apply for an operating approval

‘A person may apply for an operating approval only if the person is a pharmacist who is authorised, under section 64(1)(f),¹ to administer or supply a controlled drug, under a drug therapy protocol, on the instruction of a doctor.

‘20C Additional requirements for applications for operating approvals

‘(1) A person who applies for an operating approval must publish a notice about the application in a newspaper circulating generally in the area in which it is proposed to operate a controlled drugs administration facility.

‘(2) The notice must—

1 Section 64 (Pharmacists)

- (a) invite members of the local community to make written submissions to the applicant about the establishment and operation of the facility; and
- (b) state a period of at least 28 days after the notice is published in which submissions under paragraph (a) must be made.

‘(3) An application for an operating approval must include—

- (a) a copy of the notice published under subsection (1); and
- (b) copies of any submissions made to the applicant by members of the local community, in response to the notice; and
- (c) a statement made by the applicant about the views of members of the local community in relation to the likely impact of the facility on the amenity of the community.

‘20D Chief executive may require further information or documents

‘(1) If the chief executive considers further information or a document is required for deciding an application for an operating approval, the chief executive may—

- (a) by written notice given to the applicant, require the applicant to give the information or document to the chief executive within a reasonable period, of at least 21 days, stated in the notice; or
- (b) ask another person to give the information or document to the chief executive.

‘(2) Despite subsection (1)(a), the chief executive and the applicant may, within the period stated in the notice, agree to extend the period for complying with a requirement in the notice to a day (the “**agreed compliance day**”) after the end of the period stated in the notice.

‘(3) If the applicant is given a notice under subsection (1)(a) and does not comply with a requirement under the notice within the period stated in the notice, or if applicable by the agreed compliance day, the applicant is taken to have withdrawn the application.

‘20E Deciding applications for operating approvals

‘(1) The chief executive must not grant an operating approval for a controlled drugs administration facility proposed for an area unless the chief executive is satisfied it is appropriate for the facility to be in the area.

‘(2) In deciding whether it is appropriate, the chief executive may only consider—

- (a) the need for the facility in the area, taking into account the type and availability of health services in and near the area; and
- (b) the likely impact of the facility on the amenity of the local community, taking into account the views of members of the community.

‘20F Time for deciding applications for operating approvals

‘(1) The chief executive must decide an application for an operating approval within 30 days after the application is made (the **“decision period”**).

‘(2) However, if the chief executive has given the applicant a notice under section 20D(1)(a), the chief executive may extend the time for deciding the application—

- (a) for up to 30 days after the chief executive receives the information or document required under the notice (the **“extended decision period”**); or
- (b) if the chief executive and the applicant agree—for a reasonable period after the period mentioned in paragraph (a) (the **“agreed extended decision period”**).

‘(3) Also, if the chief executive has asked a person for information or a document under section 20D(1)(b), the chief executive may extend the time for deciding the application—

- (a) for up to 60 days after the chief executive receives the application (also the **“extended decision period”**); or
- (b) if the chief executive and the applicant agree—for a reasonable period after the period mentioned in paragraph (a) (also the **“agreed extended decision period”**).

‘(4) The chief executive must give the applicant a written notice about the extended decision period, or the agreed extended period, for a decision.

‘(5) If the chief executive fails to decide the application within the decision period, or if applicable, the latest extended decision period or agreed extended decision period, the failure is taken to be a decision by the chief executive to refuse to grant the operating approval.’.

4 Amendment of s 23 (Grounds for suspension or cancellation of endorsement)

Section 23—

insert—

‘(f) if the endorsement is an operating approval—the authority of the holder of the endorsement under section 64(1)(f) is suspended, cancelled or otherwise ceases.’.

5 Amendment of s 64 (Pharmacists)

Section 64(1)(f), before ‘supply’—

insert—

‘administer or’.

6 Amendment of s 84 (Dealing with prescriptions and certain written instructions)

Section 84(1), ‘supplying’—

omit, insert—

‘administering or supplying’.

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

(1) Section 85(5)—

omit.

(2) Section 85(6)—

renumber as section 85(5).

8 Amendment of s 86 (Record of transactions involving controlled drugs to be kept by pharmacist)

Section 86(6), ‘dispenses’—

omit, insert—

‘administers, dispenses’.

9 Insertion of new s 122A

After section 122—

insert—

‘122A Approval needed to establish or operate a controlled drugs administration facility

‘A person must not, without an operating approval, establish or operate a controlled drugs administration facility.

Maximum penalty—20 penalty units.’.

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

Section 142(2), from ‘supplying’ to ‘supply’—

omit, insert—

‘giving a restricted drug to the wholesaler’s representative to display or give’.

11 Amendment of s 144 (Records of transactions to be kept by licensee)

Section 144(4), ‘supplied’—

omit, insert—

‘given’.

12 Amendment of s 145 (Supply of samples)

(1) Section 145, heading—

omit, insert—

‘145 Persons to whom a licensee may give samples’.

(2) Section 145, ‘supply’—

omit, insert—

‘give’.

13 Amendment of s 147 (Wholesale representative licence)

(1) Section 147(a)—

omit, insert—

‘(a) is employed by a licensee or an interstate licensee in a capacity requiring the person to possess restricted drugs for—

(i) displaying, as samples, to pharmacists; or

(ii) displaying or giving, as samples, to dentists, doctors or veterinary surgeons; and’.

(2) Section 147, after paragraph (b)—

insert—

‘(2) In this section—

“interstate licensee” means a person who holds a licence, under a law of another State, equivalent to a restricted drug manufacturer licence or restricted drug wholesaler licence.’.

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

Section 148, from ‘possess’—

omit, insert—

‘possess it for—

(a) displaying, as samples, to a pharmacist; or

- (b) displaying or giving, as samples, to a dentist, doctor or veterinary surgeon.’.

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

(1) Section 149(1), from ‘displaying’ to ‘veterinary surgeon’—

omit, insert—

‘, under section 148, displaying or giving restricted drugs to a person’.

(2) Section 149(2), ‘supplies’—

omit, insert—

‘gives, under section 148,’.

(3) Section 149(2)(a), ‘supplying the drug’—

omit, insert—

‘giving the drug to the practitioner’.

(4) Section 149(2)(b), ‘the day of supply’—

omit, insert—

‘giving the drug to the practitioner’.

(5) Section 149(3), ‘the day of supply’—

omit, insert—

‘returning the drug’.

(6) Section 149(4)(b)(i) and (ii)—

omit, insert—

(i) the day the drug is given or returned; and

(ii) if the drug is given to a dentist, doctor or veterinary surgeon—the name and address of the person to whom the drug is given; and’.

(7) Section 149(4)(c), ‘supplied’—

omit, insert—

‘given’.

(8) Section 149(5)(a), ‘supplies’—

omit, insert—

‘gives’.

16 Amendment of s 150 (Returns of transactions)

Section 150(2)(b)—

omit, insert—

‘(b) include the quantity of each class of restricted drugs—

(i) received by the representative; and

(ii) given as a sample, or returned by, the representative; and

(c) include the invoice number for the restricted drugs given as samples or returned.’.

17 Amendment of s 153 (Supply of samples)

(1) Section 153, heading—

omit, insert—

‘153 Giving samples’.

(2) Section 153(1) and (2), ‘supply’—

omit, insert—

‘give’.

18 Amendment of s 168 (Mine sites etc.)

Section 168(2)(b), ‘supply’—

omit, insert—

‘give’.

19 Amendment of s 179A (Universities)

Section 179A(1)(c), ‘supply’—

omit, insert—

‘give’.

20 Amendment of s 265A (Universities)

Section 265A(1), ‘supply’—

omit, insert—

‘give’.

21 Amendment of s 267 (Watch-house keepers etc.)

Section 267, ‘issue’—

omit, insert—

‘give’.

22 Amendment of s 267A (Wholesale representatives)

Section 267A, ‘supply’—

omit, insert—

‘give’.

23 Amendment of s 272 (Fluoroacetic acid in baits)

Section 272(1), ‘supply’—

omit, insert—

‘give’.

24 Insertion of new ch 5, part 2, div 1 hdg

After chapter 5, part 2 heading—

insert—

***‘Division 1—Transitional provisions for Health (Drugs and Poisons)
Amendment Regulation (No. 1) 2000’.***

25 Amendment of s 309 (Definition for pt 3)

(1) Section 309, heading ‘pt 3’—

omit, insert—

‘div 1’.

(2) Section 309, ‘In this part’—

omit, insert—

‘In this division’.

(3) Section 309, ‘of this part’—

omit, insert—

‘of this section’.

26 Insertion of new ch 5, pt 2, div 2

After section 311—

insert—

***‘Division 2—Transitional provision for Health (Drugs and Poisons)
Amendment Regulation (No. 2) 2003***

‘312 Certain persons may operate a controlled drugs administration facility without an approval

‘(1) This section applies to a person who, immediately before the commencement, operated a facility that is, from the commencement, a controlled drugs administration facility.

‘(2) Despite section 122A, the person may operate the facility without an operating approval for so long as it operates—

(a) continuously from the commencement; and

(b) at the place where it operated immediately before the commencement.

‘(3) In this section—

“commencement” means commencement of this section.’.

27 Amendment of appendix 9 (Dictionary)

(1) Appendix 9, definitions “approval” and “supply”—

omit.

(2) Appendix 9—

insert—

‘**“approval”** means an approval given by the chief executive under this regulation, for a person to do a thing.

“controlled drugs administration facility” means a facility of which the primary purpose is administering controlled drugs under a drug therapy protocol.

“operating approval” means an approval granted by the chief executive to a person to establish and operate a controlled drugs administration facility.

“supply”, for a controlled or restricted drug or a poison, means give, or offer to give, a person 1 or more treatment doses of the drug or poison, to be taken by the person during a certain period.’

(3) Appendix 9, definition “administer”, after ‘the drug or poison’—

insert—

‘, to be taken by the person immediately’.

(4) Appendix 9, definition “treatment approval”, after ‘following’—

insert—

‘approvals’.

ENDNOTES

1. Made by the Governor in Council on 30 October 2003.
2. Notified in the gazette on 31 October 2003.
3. Laid before the Legislative Assembly on . . .
4. The administering agency is the Department of Health.