



Australian Capital Territory

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2014 (No 2)

Subordinate Law SL2014-26

The Australian Capital Territory Executive makes the following regulation under the *Medicines, Poisons and Therapeutic Goods Act 2008*.

Dated 21 October 2014.

KATY GALLAGHER
Minister

ANDREW BARR
Minister



Australian Capital Territory

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[Medicines, Poisons and Therapeutic Goods Act 2008](#)

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1 Name of regulation

This regulation is the *Medicines, Poisons and Therapeutic Goods Amendment Regulation 2014 (No 2)*.

2 Commencement

This regulation commences on the day after its notification day.

Note The naming and commencement provisions automatically commence on the notification day (see [Legislation Act](#), s 75 (1)).

3 Legislation amended

This regulation amends the *Medicines, Poisons and Therapeutic Goods Regulation 2008*.

4 Section 557 (3) (d)

omit

directions

substitute

recommendations

5 Section 563 (a)

substitute

- (a) must comply with any guidelines approved under section 574 (Guidelines for CHO decisions on applications); and

6 Section 566 (3) and (4)

substitute

- (3) After considering the application and any further information provided in accordance with a notice under subsection (2), the medicines advisory committee must—
- (a) for an application for review of a decision by the chief health officer—
 - (i) recommend that the chief health officer confirm the decision made; or
 - (ii) do both of the following:
 - (A) recommend that the chief health officer revoke the decision made;
 - (B) make a recommendation under paragraph (b) (i), (ii) or (iii); or
 - (b) recommend that the chief health officer—
 - (i) approve the application to prescribe a controlled medicine in the terms applied for; or
 - (ii) approve the application in terms different from those applied for; or
 - (iii) refuse to approve the application.
- Note 1* The medicines advisory committee may recommend that the chief health officer include conditions in the approval (see s 570 (2)).
- Note 2* The chief health officer must consider the committee's recommendation (see s 573).
- (4) A recommendation must be in writing.

7 Section 567 (2) and (3)

substitute

- (2) The medicines advisory committee may recommend that the chief health officer amend or revoke a controlled medicines approval, whether or not the approval was given on the recommendation of the committee.

Note The chief health officer must consider the committee's recommendation (see s 573).

- (3) A recommendation must be in writing.

8 Section 568 (4)

omit

on direction

substitute

following a recommendation

9 Section 569 (3) and (4)

substitute

- (3) After considering the application for review and any further information provided in accordance with a notice under subsection (2), the medicines advisory committee must recommend that the chief health officer—
- (a) confirm the original decision; or
 - (b) revoke the original decision; or

- (c) revoke the original decision and approve the application as recommended by the committee.

Note 1 The medicines advisory committee may recommend that the chief health officer include conditions in the approval (see s 570 (2)).

Note 2 The chief health officer must consider the committee's recommendation (see s 573).

- (4) A recommendation must be in writing.

10 Section 570 (2) and note

substitute

- (2) The medicines advisory committee may recommend that the chief health officer include conditions for the safe or proper use of a controlled medicine in a controlled medicines approval.

Note The chief health officer must consider the committee's recommendation (see s 573).

11 Section 573 heading

substitute

573 Medicines advisory committee—recommendations to CHO

12 Section 573 (1)

omit everything before paragraph (a), substitute

- (1) This section applies if the medicines advisory committee recommends that the chief health officer make a decision in relation to—

13 Section 573 (2) (a)

substitute

- (a) make the decision after considering the medicines advisory committee's recommendation; and

14 Section 574

substitute

574 Guidelines for CHO decisions on applications

- (1) The medicines advisory committee may give draft guidelines to the chief health officer in relation to decisions on applications under section 560 (Applications for CHO controlled medicines approvals).
- (2) The chief health officer may approve a draft guideline.
- (3) An approved guideline is a notifiable instrument.

Note A notifiable instrument must be notified under the [Legislation Act](#).

15 Section 584 (5) and (6)

substitute

- (5) After considering the application and any further information provided in accordance with a notice under subsection (4), the medicines advisory committee must—
 - (a) recommend that the chief health officer confirm the decision made; or
 - (b) recommend that the chief health officer revoke the decision made and approve the application as recommended by the committee.

Note The chief health officer must consider the committee's recommendation (see s 573).

- (6) A recommendation must be in writing.

16 Section 635 (1) (b)

substitute

(b) 6 other members.

17 Section 635 (2)

after

A person

insert

(other than a person mentioned in subsection (3) (ac) or (ad))

18 New section 635 (3) (aa) to (ad)

insert

(aa) at least 1 member who has had experience in the teaching or practice of pain or addiction medicine; and

(ab) at least 1 member who is a general practitioner; and

(ac) 1 member who is a pharmacist; and

Note **Pharmacist** does not include an intern pharmacist (see dict).

(ad) 1 member who represents consumers; and

19 New section 635 (3A)

insert

(3A) However, for subsection (3) only, if the appointment of a member (a **former member**) is ended before the last day of the period for which the former member was appointed, the medicines advisory committee is taken to still include the former member until the earlier of—

(a) 4 months from the day the former member's appointment ended; or

(b) a member is appointed to replace the former member.

20 Section 640

omit

2

substitute

4

21 Section 643 (4)

omit

1 member

substitute

the members who do not have a material interest in the issue

22 Section 643 (4), example

substitute

Example

if 6 members are present at the meeting and 2 members disclose a material interest, the other 4 members may decide whether the members who made the disclosure can take part in a decision by the committee

23 Section 644 (2) (a)

substitute

(a) if the member (other than a member mentioned in section 635 (3) (ac) or (ad)) ceases to be a doctor; or

(aa) for a member mentioned in section 635 (3) (ac)—if the member ceases to be a pharmacist; or

Endnotes

1 Notification

Notified under the [Legislation Act](#) on 22 October 2014.

2 Republications of amended laws

For the latest republication of amended laws, see www.legislation.act.gov.au.

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