



Australian Capital Territory

Medicines, Poisons and Therapeutic Goods (Controlled Medicines) Amendment Regulation 2016 (No 1)

Subordinate Law SL2016-16

The Australian Capital Territory Executive makes the following regulation under the [Medicines, Poisons and Therapeutic Goods Act 2008](#).

Dated 21 June 2016.

MEEGAN FITZHARRIS
Minister

YVETTE BERRY
Minister



Australian Capital Territory

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1 Name of regulation

This regulation is the *Medicines, Poisons and Therapeutic Goods (Controlled Medicines) Amendment Regulation 2016 (No 1)*.

2 Commencement

This regulation commences 1 month 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 41 (1) (g) (i)

omit

5 Section 41 (2) (b)

omit

controlled medicine or

6 Section 41 (4), definition of *relevant approval particulars*

substitute

relevant approval particulars means—

- (a) for an approval under section 591 (Standing approval to prescribe designated appendix D medicines)—the words ‘standing approval’ and the specialist area, or the area, in which the prescriber practices; or

- (b) for an approval under section 593 (CHO decisions on applications to prescribe designated appendix D medicines)—the words ‘CHO approval number’ followed by the identifying number for the approval.

7 Section 561 (1) (c) and (d)

substitute

- (c) the medicine, and either—
- (i) the form, strength and quantity of the medicine, and the daily dose, that may be prescribed; or
- Note* Other forms and strengths may be prescribed in accordance with s 32.
- (ii) for an approval authorised under a category approval determination under section 575—details of the approval sought;

8 Section 561 (2)

omit

9 Section 563 (b)

omit

10 Section 564

omit

1 year

substitute

3 years

11 Section 571 (1) (b) and (c)

substitute

(b) either—

- (i) the form and strength, and the maximum quantity, of the medicine that may be prescribed under the approval; or
- (ii) for an approval authorised under a category approval determination under section 575—details of the approval given;

12 Section 571 (1) (e)

omit

13 Section 571 (2)

omit

14 New section 575

in division 13.1.3, insert

575 Category approval determination

- (1) The chief health officer may determine circumstances in which approval to prescribe a controlled medicine may be given, other than approval for a stated form, strength and quantity of a stated medicine (a *category approval determination*).

Examples

- 1 approval to prescribe all forms, strengths and quantities of certain controlled medicines for people with terminal illness
- 2 approval to prescribe up to a stated maximum dose of a particular controlled medicine

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see [Legislation Act](#), s 126 and s 132).

- (2) A category approval determination is a notifiable instrument.

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

Endnotes

1 Notification

Notified under the [Legislation Act](#) on 30 June 2016.

2 Republications of amended laws

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