Australian Capital Territory

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2019 (No 1)

Subordinate Law SL2019-23

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

Dated 5 September 2019.

RACHEL STEPHEN-SMITH
Minister

SUZANNE ORR
Minister

J2018-149

Australian Capital Territory

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Medicines, Poisons and Therapeutic Goods Act 2008

Contents

1 Name of regulation

This regulation is the *Medicines, Poisons and Therapeutic Goods Amendment Regulation 2019 (No 1)*.

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 30 (2), definition of *restricted medicine*, paragraph (b)

substitute

(b) an appendix D medicine; or

5 Section 31 (1) (e)

substitute

(e) if the medicine is an appendix D medicine—

(i) the prescriber has an appendix D medicines approval to prescribe the medicine; and

(ii) the prescriber complies with each condition (if any) of the approval (including any conditions in schedule 3, part 3.2, column 4 in relation to the medicine).

6 Section 33

omit

7 Section 41 (1) (h)

omit

8 Section 41 (2), except notes

substitute

(2) However, if the prescription is written for an in-patient at a hospital in the patient's medical records, the prescription need not include the prescriber's professional qualifications and business address and telephone number.

9 Section 41 (4), definition of *relevant approval particulars*, paragraph (a)

omit

designated

substitute

ACT listed

10 Section 41 (4), definition of *relevant approval particulars*, paragraph (b)

omit

designated

11 Section 160 (c)

omit everything before subparagraph (i), substitute

(c) if the medicine is an appendix D medicine—

12 Section 250, definition of *designated prescription only medicine*, paragraph (b)

substitute

(b) an appendix D medicine; and

13 Section 561 (1) (c) (ii)

omit

determination

14 New section 563 (2) (aa)

insert

(aa) must comply with any standards determined under section 575 (Controlled medicines prescribing standards); and

15 New section 563 (3) and (4)

insert

(3) However, the decision of the chief health officer under section 562 need not comply with a controlled medicines prescribing standard if the decision—

(a) is in accordance with a recommendation of the medicines advisory committee that the prescribing standard not apply in the particular circumstances; or

(b) is in accordance with an entry for a controlled medicine listed in the Australian Register of Therapeutic Goods; or

(c) is necessary for the continuation of the patient's treatment in the particular circumstances.

(4) In this section:

Australian Register of Therapeutic Goods means the register maintained under the *Therapeutic Goods Act 1989* (Cwlth).

Note The Australian Register of Therapeutic Goods can be accessed at www.tga.gov.au.

16 Section 571 (1) (b) (ii)

omit

determination

17 Section 575

substitute

575 Controlled medicines prescribing standards

(1) The chief health officer may determine standards setting out the circumstances in which approval may be given (the ***controlled medicines prescribing standards***) to prescribe the following:

(a) a category of controlled medicine (a ***category approval***);

(b) a stated form, strength or quantity of a controlled medicine.

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

(2) The controlled medicines prescribing standards are a notifiable instrument.

Note A notifiable instrument must be notified under the Legislation Act.

18 Part 13.2 heading, note

substitute

Note It is a condition of an authorisation to prescribe an ACT listed appendix D medicine for the prescriber to have an approval under this part (see s 31 (1) (e)).

19 New sections 588 and 589

in part 13.2, insert

588 Modification of medicines and poisons standard—Act, s 15 (1), def *medicines and poisons standard*

In this regulation:

appendix D medicine—

(a) means a medicine included in the medicines and poisons standard, appendix D; but

(b) does not include a controlled medicine.

589 Meaning of *ACT listed appendix D medicine*

In this regulation:

ACT listed appendix D medicine means an appendix D medicine listed in schedule 3, part 3.2, column 3.

20 Section 591

substitute

591 Standing approval to prescribe ACT listed appendix D medicines

(1) A prescriber mentioned in schedule 3, part 3.2, column 2 is approved to prescribe an ACT listed appendix D medicine mentioned in column 3 in relation to the prescriber.

(2) However, the prescriber must only prescribe the medicine—

(a) for a purpose (if any) mentioned in schedule 3, part 3.2, column 3; and

(b) in accordance with a condition (if any) mentioned in schedule 3, part 3.2, column 4.

Example—par (b)

If sch 3, pt 3.2, col 4 includes a condition requiring a prescriber to advise a woman of child-bearing age to avoid becoming pregnant during or for a certain period after the completion of treatment, the prescriber is authorised to prescribe the medicine only if the prescriber gives the patient the advice.

21 Section 592 heading

substitute

592 Applications for CHO approval to prescribe appendix D medicines

22 Section 592 (1) and note

substitute

(1) A prescriber may, in writing, apply to the chief health officer for approval to prescribe an appendix D medicine.

23 Section 592 (2)

omit

doctor's

substitute

prescriber's

24 Section 592 (2) and (3)

omit

doctor

substitute

prescriber

25 Section 593

substitute

593 CHO decisions on applications to prescribe appendix D medicines

(1) The chief health officer must approve, or refuse to approve, an application by a prescriber under section 592 for approval to prescribe an appendix D medicine.

(2) An approval under subsection (1) to prescribe an appendix D medicine is subject to the following conditions:

(a) if the medicine is an ACT listed appendix D medicine—that the prescriber complies with any conditions in schedule 3, part 3.2, column 4 in relation to the medicine;

(b) any other condition included in the approval by the chief health officer.

Example—par (a)

If sch 3, pt 3.2, col 4 includes a condition requiring a prescriber to advise a woman of child-bearing age to avoid becoming pregnant during or for a certain period after the completion of treatment, the prescriber is authorised to prescribe the medicine only if the prescriber gives the patient the advice.

(3) For this section, the chief health officer—

(a) must have regard to the specialist area (if any) in which the prescriber practises and the requirements (if any) stated in the medicines and poisons standard, appendix D for the medicine to which the application relates; and

(b) may have regard to anything else the chief health officer considers appropriate.

(4) The chief health officer must send the prescriber written notice of the chief health officer's decision not later than 7 days after the day the decision is made.

26 Section 594 (a)

omit

doctor's

substitute

prescriber's

27 Schedule 3 heading

substitute

Schedule 3 ACT listed appendix D medicines—standing approvals

(see s 31, s 41, s 160, s 591, s 592 and s 593)

28 Schedule 3, section 3.1

substitute

3.1 Definitions—sch 3

In this schedule:

condition 1, for a prescriber prescribing or supplying an ACT listed appendix D medicine to a woman of child-bearing age, means the prescriber must ensure that the possibility of pregnancy by the woman has been excluded prior to commencement of treatment.

condition 2, for a prescriber prescribing or supplying an ACT listed appendix D medicine to a woman of child-bearing age, means the prescriber must advise the woman to avoid becoming pregnant during, or for a period of 1 month after the completion of, treatment.

condition 3, for a prescriber prescribing or supplying an ACT listed appendix D medicine to a woman of child-bearing age, means the prescriber must advise the woman to avoid becoming pregnant during, or for a period of 3 months after the completion of, treatment.

condition 4, for a prescriber prescribing or supplying an ACT listed appendix D medicine to a woman of child-bearing age, means the prescriber must advise the woman to avoid becoming pregnant during, or for a period of 24 months after the completion of, treatment.

29 Schedule 3, part 3.2

substitute

Part 3.2 Standing approvals for ACT listed appendix D medicines

column 1 item	column 2 prescriber	column 3 medicine	column 4 conditions (if any)
1	specialist practising in specialist area of dermatology	acitretin for human use	conditions 1 and 4
		alefacept for human use	
		bexarotene for human use	conditions 1 and 2
		etretinate for human use	conditions 1 and 4
		isotretinoin for human oral use	conditions 1 and 2
		thalidomide for human use	conditions 1 and 2
2	specialist practising in specialist area of endocrinology, gynaecology or obstetrics	clomiphene for human use	
		corifollitropin alfa for human use	
		cyclofenil for human use	
		dinoprost for human use	
		dinoprostone for human use	
		follitropin alpha (recombinant human follicle-stimulating hormone) for human use	
		follitropin beta (recombinant human follicle-stimulating hormone) for human use	
		follitropin delta (recombinant human follicle-stimulating hormone) for human use	
		luteinising hormone for human use	
		urofollitropin (human follicle-stimulating hormone) for human use	

column 1 item	column 2 prescriber	column 3 medicine	column 4 conditions (if any)
3	specialist practising in specialist area of mental health doctor employed by Territory and working under supervision of chief psychiatrist under *Mental Health Act 2015*	clozapine for human use	
4	specialist physician	ambrisentan for human use acitretin for human use etretinate for human use bexarotene for human use bosentan for human use enzalutamide for human use isotretinoin for human oral use lenalidomide for human use macitentan for human use pomalidomide riociguat for human use sitaxentan for human use teriparatide for human use thalidomide for human use tretinoin for human oral use	conditions 1 and 3 conditions 1 and 4 conditions 1 and 4 conditions 1 and 2 conditions 1 and 3 conditions 1 and 3 conditions 1 and 2 conditions 1 and 2 conditions 1 and 3 conditions 1 and 2 conditions 1 and 2 conditions 1 and 3 conditions 1 and 2 conditions 1 and 2

Note ***Specialist*** includes a doctor training in a specialist area—see the dictionary.

30 Dictionary, note 3

insert

- medicines advisory committee

31 Dictionary, new definitions

insert

ACT listed appendix D medicine—see section 589.

appendix D medicine—see section 588.

32 Dictionary, definitions of *condition 1* etc

substitute

condition 1, for a prescriber prescribing or supplying an ACT listed appendix D medicine to a woman of child-bearing age, for schedule 3 (ACT listed appendix D medicines—standing approvals)—see schedule 3, section 3.1.

condition 2, for a prescriber prescribing or supplying an ACT listed appendix D medicine to a woman of child-bearing age, for schedule 3 (ACT listed appendix D medicines—standing approvals)—see schedule 3, section 3.1.

condition 3, for a prescriber prescribing or supplying an ACT listed appendix D medicine to a woman of child-bearing age, for schedule 3 (ACT listed appendix D medicines—standing approvals)—see schedule 3, section 3.1.

condition 4, for a prescriber prescribing or supplying an ACT listed appendix D medicine to a woman of child-bearing age, for schedule 3 (ACT listed appendix D medicines—standing approvals)—see schedule 3, section 3.1.

33 Dictionary, new definition of *controlled medicines prescribing standards*

insert

controlled medicines prescribing standards—see section 575.

34 Dictionary, definition of *designated appendix D medicine*

omit

Endnotes

1 Notification

Notified under the Legislation Act on 12 September 2019.

2 Republications of amended laws

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