2018

THE LEGISLATIVE ASSEMBLY
FOR THE AUSTRALIAN CAPITAL TERRITORY

(As presented)

(Minister for Health and Wellbeing)

Medicines, Poisons and Therapeutic Goods Amendment Bill 2018

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Medicines, Poisons and Therapeutic Goods Amendment Bill 2018

A Bill for

An Act to amend the *Medicines, Poisons and Therapeutic Goods Act 2008* and the *Medicines, Poisons and Therapeutic Goods Regulation 2008*

The Legislative Assembly for the Australian Capital Territory enacts as follows:

Part 1 Preliminary

1 Name of Act

This Act is the *Medicines, Poisons and Therapeutic Goods Amendment Act 2018*.

2 Commencement

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

Part 2 Medicines, Poisons and Therapeutic Goods Act 2008

4 Supply of certain declared substances—information for chief health officer Section 31 (1) (a) and (2) (a)

omit

controlled medicine

substitute

monitored medicine

5 New chapter 6A

insert

Chapter 6A Monitored medicines database

97A Meaning of *monitored medicine*

(1) In this Act:

monitored medicine means—

(a) a controlled medicine; or

(b) a medicine declared by the Minister to be a monitored medicine.

(2) For the definition of ***monitored medicine***, paragraph (b), the Minister may declare a medicine to be a monitored medicine if satisfied that the declaration is consistent with the purposes of the monitored medicines database.

(3) A declaration under this section is a disallowable instrument.

Note A disallowable instrument must be notified, and presented to the Legislative Assembly, under the Legislation Act.

97B Definitions—ch 6A

In this chapter:

another jurisdiction means the Commonwealth or a State.

Note ***State*** includes the Northern Territory (see Legislation Act, dict, pt 1).

approved data source entity means an entity engaged by another jurisdiction to collect, access, store or otherwise deal with information about monitored medicines.

monitored medicines database—see section 97D.

relevant health practitioner means a health practitioner authorised by regulation to prescribe or supply a monitored medicine.

required information, about the supply of a monitored medicine—see section 31 (4).

97C Monitored medicines database—purposes

(1) The main purpose of the monitored medicines database is to promote and protect public health and safety by ensuring that information is available to—

(a) monitor and evaluate the supply of monitored medicines to a person; and

(b) support the exercise of the chief health officer's functions.

(2) A regulation may prescribe additional purposes for the monitored medicines database.

97D Monitored medicines database—scope

(1) The chief health officer may keep a database (the ***monitored medicines database***) to record information relating to monitored medicines.

(2) The monitored medicines database may be kept in any form, including electronically, that the chief health officer decides.

(3) The chief health officer may—

(a) correct an error or omission in the monitored medicines database; and

(b) change information included in the database to keep the database accurate and up-to-date.

(4) The monitored medicines database may include the following:

(a) required information about the supply of a monitored medicine under a supply authority;

(b) information about the approval to prescribe a monitored medicine;

(c) information from another jurisdiction in relation to the supply or prescription of a monitored medicine in the other jurisdiction;

(d) information in relation to a monitored medicine from an approved data source entity;

(e) any other information prescribed by regulation.

97E Monitored medicines database—chief health officer functions

The chief health officer has the following functions in relation to the monitored medicines database:

(a) to collect and store required information about monitored medicines;

(b) to enter into an arrangement with another jurisdiction or an approved data source entity to—

(i) collect and store information for the database; and

(ii) allow access to information on the database; and

(iii) allow the use and disclosure of information on the database;

(c) to access and use the database to—

(i) monitor, promote and protect public health and safety; and

(ii) facilitate research into the provision of healthcare; and

(iii) administer, develop and operate the database; and

(iv) ensure compliance with the Act;

(d) to allow access to, and the use and disclosure of, information on the database by a person mentioned in section 97F or section 97G (Monitored medicines database—access authority);

(e) any other function under this Act or another territory law.

Note A provision of a law that gives an entity (including a person) a function also gives the entity powers necessary and convenient to exercise the function (see Legislation Act, s 196 and dict, pt 1, def ***entity***).

97F Monitored medicines database—access and use by relevant health practitioners

(1) A relevant health practitioner may access and use the monitored medicines database for 1 or more of the following purposes:

(a) to inform decisions in relation to the prescription or supply of a monitored medicine to a person under the relevant health practitioner's care;

(b) to inform decisions in relation to the treatment or care of a person under the relevant health practitioner's care;

(c) to disclose information about a person under the relevant health practitioner's care to that person;

(d) to disclose information about a person under the relevant health practitioner's care to another health practitioner involved in the person's treatment or care;

(e) a purpose prescribed by regulation.

(2) The chief health officer must make the monitored medicines database available to a relevant health practitioner at no cost.

97G Monitored medicines database—access authority

(1) A person, other than a relevant health practitioner, may apply to the chief health officer for authorisation to access and use the monitored medicines database (an ***access authority***).

Note 1 If a form is approved under s 198 for this provision, the form must be used.

Note 2 A fee may be determined under s 197 for this provision.

(2) The chief health officer may issue the access authority only if satisfied that giving the access authority to the person is—

(a) consistent with a purpose of the monitored medicines database; and

(b) otherwise in the public interest.

(3) An access authority must—

(a) be in writing; and

(b) include the following information:

(i) the name of the person to whom the authority is issued;

(ii) the purpose for which the authority is issued;

(iii) any conditions applying to the authority;

(iv) the expiry date of the authority.

97H Monitored medicines database—offences

(1) A person commits an offence if—

(a) the person accesses information from the monitored medicines database; and

(b) the access is not authorised under this chapter.

Maximum penalty: 30 penalty units.

(2) A person commits an offence if—

(a) the person accesses information from the monitored medicines database; and

(b) the person uses the accessed information; and

(c) the use is not authorised under this chapter.

Maximum penalty: 50 penalty units.

(3) A person commits an offence if—

(a) the person accesses information from the monitored medicines database; and

(b) the person discloses the accessed information to someone else; and

(c) the disclosure is not authorised under this chapter.

Maximum penalty: 50 penalty units.

(4) Strict liability applies to subsections (1) (a), (2) (a) and (3) (a).

(5) In this section:

disclose, in relation to information accessed from the monitored medicines database, includes—

(a) communicate the information; or

(b) publish the information.

use, in relation to information accessed from the monitored medicines database, includes make a record of the information.

6 Disciplinary action against authorisation holders Section 141 (1) (d)

omit

varying

substitute

amending

7 New section 141 (1) (h)

insert

(h) if the authorisation holder is authorised to access and use the monitored medicines database—amending, suspending or cancelling the authority to access and use the database.

8 Sections 144 (2) (b) and 145 (1) (b)

omit

varied

substitute

amended

9 Section 145 (1) (c)

omit

variation

substitute

amendment

10 Action by chief health officer in relation to certain licences and approvals Section 146 (1)

substitute

(1) If a licence or approval amended under this part is returned to the chief health officer, the chief health officer must—

(a) amend the licence or approval and return it to the authorisation holder; or

(b) give the authorisation holder a replacement licence or approval that includes the amendment.

Note A licence or approval is taken to be amended if an authorised dealing under the licence or approval is suspended (see s 144 (2)).

11 Reviewable decisions Schedule 1, item 6, column 3, 4th dot point

omit

vary

substitute

amend

12 Dictionary, new definitions

insert

another jurisdiction, for chapter 6A (Monitored medicines database)—see section 97B.

approved data source entity, for chapter 6A (Monitored medicines database)—see section 97B.

monitored medicine—see section 97A.

monitored medicines database, for chapter 6A (Monitored medicines database)—see section 97B.

relevant health practitioner, for chapter 6A (Monitored medicines database)—see section 97B.

required information, about the supply of a monitored medicine, for chapter 6A (Monitored medicines database)—see section 31 (4).

Part 3 Medicines, Poisons and Therapeutic Goods Regulation 2008

13 Section 81

substitute

81 Information for CHO about monitored medicines supplied on supply authorities—Act, s 31 (1) (b) and (4), def *required information*

(1) A person (the ***supplier***) who supplies a monitored medicine on a supply authority must, not later than 7 days after the day when the medicine is supplied, give the chief health officer the following information in writing:

(a) the supplier's name, business address and telephone number;

(b) the name of the person who issued the supply authority;

(c) the date of the supply authority;

(d) the name, date of birth and address of the person to whom the medicine is supplied;

(e) the date of supply;

(f) the monitored medicine, and the form, strength and quantity of the medicine, supplied.

(2) However, this section does not apply to any of the following who report the supply of a monitored medicine on a supply authority to the Therapeutic Goods Administration:

(a) a medicines wholesalers licence-holder;

(b) a person who is authorised (however described) under a Commonwealth or State law to manufacture a monitored medicine or supply a monitored medicine by wholesale.

14 Section 164

substitute

164 Information for CHO about monitored medicines supplied during consultations—Act, s 31 (2) (b) and (4), def *required information*

(1) This section applies if a prescriber supplies a monitored medicine for human use during a consultation.

Note ***Supply*** does not include administer (see Act, s 24).

(2) The prescriber must, not later than 7 days after the end of the month when the monitored medicine is supplied, give the chief health officer the following information in writing:

(a) the prescriber's name, business address and telephone number;

(b) the name, date of birth and address of the person to whom the medicine is supplied;

(c) the date of supply;

(d) the monitored medicine, and the form, strength and quantity of the medicine, supplied.

Endnotes

1 Presentation speech

Presentation speech made in the Legislative Assembly on 10 May 2018.

2 Notification

Notified under the Legislation Act on 2018.

3 Republications of amended laws

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