New South Wales

Poisons and Therapeutic Goods Amendment (Authority Management) Regulation 2023

under the

Poisons and Therapeutic Goods Act 1966

Her Excellency the Governor, with the advice of the Executive Council, has made the following regulation under the *Poisons and Therapeutic Goods Act 1966*.

RYAN PARK, MP
Minister for Health

Explanatory note

The object of this regulation is to amend the *Poisons and Therapeutic Goods Regulation 2008* as follows—

(a) to prescribe N,α-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) and psilocybine as type A drugs of addiction,

(b) to extend provisions relating to prescription monitoring to apply to substances that require an authority under the Act or the regulation, including—

  (i) managing authorities for substances that require an authority, and

  (ii) allowing certain persons prescribing, supplying and administering the substances and the Secretary to record or include information on the database, and

  (iii) extending the purposes for which information in the database may be accessed, used and disclosed, and

  (iv) providing that a person has a lawful authority to access the database if accessed under the direction of a dentist, medical practitioner or nurse practitioner, for a particular purpose,

(c) to make it clear that a person employed at a hospital or managed correctional centre who holds an authority under the *Poisons and Therapeutic Goods Regulation 2008*, Part 8 to administer a substance may do so,

(d) to remove ivermectin from the list of substances that are restricted substances requiring a particular authority,

(e) to allow a pharmacist to supply a repeat of a prescription for a restricted substance or a drug of addiction if the prescription fails to specify the patient's date of birth.

This regulation is made under the *Poisons and Therapeutic Goods Act 1966*, including sections 17, 24, 28 and 45C, the general regulation-making power.

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Poisons and Therapeutic Goods Amendment (Authority Management) Regulation 2023

under the

Poisons and Therapeutic Goods Act 1966

1 Name of regulation

This regulation is the *Poisons and Therapeutic Goods Amendment (Authority Management) Regulation 2023*.

2 Commencement

This regulation commences as follows—

(a) for Schedule 1[6] and [7]—1 July 2023,

(b) otherwise—on the day on which it is published on the NSW legislation website.

Schedule 1 Amendment of Poisons and Therapeutic Goods Regulation 2008

[1] Clauses 37(1) and 52(1)

Omit "ivermectin" wherever occurring.

[2] Clause 39 Prescriptions may be filled only if in proper form

Omit "subclause (2)(a) or (b)" from clause 39(3).

Insert instead "subclause (2)(a), (a1) or (b)".

[3] Clause 58 Administration by persons employed at hospitals and managed correctional centres

Insert after clause 58(6)—

(6A) Subclause (1) does not apply to a person employed at a hospital or managed correctional centre who holds an authority under Part 8 to administer the substance.

[4] Clause 85 Pharmacists may supply drugs of addiction on prescription

Omit "subclause (2)" from clause 85(3). Insert instead "subclause (2)(a) or (b)".

[5] Clause 120 Administration by persons employed at hospitals and managed correctional centres

Insert after clause 120(6)—

(6A) Subclause (1) does not apply to a person employed at a hospital or managed correctional centre who holds an authority under Part 8 to administer the substance.

[6] Clause 122 Prescribed type A drugs of addiction

Omit clause 122(b1). Insert instead—

(b1) N,α-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA),

(b2) lisdexamfetamine,

[7] Clause 122(g)

Insert after clause 122(f)—

(g) psilocybine,

[8] Part 8A, heading

Insert "**and authority management**" after "**monitoring**".

[9] Clause 174A Interpretation

Omit "monitored medicines" from the definition of ***database***.

[10] Clause 174B Objects

Omit clause 174B(a)–(d). Insert instead—

(a) establish a system for—

(i) the real time monitoring of the prescribing and supply of monitored medicines, and

(ii) managing the prescribing, supply and administration of substances that require an authority under the Act or this regulation, and

(b) require the establishment of a database of information about the—

(i) prescribing and supply of monitored medicines, and

(ii) prescribing, supply and administration of substances that require an authority under the Act or this regulation, and

(c) authorise the following persons to provide information for inclusion in the database—

(i) prescribers, pharmacists and data source entities,

(ii) other persons administering, supplying or issuing a prescription for a patient,

(iii) the Secretary, and

(d) allow for the use and disclosure of information in the database for purposes that include—

(i) monitoring the prescribing and supply of monitored medicines, and

(ii) regulating the prescribing, supply and administration of substances that require an authority under the Act or this regulation.

[11] Clause 174C Establishment and purpose of database

Omit clause 174C(1). Insert instead—

(1) The Secretary must establish and keep a database to record data about the—

(a) prescribing and supply of monitored medicines, and

(b) prescribing, supply and administration of substances that require an authority under the Act or this regulation.

[12] Clauses 174EA and 174EB

Insert after clause 174E—

174EA Recording or including information on database for substances requiring authority

A person who applies for, or holds, an authority required under the Act or this regulation for the purposes of prescribing, supplying or administering a substance may record for the purposes of the database, or include in the database, the following information—

(a) information relating to the person's application for the authority, or

(b) information relating to the cancellation of the authority.

174EB Secretary may include information in database

The Secretary may include in the database any information obtained under the Act or this regulation that is relevant for the purposes of the database.

[13] Clause 174F Authority to transfer information

Insert after clause 174F(b)—

(b1) information the entity receives from a person under clause 174EA,

[14] Clause 174G Use and disclosure of information by Secretary

Insert after clause 174G(b)—

(b1) regulating the prescribing, supply and administration of substances that require an authority under the Act or this regulation—

(i) by persons administering, supplying, or issuing a prescription, or

(ii) on a more general, including State-wide, basis, and

[15] Clause 174G(d)

Omit "regulating the prescribing, supply or use of monitored medicines, and".

Insert instead—

regulating—

(i) the prescribing, supply or use of monitored medicines, and

(ii) the prescribing, supply or administration of substances that require an authority under the Act or this regulation, and

[16] Clause 174G(e)

Omit "connected to monitoring the prescribing or supply of monitored medicines, and".

Insert instead—

connected to—

(i) monitoring the prescribing or supply of monitored medicines, and

(ii) managing applications and issuing authorities required for substances that require an authority under the Act or this regulation, and

[17] Clause 174H Use of information by certain prescribers and by pharmacists

Insert at the end of the clause—

(2) Information in the database may be accessed, used or disclosed by a dentist, a medical practitioner or a nurse practitioner for the purposes of applying for, reviewing or applying to cancel an authority under the Act or this regulation.

(3) Information in the database may be accessed, used or disclosed by a pharmacist for the purpose of reviewing an authority for the prescribing or supply of a substance under the Act or this regulation.

[18] Clause 174I Unauthorised access to database

Insert at the end of the clause, after the penalty—

(2) For this clause, a person has ***lawful authority*** if—

(a) the person is acting under the direction of a dentist, medical practitioner or nurse practitioner, and

(b) the person accesses, uses or discloses the information on the database in a way authorised under clause 174H(2).