New South Wales

Poisons and Therapeutic Goods Amendment Regulation 2014

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*.

JILLIAN SKINNER, MP
Minister for Health

Explanatory note

The objects of this Regulation are as follows:

(a) in relation to nabiximols (a refined and standardised extract of cannabis in a medicine to be sprayed in the mouth):

  (i) to clarify that it is not a hallucinogen (this removes the need for the Director-General to issue an authority to each patient to possess and use it), and

  (ii) to provide that it is a "type A" drug of addiction (this requires a medical practitioner to hold an authority from the Director-General to prescribe or supply it), and

  (iii) to provide that pharmacists may supply it on prescription only if the prescription bears the reference number of the authority to issue the prescription, and

  (iv) to prohibit nurse practitioners, midwife practitioners, dentists and veterinary practitioners from possessing, prescribing or supplying it,

(b) in relation to lisdexamfetamine (which is no longer legally treated as a derivative of dexamphetamine, a "type A" drug of addiction, but is to continue to be treated in the same way as dexamphetamine):

  (i) to require an authority of the Director-General for a medical practitioner to prescribe it, and

  (ii) to provide that pharmacists may supply it on prescription only if the prescription bears the reference number of the authority to issue the prescription, and

  (iii) to prohibit nurse practitioners, midwife practitioners, dentists and veterinary practitioners from possessing, prescribing or supplying it, and

  (iv) to provide that it is a "type A" drug of addiction, and

  (v) to provide that, when dispensed to a patient, lisdexamfetamine must bear a specified label symbol and a warning that it may affect alertness and/or coordination, and that affected patients should not drive a motor vehicle or operate machinery,

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(c) in relation to alprazolam:

(i) to provide that it is a "type B" drug of addiction (this requires a medical practitioner or nurse practitioner to hold an authority from the Director-General in order to prescribe or supply it for continuous therapeutic use by a person for a period exceeding 2 months), and

(ii) to remove its listing as a prescribed restricted substance (as it is to be in the more restricted category of a Schedule Eight drug of addiction),

(d) to include drugs of addiction for administration by inhalation, spray or application to mucous membranes as "type B" drugs of addiction,

(e) to include darbepoetin, enobosarm, epoetins, erythropoietins, follistatin, insulin-like growth factors, selective androgen receptor modulators and somatropin (human growth hormone) as prescribed restricted substances.

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

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Poisons and Therapeutic Goods Act 1966

1 Name of Regulation

This Regulation is the *Poisons and Therapeutic Goods Amendment Regulation 2014*.

2 Commencement

This Regulation commences on the day on which it is published on the NSW legislation website.

Schedule 1 Amendment of Poisons and Therapeutic Goods Regulation 2008

[1] Clause 3 Definitions

Insert "(other than nabiximols)" after "homologues" in paragraph (b) of the definition of ***hallucinogen*** in clause 3 (1).

[2] Clause 3 (1)

Insert in alphabetical order:

nabiximols means a botanical extract of Cannabis sativa in a buccal spray for human therapeutic use:

(a) that includes the following cannabinoids:

(i) tetrahydrocannabinol,

(ii) cannabidiol,

(iii) cannabinol,

(iv) cannabigerol,

(v) cannabichromene,

(vi) cannabidiolic acid,

(vii) tetrahydrocannabinolic acid,

(viii) tetrahydrocannabivarol,

(ix) cannabidivarol, and

(b) in which tetrahydrocannabinol and cannabidiol (in approximately equal proportions) comprise not less than 90 per cent of the total cannabinoid content.

[3] Clause 84 Exceptions to section 28—prescriptions for amphetamines and nabiximols

Insert in alphabetical order in clause 84 (1):

lisdexamfetamine

nabiximols

[4] Clause 84 (2)

Insert ", lisdexamfetamine" after "dexamphetamine".

[5] Clause 90 Supply by pharmacists of amphetamines and nabiximols

Insert in alphabetical order in clause 90 (1):

lisdexamfetamine

nabiximols

[6] Clause 98 Supply of amphetamines and nabiximols

Insert in alphabetical order in clause 98 (1):

lisdexamfetamine

nabiximols

[7] Clause 98 (2)

Insert ", lisdexamfetamine" after "dexamphetamine".

[8] Clause 101 Possession and supply of drugs of addiction

Insert in alphabetical order in clause 101 (5):

lisdexamfetamine

nabiximols

[9] Clause 101 (5)

Insert ", in the case of a veterinary practitioner" after "dosage form" in the item for methylphenidate.

[10] Clause 122 Prescribed type A drugs of addiction

Insert after clause 122 (b):

(b1) lisdexamfetamine,

[11] Clause 122

Insert after clause 122 (d):

(d1) nabiximols,

[12] Clause 123 Prescribed type B drugs of addiction

Omit clause 123 (a). Insert instead:

(a) a drug of addiction that is packaged and labelled in a manner that is consistent with the drug being intended for administration by injection, inhalation, spray or application to mucous membranes,

(a1) alprazolam,

[13] Appendix A Labelling of therapeutic substances

Insert in alphabetical order in clause 5 (1):

lisdexamfetamine

[14] Appendix D Prescribed restricted substances

Omit the matter relating to Alprazolam.

[15] Appendix D

Insert the following in alphabetical order:

Darbepoetin	0.015 grams
Enobosarm	0.3 grams
Epoetins	0.01 grams or 1,000,000 International Units
Erythropoietins (except when referred to elsewhere in this Appendix)	1,000,000 International Units
Follistatin	0.1 grams
Insulin-like growth factors	0.005 grams
Selective androgen receptor modulators	0.3 grams
Somatropin (human growth hormone)	0.25 grams