



New South Wales

Poisons Amendment (Therapeutic Goods) Act 1996 No 2

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New South Wales

Poisons Amendment (Therapeutic Goods) Act 1996 No 2

Act No 2, 1996

An Act to amend the *Poisons Act 1966* to apply as laws of New South Wales laws of the Commonwealth relating to therapeutic goods, to regulate the supply and use in New South Wales of certain therapeutic goods, to provide for related matters, to repeal the *Therapeutic Goods and Cosmetics Act 1972*, and to make consequential amendments to certain other Acts. [Assented to 8 May 1996]

The Legislature of New South Wales enacts:

1 Name of Act

This Act is the *Poisons Amendment (Therapeutic Goods) Act 1996*.

2 Commencement

This Act commences on a day or days to be appointed by proclamation.

3 Amendment of Poisons Act 1966 No 31

Schedule 1 has effect.

4 Consequential amendment of other Acts

Schedule 2 has effect.

5 Repeal of Therapeutic Goods and Cosmetics Act 1972 No 14 and Regulations

- (1) The *Therapeutic Goods and Cosmetics Act 1972* is repealed.
- (2) The *Therapeutic Goods and Cosmetic Regulations* are repealed.

Schedule 1 Amendment of Poisons Act 1966

(Section 3)

[1] Long title

Omit "and certain dangerous drugs".

Insert instead ", certain dangerous drugs and certain therapeutic goods".

[2] Section 1 Short title

Insert "and Therapeutic Goods" after "Poisons".

[3] Section 4 Definitions

Section 4 (1)

Insert in alphabetical order:

Analyst means an analyst appointed or taken to be appointed under section 37A.

Animal means any animal (other than a human being), whether vertebrate or invertebrate, and includes but is not limited to:

- (a) mammals, birds, bees, reptiles, amphibians, fish, crustaceans and molluscs, and
- (b) the semen, ova or embryo of an animal (other than a human being) or any other substance or thing directly relevant to the reproduction of an animal (other than a human being).

Applied provisions means the Commonwealth therapeutic goods laws that apply as a law of New South Wales because of section 31.

Authority means an authority issued and in force for the purposes of this Act or the regulations.

Commonwealth Act means the *Therapeutic Goods Act 1989* of the Commonwealth.

Commonwealth administrative laws means the following Acts and regulations of the Commonwealth:

- (a) the *Administrative Appeals Tribunal Act 1975*,
- (b) the *Administrative Decisions (Judicial Review) Act 1977*,
- (c) the *Freedom of Information Act 1982*,
- (d) the *Ombudsman Act 1976*,
- (e) the *Privacy Act 1988*,
- (f) the regulations in force under any of those Acts.

Commonwealth Department means the Department of Human Services and Health or such other Department of the Commonwealth as is the relevant Department for the purposes of the Commonwealth therapeutic goods laws.

Commonwealth Minister means the Minister responsible for administering the Commonwealth therapeutic goods laws.

Commonwealth Secretary means the Secretary of the Commonwealth Department.

Commonwealth therapeutic goods laws means:

- (a) the *Therapeutic Goods Act 1989* of the Commonwealth, and
- (b) all regulations, orders and manufacturing principles in force under that Act.

Listed goods has the same meaning as in the Commonwealth Act.

Manufacturer's licence means a licence in force under Part 4 of the Commonwealth Act.

Registered goods has the same meaning as in the Commonwealth Act.

Regulated goods means:

- (a) any substance of a kind specified in a Schedule of the Poisons List, or
- (b) therapeutic goods that are not a substance so specified.

Representation means a verbal representation, a written representation or representation by conduct.

Supply by wholesale, in relation to a substance or goods, means:

- (a) supply of the substance or goods for the purposes of resupply, or
- (b) supply of an ingredient for the purposes of incorporation in the substance or goods,

and includes supply of the substance or goods in wholesale quantities for use:

- (c) in a public institution, or
- (d) in connection with the carrying on by persons, in circumstances prescribed by the regulations, of any activity so prescribed.

Therapeutic device and ***Therapeutic goods*** have the same meanings as in the Commonwealth Act.

[4] Section 4 (1), definition of "Licence"

Omit the definition. Insert instead:

Licence means a licence issued and in force for the purposes of this Act or the regulations.

[5] Section 4 (1), definition of "Supply"

Omit the definition. Insert instead:

Supply includes:

- (a) sell, dispense and distribute, and

- (b) supply, whether free of charge or otherwise, by way of sample or advertisement, and
- (c) supply, whether free of charge or otherwise, in the course of testing for safety or efficacy on persons or animals, and
- (d) agree or offer to sell or distribute, and
- (e) keep or have in possession for sale, dispensing or distribution, and
- (f) send, forward, deliver or receive for sale, dispensing or distribution, and
- (g) authorise, direct, cause, suffer, permit or attempt any act mentioned in paragraphs (a)–(f).

[6] Section 4 (1), definition of “Therapeutic use”

Omit the definition. Insert instead:

Therapeutic use has the same meaning as in the Commonwealth Act.

[7] Section 4 (1), definition of “Veterinary surgeon”

Omit “1923”. Insert instead “1986”.

[8] Section 4 (1), definitions of “Wholesale” and “Wholesale dealing”

Omit the definitions.

[9] Section 4 (3)

Insert after section 4 (2):

- (3) Nothing in this Act precludes a substance from being both:
 - (a) a poison, restricted substance or drug of addiction, and
 - (b) therapeutic goods.

[10] Section 5 Exemption from operation of Act

Omit section 5 (1) (b). Insert instead:

- (b) any rural lands protection board constituted or continued by or under the *Rural Lands Protection Act 1989*.

[11] Section 5 (1)

Omit "pastures protection board".

Insert instead "rural lands protection board".

[12] Sections 9–12

Omit sections 9 and 9A. Insert instead:

9 Prohibition on wholesale supply of certain substances for therapeutic use

- (1) A person who supplies by wholesale any poison or restricted substance for therapeutic use, except under, and in accordance with the conditions of, a wholesaler's licence or authority issued under the regulations is guilty of an offence.

Maximum penalty:

- (a) 20 penalty units or imprisonment for 2 years, or both, if the offence involves a restricted substance of a kind prescribed by the regulations for the purposes of this section, or
- (b) 15 penalty units or imprisonment for 6 months, or both, in any other case.
- (2) A wholesaler's licence authorises its holder to supply by wholesale poisons and restricted substances for therapeutic use in or on humans or both in or on humans and in or on animals.
- (3) A wholesaler's authority authorises its holder to supply by wholesale poisons and restricted substances for therapeutic use only in or on animals.

- (4) This section does not apply to a poison specified in Schedule 5 or 6 of the Poisons List.
- (5) For the purposes of this section:
 - (a) poisons or restricted substances are taken to be for use in or on animals if the poisons or restricted substances bear information that indicates that they are, or are otherwise represented as being, for use only in or on animals, and
 - (b) poisons or restricted substances are taken to be for use in or on humans if they are not exclusively for use in or on animals.

10 Prohibition on supply of certain substances otherwise than by wholesale

- (1) A person who supplies otherwise than by wholesale any substance specified in Schedule 1, 2 or 3 of the Poisons List except under, and in accordance with the conditions of, a general supplier's licence or a general supplier's authority issued under the regulations is guilty of an offence.

Maximum penalty: 15 penalty units or imprisonment for 6 months, or both.

- (2) Subsection (1) does not apply to a supply:
 - (a) by a medical practitioner, dentist, veterinary surgeon or pharmacist in the lawful practice of his or her profession, or
 - (b) by any other person, or person of a class, licensed or authorised by or under this Act to supply the substance.

- (3) A person who supplies a restricted substance otherwise than by wholesale is guilty of an offence.

Maximum penalty:

- (a) 20 penalty units or imprisonment for 2 years, or both, if the restricted substance involved in the offence is of a kind prescribed by the regulations for the purposes of this section, or

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- (b) 15 penalty units or imprisonment for 6 months, or both, in any other case.
- (4) Subsection (3) does not apply to a supply of a restricted substance:
- (a) by a medical practitioner, dentist or veterinary surgeon in the lawful practice of his or her profession, or
 - (b) by a pharmacist in accordance with the prescription of a medical practitioner, dentist or veterinary surgeon, or
 - (c) to a patient of a designated hospital, or an inmate of a designated institution, by a person authorised to supply the substance to patients or inmates of the hospital or institution in accordance with the prescription of a medical practitioner or a dentist, or
 - (d) by any other person, or person of a class, licensed or authorised by or under this Act to supply the substance.
- (5) The Director-General may at any time revoke an authorisation or designation given for the purposes of subsection (4) (c) for any reason that the Director-General considers appropriate.
- (6) As soon as practicable after revoking such an authorisation or designation, the Director-General must notify the revocation in writing to the person, hospital or institution concerned. The notice must specify the reason for the revocation.
- (7) In this section:

authorised means authorised by the Director-General, either specifically or as a member of a class.

designated hospital means a hospital, or a hospital of a class, designated in writing by the Director-General.

designated institution means an institution, or an institution of a class, designated in writing by the Director-General.

11 Restriction on wholesale supply of certain substances

- (1) A holder of a wholesaler's licence or a wholesaler's authority who supplies to a person other than an authorised person:

- (a) a substance specified in Schedule 1, 2, 3 or 7 of the Poisons List, or
- (b) a restricted substance,

is guilty of an offence.

Maximum penalty:

- (c) 20 penalty units or imprisonment for 2 years, or both, if the offence involves a restricted substance of a kind prescribed by the regulations for the purposes of this section, or
 - (d) 15 penalty units or imprisonment for 6 months, or both, in any other case.
- (2) In this section, ***authorised person*** means:
- (a) a medical practitioner, dentist, veterinary surgeon or pharmacist, or
 - (b) a holder of a manufacturer's licence, a wholesaler's licence or a wholesaler's authority, or
 - (c) a holder of a general supplier's licence or a general supplier's authority, or
 - (d) any other person licensed or authorised by or under this Act to supply or use, or have possession of, the substance concerned.

12 Obtaining substances by false representation

- (1) A person who, by a representation that the person knows, or ought reasonably to know, is false or misleading in a material respect, obtains, or attempts to obtain, from an authorised person:

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- (a) a substance specified in Schedule 1, 2, 3 or 7 of the Poisons List, or
 - (b) a restricted substance,
- is guilty of an offence.

Maximum penalty: 10 penalty units or imprisonment for 6 months, or both.

- (2) In this section, *authorised person* means:

- (a) a medical practitioner, dentist, veterinary surgeon or pharmacist, or
- (b) a holder of a manufacturer's licence, a wholesaler's licence or a wholesaler's authority, or
- (c) a holder of a general supplier's licence or a general supplier's authority, or
- (d) any other person licensed or authorised by or under this Act to supply or use, or have possession of, the substance concerned.

[13] Section 16 Offences relating to prescribed restricted substances

Omit "section 19 (1) (b)" from section 16 (1) (c).
Insert instead "section 10 (4) (c)".

[14] Section 16 (1) (e)

Insert "this Act or" after "authorised by".

[15] Section 16 (1) and (2)

Insert at the end of section 16 (1) and (2):

Maximum penalty: 20 penalty units or imprisonment for 6 months, or both.

[16] Section 16 (3)

Omit the subsection. Insert instead:

- (3) A person who:
- (a) by a representation that the person knows, or ought reasonably to know, is false or misleading:
 - (i) obtains, or attempts to obtain, from a medical practitioner, dentist or veterinary surgeon a prescription that includes a restricted substance of a kind prescribed by the regulations for the purposes of this section, or
 - (ii) induces, or attempts to induce, a pharmacist to dispense a prescription that includes such a substance, knowing the prescription to be forged or fraudulently altered, or
 - (iii) induces, or attempts to induce, a pharmacist to dispense a prescription that includes such a substance, knowing the prescription to have been obtained as referred to in subparagraph (i), or
 - (b) is in actual possession of a prescription that includes such a substance, knowing the prescription to be forged or fraudulently altered, or
 - (c) is in actual possession of a prescription obtained as referred to in paragraph (a) (i), knowing the prescription to be so obtained,

is guilty of an offence.

Maximum penalty: 20 penalty units or imprisonment for 6 months, or both.

[17] Section 17 Regulations under Part 3

Omit section 17 (1) (a). Insert instead:

- (a) the issue, renewal, refusal to issue or renew, suspension and cancellation of licences and authorities for the purposes of this Part and the conditions subject to which licences or authorities may be issued or renewed for those purposes,

[18] Section 17 (1) (j)

Omit the paragraph.

[19] Sections 18 and 18A

Omit the sections. Insert instead:

18 Offence to fail to comply with condition of licence or authority

A person who fails to comply with a condition of a licence or authority issued for the purposes of this Part is guilty of an offence.

Maximum penalty:

- (a) 20 penalty units or imprisonment for 2 years, or both, if the offence involves a restricted substance of a kind prescribed by the regulations for the purposes of this section, or
- (b) 15 penalty units or imprisonment for 6 months, or both, in any other case.

18A Evidentiary provisions

- (1) A person who has actual possession of a quantity of a prescribed restricted substance exceeding the quantity prescribed for the purposes of this subsection is, for the purposes of any proceedings for an offence involving the supply of a quantity of that substance, taken to have possession of the substance for the purposes of supply unless the person:
 - (a) proves the contrary, or
 - (b) proves that the possession of the substance was obtained in accordance with the prescription of a medical practitioner, dentist or veterinary surgeon.

- (2) A substance that, for the purpose of being supplied, is represented as being a particular prescribed restricted substance is taken to be that particular restricted substance for the purposes of any proceedings for an offence involving the supply of a prescribed restricted substance.
- (3) In this section, *prescribed restricted substance* means a restricted substance prescribed by the regulations for the purposes of section 16.

[20] Part 3, Division 2 Exemptions

Omit the Division.

[21] Section 24 Regulations under Division 1 of Part 4

Omit section 24 (2) (e) and (f). Insert instead:

and

- (e) the withdrawal and suspension of any such licence or authority by the Director-General.

[22] Section 25 Further offences against this Division

Omit section 25 (a).

[23] Part 4A

Insert after Part 4:

**Part 4A Application in New South Wales of
Commonwealth therapeutic goods laws**

Division 1 The applied provisions

**31 Application of Commonwealth therapeutic goods laws to
New South Wales**

- (1) The Commonwealth therapeutic goods laws, as in force for the time being and as modified by or under this Part, apply as a law of New South Wales.

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- (2) Those Commonwealth therapeutic goods laws so apply as if they extended to:
- (a) things done or omitted to be done by persons who are not corporations, and
 - (b) things done or omitted to be done in the course of trade or commerce within the limits of New South Wales.
- (3) The regulations under this Act may modify the Commonwealth therapeutic goods laws for the purposes of this section.

32 Interpretation of Commonwealth therapeutic goods laws

- (1) The *Acts Interpretation Act 1901* of the Commonwealth, as in force for the time being, applies as a law of New South Wales in relation to the interpretation of the applied provisions, and so applies as if those provisions were respectively an Act of the Commonwealth or regulations or orders under such an Act, as the case requires.
- (2) The *Interpretation Act 1987* does not apply to the applied provisions.

Division 2 Functions and powers under applied provisions

33 Functions and powers of Commonwealth Minister

The Commonwealth Minister has the same functions and powers under the applied provisions as that Minister has under the Commonwealth therapeutic goods laws as those laws apply to the Commonwealth.

33A Functions and powers of Commonwealth Secretary

- (1) The Commonwealth Secretary has the same functions and powers under the applied provisions as that Secretary has under the Commonwealth therapeutic goods laws as those laws apply to the Commonwealth.

- (2) Without limiting subsection (1), the Commonwealth Secretary has the function of including goods in the Australian Register of Therapeutic Goods kept under the applied provisions and is authorised to cancel the inclusion of goods in that Register in accordance with those provisions.

33B Functions and powers of other persons

An authorised person, authorised officer or official analyst appointed under the Commonwealth therapeutic goods laws has the same functions and powers under the applied provisions as the person, officer or analyst has under those Commonwealth laws as they apply to the Commonwealth.

33C Delegations by the Commonwealth Minister or Secretary

Any delegation by the Commonwealth Minister or the Commonwealth Secretary under section 57 of the Commonwealth Act is taken to extend to, and have effect for the purposes of, the corresponding provision of the applied provisions.

33D Appointments under Commonwealth therapeutic goods laws

The appointment of a person to an office or position under a provision of the Commonwealth therapeutic goods laws is taken to extend to, and have effect for the purposes of, the applied provisions.

Division 3 Administrative law matters

33E Application of Commonwealth administrative laws to applied provisions

- (1) The Commonwealth administrative laws apply as laws of New South Wales to any matter arising in relation to the applied provisions as if those provisions were a law of the Commonwealth and not a law of New South Wales.

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- (2) For the purposes of a law of New South Wales, a matter arising in relation to the applied provisions:
- (a) is taken to be a matter arising in relation to laws of the Commonwealth in the same way as it would if those provisions were a law of the Commonwealth, and
 - (b) is taken not to be a matter arising in relation to laws of New South Wales.
- (3) Subsection (2) has effect for the purposes of a law of New South Wales except as prescribed by the regulations.

33F Functions and powers conferred on Commonwealth officers and authorities

- (1) A Commonwealth administrative law applying because of section 33E that confers on a Commonwealth officer or authority a function or power also confers on the officer or authority the same function or power in relation to a matter arising in relation to the applied provisions.
- (2) In performing a function, or exercising a power, conferred by this section, the Commonwealth officer or authority must act as nearly as is practicable as the officer or authority would act in performing or exercising the same function or power under the Commonwealth administrative law.
- (3) A function or power conferred on a Commonwealth officer or authority because of this section cannot be performed or exercised by an officer or authority of New South Wales.

Division 4 Offences

33G Object of this Division

- (1) The object of this Division is to further the object of this Part by providing for an offence against the applied provisions to be treated as if it were an offence against a law of the Commonwealth.

- (2) The purposes for which an offence is to be treated as mentioned in subsection (1) include, for example (but without limitation):
- (a) the investigation and prosecution of offences, and
 - (b) the arrest, custody, bail, trial and conviction of offenders or persons charged with offences, and
 - (c) proceedings relating to a matter referred to in paragraph (a) or (b), and
 - (d) appeals and review relating to criminal proceedings and to proceedings of the kind referred to in paragraph (c), and
 - (e) the sentencing, punishment and release of persons convicted of offences, and
 - (f) fines, penalties and forfeitures, and
 - (g) liability to make reparation in connection with offences, and
 - (h) proceeds of crime, and
 - (i) spent convictions.

33H Application of Commonwealth criminal laws to offences against applied provisions

- (1) The relevant Commonwealth laws apply as laws of New South Wales in relation to an offence against the applied provisions as if those provisions were a law of the Commonwealth and not a law of New South Wales.
- (2) For the purposes of a law of New South Wales, an offence against the applied provisions:
 - (a) is taken to be an offence against the laws of the Commonwealth, in the same way as if those provisions were a law of the Commonwealth, and
 - (b) is taken not to be an offence against the laws of New South Wales.

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- (3) Subsection (2) has effect for the purposes of a law of New South Wales except as provided by the regulations.

33I Functions and powers conferred on certain Commonwealth officers and authorities relating to offences

- (1) A provision of the applied provisions applying because of section 33H that confers on a Commonwealth officer or authority a function or power in relation to an offence against the Commonwealth therapeutic goods laws also confers on the officer or authority the same function or power in relation to an offence against the corresponding provision of the applied provisions.
- (2) In performing a function or exercising a power conferred by subsection (1), the Commonwealth officer or authority must act as nearly as practicable as the officer or authority would act in performing or exercising the same function or power in relation to an offence against the corresponding provision of the Commonwealth therapeutic goods laws.

33J No double jeopardy for offences against applied provisions

If:

- (a) an act or omission is an offence against both the applied provisions and an offence against the Commonwealth therapeutic goods laws, and
- (b) the offender has been punished for that offence under those Commonwealth laws,

the offender is not liable to be punished for the offence under the applied provisions.

Division 5 Miscellaneous

33K Jurisdiction of courts

- (1) Jurisdiction is conferred on the Federal Court of Australia with respect to all civil matters arising under the applied provisions.

- (2) This section does not limit the jurisdiction of the courts of New South Wales.
- (3) This Act does not affect the operation of any law of New South Wales relating to cross-vesting of jurisdiction.

33L Commonwealth may retain fees paid to Commonwealth Secretary

The Commonwealth may retain fees paid to, or recovered by, the Commonwealth Secretary in respect of the performance or exercise of functions or powers conferred on that Secretary by the applied provisions.

[24] Heading to Part 5, Division 1

Insert after the heading to Part 5 “**Division 1 Offences**”.

[25] Sections 34–36D

Omit sections 34–36. Insert instead:

34 Hawking of poisons and therapeutic goods

- (1) A person who:
 - (a) goes from house to house supplying regulated goods, or
 - (b) while in a public street or other public place, supplies regulated goods,

is guilty of an offence.

Maximum penalty: 20 penalty units.

- (2) Subsection (1) does not apply to a person or a person of a class of persons, or regulated goods or regulated goods of a class, exempted by an order under subsection (3).

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- (3) The Minister may, by order published in the Gazette, exempt any person or class of persons, or any regulated goods or class of regulated goods, from the operation of subsection (1). Such an exemption may be unconditional or subject to conditions.

- (4) In this section:

house means any premises where people reside, whether permanently or not.

public place means any place where members of the public are lawfully entitled, invited or permitted to be present in their capacity as members of the public, whether conditionally or unconditionally, but does not include:

- (a) a shop, or
- (b) premises where a medical practitioner, dentist, veterinary surgeon or pharmacist carries on the practice of his or her profession.

35 Director-General can obtain information about certain substances and goods

- (1) The Director-General may, by notice served on a person who manufactures in, imports into or supplies in New South Wales any regulated goods, require the person to give to the Director-General, or to such other person as may be identified in the notice, such information about the substance or goods as is specified in the notice. Such a notice may specify a period of not less than 14 days within which the requirement of the notice is to be complied with.
- (2) A notice under this section may be served on a person even though the person has previously given information about the substance or goods specified in the notice.
- (3) A person who, without reasonable excuse, fails to comply with a notice given to the person under this section is guilty of an offence.

Maximum penalty: 20 penalty units.

- (4) A person who, in purporting to comply with a notice under this section, gives information that the person knows, or ought reasonably to know, is false or misleading in a material respect is guilty of an offence.

Maximum penalty: 20 penalty units.

- (5) In this section, *regulated goods* includes any substance that might warrant inclusion in the Poisons List.

36 Offence to supply certain substances and goods by automatic machine

- (1) A person who, whether in premises under the person's control or elsewhere:

- (a) installs an automatic machine for the supply of regulated goods, or
- (b) supplies regulated goods by means of an automatic machine,

is guilty of an offence.

Maximum penalty: 20 penalty units.

- (2) A person who occupies or controls premises is guilty of an offence if:

- (a) an automatic machine for the supply of regulated goods is installed on the premises, or
- (b) regulated goods are stored in an automatic machine that is installed on the premises, or
- (c) regulated goods are supplied by means of an automatic machine.

Maximum penalty: 20 penalty units.

- (3) Subsections (1) and (2) do not apply to a person or a person of a class of persons, or regulated goods or regulated goods of a class, exempted by an order under subsection (4).

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- (4) The Minister may, by order published in the Gazette, exempt any person or class of persons, or any regulated goods or class of regulated goods, from the operation of subsection (1) or (2). Such an exemption may be unconditional or subject to conditions.

36A Offence to supply unregistered or unlisted goods

- (1) A person who supplies by retail therapeutic goods to a person is guilty of an offence unless:
- (a) the goods are registered goods or listed goods, or
 - (b) the goods are exempt goods or are the subject of an approval or authority under section 19 of the Commonwealth Act.

Maximum penalty: 20 penalty units.

- (2) This section applies to therapeutic goods that are for use in or on humans, but does not apply to:
- (a) a supply of therapeutic goods that are listable devices within the meaning of the Commonwealth Act, or
 - (b) a supply of therapeutic goods by a person who is a sponsor within the meaning of that Act.

Note. Section 19 of the Commonwealth Act empowers the Commonwealth Secretary to grant approval for the import, export or supply of therapeutic goods for the treatment of a person or for use solely for experimental purposes in humans.

36B Offence to supply regulated goods by retail after expiry date

- (1) A person who supplies by retail regulated goods after the expiry date that is, in accordance with a standard that is applicable to the goods, stated on or in relation to the goods is guilty of an offence.

Maximum penalty: 20 penalty units.

- (2) A standard is applicable to regulated goods if:
- (a) a standard specified in an order under section 10 of the Commonwealth Act is applicable to the goods, or
 - (b) if no such order is applicable to the goods but the goods are the subject of a monograph in the British Pharmacopoeia in the case of goods for use in or on humans, or the British Pharmacopoeia (Veterinary) in the case of goods for use in or on animals—a standard that is constituted by the statements in that monograph.

Note. Section 10 of the Commonwealth Act empowers the Commonwealth Minister to make orders determining standards for therapeutic goods.

36C Offence to use certain therapeutic devices without licence

A person who, in New South Wales, uses a therapeutic device of a kind prescribed by the regulations for the purposes of this section is guilty of an offence, unless the use is under, and is in accordance with the conditions of, a user's licence issued in accordance with the regulations.

Maximum penalty: 50 penalty units

36D Offences by bodies corporate

- (1) If a body corporate contravenes, whether by act or omission, any provision of this Act or the regulations, each person who is a director, or a person concerned in the management, of the body is taken to have contravened the same provision if the person knowingly authorised or permitted the contravention.
- (2) A person may be proceeded against and convicted under a provision under this section whether or not the body corporate has been proceeded against or convicted.

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- (3) This section does not affect any liability imposed on a body corporate for an offence committed by the body against this Act or the regulations.

[26] Part 5, Division 2

Insert after section 37:

Division 2 Analysts and analysis

37A Appointment of analysts

- (1) The Minister may appoint particular persons or a class of persons to be analysts for the purposes of this Act.
- (2) The appointment of a particular person as an analyst is to be by a document of appointment given to the person.
- (3) The appointment of a class of persons to be analysts is to be by means of a notice published in the Gazette.
- (4) Persons may be appointed as analysts whether or not they are employed under Part 2 of the *Public Sector Management Act 1988*.

Note. Section 47 of the *Interpretation Act 1987* provides, among other things, that a power of appointment includes a power to remove or suspend an appointee and power to appoint another person to act in place of an appointee who is removed or suspended from appointment.

37B Conduct of analyses

- (1) An inspector may submit for analysis under this section any substance or goods seized under this Act.
- (2) An analyst is required to carry out or personally supervise the carrying out of an analysis of a substance or goods submitted to the analyst for analysis.
- (3) An analyst who has carried out or personally supervised the carrying out of an analysis of any such substance or goods may, and must on request, issue a certificate of analysis setting out the results of the analysis.

- (4) The owner of any such substance or goods, or the person in whose possession or under whose control the substance or goods were when they were seized, is entitled to be provided with a copy of the certificate of analysis relating to the substance or goods on payment of the fee (if any) prescribed by the regulations.
- (5) A person who, for trade purposes or advertisement, uses the results of an analysis carried out for the purposes of this Act, or a certificate of analysis issued under this section, is guilty of an offence.

Maximum penalty (subsection (5)): 20 penalty units.

[27] Heading to Part 5, Division 3

Insert after section 38 **"Division 3 Evidentiary matters"**.

[28] Section 39 Certificate of Director-General prima facie evidence

Insert "or the regulations" after "this Act" wherever occurring.

[29] Section 40 Proof of certificate of an analyst

Section 40 (2)

Insert "or the regulations," after "this Act".

[30] Section 40 (3)

Omit the subsection.

[31] Section 41 Evidence in prosecutions under this Act

Insert at the end of section 41 (d):

or

(d1) that is therapeutic goods,

[32] Section 41 (e)

Omit "or (d) shall be prima facie evidence that the said".

Insert instead ", (d) or (d1) is prima facie evidence that the".

[33] Heading to Part 5, Division 4

Insert after section 41 "**Division 4 Enforcement**".

[34] Sections 42-43A

Omit sections 42 and 43. Insert instead:

42 Inspectors

- (1) The Director-General may, in writing, appoint a person to be an inspector for the purposes of this Act.
- (2) An appointment under this section may authorise the exercise of all the functions of an inspector under this Act or only specified functions and may authorise the exercise of functions generally or in a particular case.
- (3) A person may be appointed to be an inspector whether or not the person is employed under Part 2 of the *Public Sector Management Act 1988*.
- (4) The Director-General must ensure that each inspector appointed under this section is issued with a certificate of identity that incorporates a recent photograph of the inspector.
- (5) A person appointed under this section must, as soon as practicable after ceasing to be an inspector, return the person's certificate of identity as an inspector to the Director-General.

Maximum penalty: 2 penalty units.

- (6) A police officer is, by virtue of his or her office, taken to be an inspector for the purposes of this Act.

Note. Section 47 of the *Interpretation Act 1987* provides, among other things, that a power of appointment includes a power to remove or suspend an appointee and power to appoint another person to act in place of an appointee who is removed or suspended from appointment.

43 Powers of entry and seizure

- (1) This section applies to:
- (a) regulated goods that are for supply or are (whether or not the goods are to be the subject of further manufacture) intended for supply, or
 - (b) goods that an inspector reasonably believes to be regulated goods referred to in paragraph (a).
- (2) For the purpose of ascertaining whether the provisions of this Act or the regulations are being complied with, an inspector may do any of the following:
- (a) enter any premises that the inspector reasonably believes to be used in or in connection with the manufacture, distribution, conveyance, storage, handling or supply of goods to which this section applies,
 - (b) search those premises,
 - (c) require the production of stocks of any such goods that are kept on those premises and any record relating to the keeping of, or dealings with, those stocks,
 - (d) inspect stocks, and inspect and make copies of a record, or part of a record, produced in accordance with such a requirement or found on the premises,
 - (e) open and examine any receptacle, container or package that the inspector reasonably believes may contain any such goods,
 - (f) examine any such goods,

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- (g) seize and remove for analysis portions or samples of any such goods,
 - (h) seize and detain any things found on those premises if the inspector reasonably believes that a contravention of this Act or the regulations has been committed with respect to those things.
 - (3) The power conferred by subsection (2) (g) or (h) to seize goods or things includes a power to remove the goods or things from the premises where they were seized.
 - (4) An inspector may enter a part of premises used for residential purposes only with the consent of the occupier or in accordance with a search warrant obtained.
 - (5) An inspector must not exercise a power conferred by this section unless the inspector:
 - (a) is in possession of a certificate of identity, and
 - (b) gives reasonable notice to the occupier of the premises of intention to exercise the power (unless giving notice would defeat the purpose for which it is intended to exercise the power), and
 - (c) exercises the power at a reasonable time (unless it is being exercised in an emergency), and
 - (d) produces the certificate of identity if asked to do so by an occupier of the premises, and
 - (e) uses no more force than is reasonably necessary to exercise the power.

A police officer in uniform is not required to comply with paragraph (a) or (d) when exercising the powers of an inspector conferred by this section.

- (6) The owner of the premises is entitled to recover from the Crown as a debt a reasonable amount of compensation for damage caused by an inspector while exercising the power to enter, inspect or search premises.

- (7) A person who:
- (a) intentionally delays or obstructs an inspector in the exercise of any of the inspector's powers under this Act, or
 - (b) without reasonable excuse, fails to produce any substance, goods or records that the person is required to produce under this Act,
- is guilty of an offence.

Maximum penalty: 20 penalty units.

- (8) In this section:

production of a record includes, if the record is not in writing or is not written in English or is not decipherable on sight, production of a statement in English that is decipherable on sight and sets out the contents of the record.

record includes any book, account, document, paper or other source of information compiled, recorded or stored in written form, on microfilm, or by electronic process, or in any other manner or by any other means.

43A Search warrant may be issued in certain cases

- (1) In this section, *authorised justice* has the same meaning as in the *Search Warrants Act 1985*.
- (2) A person who is authorised by the Minister or the Director-General to do so may apply to an authorised justice for a search warrant for premises if entry to the premises has been refused, or an attempt to enter has been, or is likely to be, unsuccessful, and:
 - (a) there are reasonable grounds for believing that an offence under this Act or the regulations has been, or is being, committed on the premises, or
 - (b) the search warrant is sought in order to exercise a power conferred by section 43 (2).

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- (3) An authorised justice to whom an application is made under this section may, if satisfied that there are reasonable grounds for doing so, issue a search warrant authorising a person named in the warrant to enter the premises.
 - (4) Part 3 of the *Search Warrants Act 1985* applies to a search warrant issued under this section.

[35] Section 45

Omit the section. Insert instead:

45 Proceedings for offences

- (1) Proceedings for an offence against this Act or the regulations are to be disposed of before a Local Court constituted by a Magistrate sitting alone.
- (2) Proceedings for an offence against this Act or the regulations may be started only within 2 years after the offence is alleged to have been committed.

[36] Section 45B Time for laying information or complaint

Omit the section.

[37] Heading to Part 5, Division 5

Insert “**Division 5 Miscellaneous**” before section 45C.

[38] Section 45C Regulations

Insert after section 45C (1):

- (1A) In particular, the regulations may make provision for or with respect to any of the following:

- (a) providing for the issue, renewal, suspension and cancellation of licences for the purposes of section 36C and the conditions subject to which such licences may be issued or renewed for those purposes,
 - (b) prohibiting or regulating the advertising of therapeutic goods by persons engaged in the supply of those goods, including the form and content of advertisements and the manner in which advertisements may be published or displayed,
 - (c) providing for labelling, sampling, examining, testing and analysing therapeutic goods,
 - (d) prescribing conditions to be complied with when preparing, supplying, storing, packing, handling, carrying and delivering therapeutic goods,
 - (e) prohibiting or regulating the supply of therapeutic goods of a specified class,
 - (f) prescribing fees that are to be paid for matters arising under this Part (including fees for the issue and renewal of licences referred to in paragraph (a)),
 - (g) requiring persons of a specified class to keep records for the purposes of this Part,
 - (h) prohibiting the supply of therapeutic goods by self-service methods specified in the regulations.
- (1B) The regulations may also make provision for or with respect to any of the following:
- (a) empowering Magistrates to order the forfeiture of regulated goods and other things seized under this Act and to order payments to be made to meet costs incurred in seizing, storing and disposing of goods or things so seized,
 - (b) providing for the storage and release of goods seized under this Act,

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- (c) conferring rights of appeal on persons aggrieved by decisions of the Director-General relating to:
- (i) the issue, renewal or refusal to issue or renew licences or authorities issued or renewed for the purposes of this Act or the regulations, or
 - (ii) the suspension, withdrawal or cancellation of licences or authorities issued or renewed for those purposes.

[39] Section 45C (5)

Insert after section 45C (4):

- (5) The regulations may create offences punishable by a penalty not exceeding 20 penalty units or imprisonment for a term not exceeding 6 months, or both.

[40] Sections 45D and 45E

Insert after section 45C:

45D Act binding on Crown in right of New South Wales

This Act binds the Crown not only in right of New South Wales but also, so far as the legislative power of the Parliament permits, the Crown in all its other capacities.

45E Notes in text

Notes in the text of this Act are explanatory notes only and do not form part of this Act.

[41] Section 46A

Insert after section 46:

46A Savings and transitional provisions

Schedule 3 has effect.

[42] Schedule 3

Insert after Schedule 2:

Schedule 3 Savings and transitional provisions

(Section 46A)

Part 1 Preliminary

1 Regulations

- (1) The regulations may contain provisions of a savings or transitional nature consequent on the enactment of:
the *Poisons Amendment (Therapeutic Goods) Act 1996*.
- (2) Any such provision may, if the regulations so provide, take effect from the date of assent to the Act concerned or a later day.
- (3) To the extent to which any such provision takes effect from a date that is earlier than the date of its publication in the Gazette, the provision does not operate so as:
 - (a) to affect, in a manner prejudicial to any person (other than the State or an authority of the State), the rights of that person existing before the date of its publication, or
 - (b) to impose liabilities on any person (other than the State or an authority of the State) in respect of anything done or omitted to be done before the date of the publication.

**Part 2 Provisions consequent on enactment of
Poisons Amendment (Therapeutic Goods)
Act 1996**

2 Definition

In this Part:

amending Act means the *Poisons Amendment (Therapeutic Goods) Act 1996*.

earlier Act means the *Therapeutic Goods and Cosmetics Act 1972*.

3 Saving of exemption orders

- (1) If an order in force under section 6 of the earlier Act was applicable to section 42 of that Act immediately before the repeal of that Act by the amending Act, the order is taken to be an order made under section 36 of this Act, as in force after the commencement of Schedule 1 [25] to the amending Act.
- (2) If an order in force under section 6 of the earlier Act was applicable to section 43 of that Act immediately before the repeal of that Act by the amending Act, the order is taken to be an order made under section 34 of this Act, as in force after the commencement of Schedule 1 [25] to the amending Act.

4 Saving for existing licences

- (1) If:
 - (a) a licence authorising its holder to sell a substance or device by wholesale is in force under Division 2 of Part 3 of the earlier Act immediately before the repeal of that Division by the amending Act, and
 - (b) the substance or device is a substance specified in Schedule 1, 2, 3 or 7 of the Poisons List or a restricted substance,

the licence is taken to be a wholesaler's licence in force for the purposes of section 9 of this Act (as substituted by the amending Act).

- (2) If:
 - (a) an authority is in force under the regulations immediately before the commencement of Schedule 1 [12] to the amending Act, and
 - (b) the authority authorises its holder to supply by wholesale for use only in or on animals a substance specified in Schedule 1, 2, 3 or 7 of the Poisons List or a restricted substance,

the authority is taken to be a wholesaler's authority in force for the purposes of section 9 of this Act.

- (3) If a licence was in force under section 9 of this Act (as in force immediately before the commencement of Schedule 1 [12] to the amending Act), the licence is taken to be a general supplier's licence in force for the purposes of section 10 of this Act (as in force after that commencement).
- (4) If:
- (a) a licence authorising its holder to use a device is in force under Division 2 of Part 3 of the earlier Act immediately before the repeal of that Division by the amending Act, and
 - (b) the device is therapeutic goods within the meaning of this Act,

the licence is taken to be a user's licence in force for the purposes of section 36C of this Act.

5 Suspension of existing licences

A licence that was, immediately before the repeal of the earlier Act by the amending Act, suspended under section 21 of that Act is taken to be suspended for the purposes of this Act. This clause applies to a licence only if the licence is otherwise saved by clause 4.

6 Appointment of inspector under earlier Act

An inspector holding office under section 29 of the earlier Act immediately before the repeal of that Act by the amending Act is taken to be an inspector appointed under section 42 of this Act (as substituted by the amending Act).

7 Appointment of analyst under earlier Act

An analyst holding office under section 39 of the earlier Act immediately before the repeal of that Act by the amending Act is taken to be an analyst appointed under section 37A of this Act.

8 Disposal of goods seized under earlier Act

Goods seized under section 30 of the earlier Act and not disposed of under that Act before the repeal of that Act by the amending Act are to be disposed of under the earlier Act as if that Act had not been so repealed.

9 Information required under section 41 of earlier Act

If a notice served on a person under section 41 of the earlier Act has not been complied with before the repeal of that Act by the amending Act, then, despite that repeal, the notice continues to have effect as if that section had not been repealed.

10 Saving for notices under sections 19 and 21 of earlier Act

If a notice served on a person under section 19 or 21 of the earlier Act has not had effect before the repeal of that Act by the amending Act, then, despite that repeal, the notice continues to have effect as if that section had not been repealed.

11 Saving for pending appeals

Section 52 of the earlier Act relating to appeals continues to apply to and in respect of an appeal made under that Act and pending immediately before the repeal of that Act by the amending Act.

12 Saving for certain regulations

Any regulations in force for the purposes of section 24 (2) (f) of this Act immediately before the commencement of Schedule 1 [21] to the amending Act are taken to be regulations made for the purposes of section 45C (1B) (c) of this Act.

Schedule 2 Consequential amendment of other Acts

(Section 4)

2.1 Animal Research Act 1985 No 123

Section 3 Definitions

Omit "*Therapeutic Goods and Cosmetics Act 1972*" from the definition of ***recognised research purpose*** in section 3 (1).

Insert instead "*Therapeutic Goods Act 1989* of the Commonwealth".

2.2 Drug Misuse and Trafficking Act 1985 No 226

Section 43 Certificate evidence

Omit "*Therapeutic Goods and Cosmetics Act 1972*" from paragraph (b) of the definition of ***analyst*** in section 43 (6).

Insert instead "*Poisons and Therapeutic Goods Act 1966*".

2.3 Health Care Complaints Act 1993 No 105

[1] Section 25 Reference of certain complaints to the Director-General

Omit "*Poisons Act 1966*" from section 25 (1).

Insert instead "*Poisons and Therapeutic Goods Act 1966*".

[2] Section 25 (1)

Omit "*Therapeutic Goods and Cosmetics Act 1972*".

2.4 Traffic Act 1909 No 5

Section 2 Definitions

Omit "*Therapeutic Goods and Cosmetics Act 1972*" from the definition of *analyst* in section 2 (1).

Insert instead "*Poisons and Therapeutic Goods Act 1966*".

[Minister's second reading speech made in—
Legislative Assembly on 23 November 1995
Legislative Council on 17 April 1996]

