

# Poisons and Therapeutic Goods Act 1966 No 31

[1966-31]



New South Wales

## Status Information

### Currency of version

Historical version for 8 December 2000 to 27 September 2001 (accessed 19 November 2024 at 6:27)

Legislation on this site is usually updated within 3 working days after a change to the legislation.

### Provisions in force

The provisions displayed in this version of the legislation have all commenced.

### Notes—

- **Previously named**  
Poisons Act 1966
- **Does not include amendments by**  
[Rural Lands Protection Act 1998 No 143](#) (not commenced)

### Authorisation

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File last modified 13 December 2000

# Poisons and Therapeutic Goods Act 1966 No 31



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# Poisons and Therapeutic Goods Act 1966 No 31



New South Wales

An Act relating to the regulation, control and prohibition of the supply and use of poisons, restricted substances, drugs of addiction, certain dangerous drugs and certain therapeutic goods; to establish a Poisons Advisory Committee and to define its powers, authorities, duties and functions; to repeal the *Poisons Act 1952* and certain other Acts; to amend the *Police Offences (Amendment) Act 1908*, the *Crimes Act 1900*, the *Motor Traffic Act 1909* and certain other Acts; and for purposes connected therewith.

## Part 1 Preliminary

### 1 Name of Act

This Act may be cited as the *Poisons and Therapeutic Goods Act 1966*.

### 2, 3 (Repealed)

### 4 Definitions

(1) In this Act, unless the context or subject matter otherwise indicates or requires:

**Advisory Committee** means the Poisons Advisory Committee constituted by section 6.

**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.

**Automatic machine** means any machine or mechanical device used or capable of being used for the purpose of supplying goods without the personal manipulation or attention of the supplier or the supplier's employee or other agent at the time of supply.

**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) (Repealed)
- (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.

**Container**, when used in relation to any substance, material, body or thing referred to in this Act, means any vessel, bottle, tube, capsule, tin, box, case, wrapper, cover or other like receptacle or envelope which immediately contains such substance, material, body or thing.

**Dentist** means a person registered, or deemed to be registered, as a dentist under the *Dentists Act 1934*.

**Director-General** means the Director-General of the Department of Health.

**Drug of addiction** means any substance specified in Schedule Eight of the Poisons List.

**Justice** means justice of the peace.

**Label** includes any tag, brand, mark or statement in writing on or attached to or used in connection with any container or package containing any poison, restricted substance or drug of addiction.

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

**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.

**Medical Committee** means the Medical Committee constituted under section 30.

**nurse practitioner** means a person authorised under the [Nurses Act 1991](#) to practise as a nurse practitioner.

**Package**, when used in relation to any substance, material, body or thing referred to in this Act, includes every means by which such substance, material, body or thing may, for transport or for carriage or for storage or for supply, be cased, covered, enclosed, contained or packed.

**Pharmacist** means a pharmacist within the meaning of the [Pharmacy Act 1964](#).

**Pharmacy trainee** means:

(a) a person who:

(i) were he or she to have served as an assistant, as referred to in section 13 of the [Pharmacy Act 1964](#), and to have had the experience referred to in subsection (1) (c) of that section, or

(ii) were he or she to have had the experience referred to in section 14, or section 15 (d), of that Act,

would be entitled to be registered under that Act as a pharmacist, and

(b) a person who has passed the examination, and served as an apprentice, as referred to in section 16 (a) of the [Pharmacy Act 1964](#), for a period of not less than 3 years or in respect of whom the Pharmacy Board of New South Wales constituted under that Act has accepted a course of training referred to in the proviso to that paragraph,

but does not include a pharmacist.

**Poison** means any substance specified in Schedule One, Schedule Two, Schedule Three, Schedule Five, Schedule Six, or Schedule Seven of the Poisons List.

**Poisons List** means the list proclaimed under section 8 as in force for the time being.

**Premises** includes any structure, building, aircraft, vehicle, vessel or place (whether built upon or not), and any part thereof.

**Prescribed** means prescribed by this Act or by the regulations.

**Public institution** means:

- (a) any Government Department, public hospital, or university within New South Wales, or
- (b) any other institution or establishment which the Governor by order published in the Gazette declares to be a public institution for the purposes of this 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.

**Regulations** means regulations made under this Act.

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

**Restricted substance** means any substance specified in Schedule Four of the Poisons List.

**Sell** includes sell whether by wholesale or retail and barter and exchange, and also includes dealing in, agreeing to sell, or offering or exposing for sale, or keeping or having in possession for sale, or sending, forwarding, delivering or receiving for sale or on sale, or authorising, directing, causing, suffering, permitting or attempting any of such acts or things.

**Substance** includes preparation or admixture and all salts and derivatives of any substance.

**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).

**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:

- (c) for use in a public institution, or
- (d) to persons who are authorised by the regulations to be supplied with wholesale quantities of the substance or goods.

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

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

**Veterinary surgeon** means a person registered as a veterinary surgeon under the [Veterinary Surgeons Act 1986](#).

- (2) For the purposes of the Poisons List, a substance may be described:
  - (a) by reference to any 1 or more of the following:
    - (i) the common or scientific name of the substance,
    - (ii) any class of substances,
    - (iii) the composition of the substance,
    - (iv) the purpose for which the substance may be used,
    - (v) the manner in which the substance is packed, or
    - (vi) such other factor or circumstance as may be specified in relation to the substance in the Poisons List or in any such proclamation,
  - (b) in any other manner so specified.
- (3) Nothing in this Act precludes a substance from being both:

- (a) a poison, restricted substance or drug of addiction, and
- (b) therapeutic goods.

(4) (Repealed)

## **5 Exemption from operation of Act**

(1) The Minister may from time to time, by order published in the Gazette, exempt:

- (a) any council within the meaning of the *Local Government Act 1993*, or
- (b) any rural lands protection board constituted or continued by or under the *Rural Lands Protection Act 1989*,

specified in the order from all of the provisions of this Act or from such of those provisions as may be specified in the order, and thereupon the provisions of this Act or such of them as are so specified, as the case may be, shall not apply to or in respect of the council or rural lands protection board specified in the order.

(2) The provisions of subsection (1) do not extend to authorising the Minister to grant an exemption from any of the provisions of this Act to the extent that they relate to restricted substances or drugs of addiction.

## **Part 2 Poisons Advisory Committee and Poisons List**

### **Division 1 Poisons Advisory Committee**

#### **6 Poisons Advisory Committee**

(1) There is constituted by this Act a Poisons Advisory Committee consisting of:

- (a) 6 nominated members, and
- (b) 10 members appointed by the Governor.

(2) Of the nominated members:

- (a) 1 is to be a person for the time being nominated by the Minister, being an officer of the Department of Health or an employee of a public health organisation within the meaning of the *Health Services Act 1997*,
- (b) 1 shall be the Head of the Department of Pharmacy, University of Sydney, or a person he or she nominates for the time being,
- (c) 1 shall be a member of the Police Force for the time being nominated by the Commissioner of Police,
- (d) 1 shall be an officer of the Department of Agriculture for the time being nominated by the Minister for Agriculture,

- (e) 1 shall be an officer of the Environment Protection Authority for the time being nominated by the Minister for the Environment, and
  - (f) 1 shall be an officer of the WorkCover Authority for the time being nominated by the Minister for Industrial Relations.
- (3) Of the members appointed by the Governor:
- (a) 1 shall be a medical practitioner nominated by the Australian Medical Association (NSW) Limited,
  - (b) 1 shall be a pharmacologist nominated by the Minister,
  - (c) 1 shall be a person nominated by the Minister for Agriculture to represent agricultural and pastoral organisations,
  - (d) 1 shall be a representative of the Proprietary Medicines Association of Australia Incorporated,
  - (e) 1 shall be a representative of the Australian Pharmaceutical Manufacturers Association Inc.,
  - (f) 1 shall be a representative of Avcare Limited,
  - (g) 1 shall be a representative of the Pharmacy Guild of Australia (New South Wales Branch),
  - (h) 1 shall be a representative of The Pharmaceutical Society of Australia (New South Wales Branch) Ltd.,
  - (i) 1 is to be a person representing the country members of The Retail Traders' Association of New South Wales, and
  - (j) 1 shall be a dentist representing The Australian Dental Association, New South Wales Branch.
- (4) Schedule 1 has effect with respect to the members of the Advisory Committee.
- (5) Schedule 2 has effect with respect to the procedure of the Advisory Committee.

#### **6A Subcommittees**

- (1) The Advisory Committee may establish subcommittees to assist it in the exercise of its functions.
- (2) Subject to the inclusion of at least 1 member of the Advisory Committee, it does not matter that the members of a subcommittee include persons who are not members of the Advisory Committee.

- (3) The procedure for the calling of meetings of a subcommittee and for the conduct of business at those meetings shall be as determined by the Advisory Committee or (subject to any determination of the Advisory Committee) by the subcommittee.

## **6B Delegation**

The Advisory Committee may delegate to a subcommittee of the Advisory Committee any of its functions other than:

- (a) this power of delegation, and
- (b) any function required by the regulations to be exercised only by the Advisory Committee.

## **7 Functions of Advisory Committee**

- (1) The Advisory Committee may initiate and refer to the Minister:
  - (a) recommendations for making, altering or repealing any regulation under this Act,
  - (b) recommendations for amending the Poisons List.
- (2) It is the duty of the Advisory Committee to consider and advise the Minister upon such matters and questions as the Minister may from time to time refer to it relating to:
  - (a) any proposal, whether or not initiated by the Committee, for making, altering or repealing any regulations under this Act,
  - (b) any proposal, whether or not initiated by the Committee, for amending the Poisons List.

## **Division 2 Poisons List**

### **8 Poisons List**

- (1) The proclamation of the Poisons List in force under this section immediately before the commencement of Schedule 2 to the *Poisons (Amendment) Act 1987* continues in force at the commencement as the proclamation of the Poisons List for the purposes of this Act.
- (2) The Poisons List shall contain 8 Schedules and the substances included in the list shall be classified as follows:

#### **Schedule One**

Substances which are of such extreme danger to life as to warrant their being supplied only by medical practitioners, nurse practitioners authorised under section 17A, pharmacists, dentists, veterinary surgeons or persons licensed under Part 3.

**Schedule Two**

Substances which are dangerous to life if misused or carelessly handled, but which should be available to the public for therapeutic use or other purposes without undue restriction.

**Schedule Three**

Substances which are for therapeutic use and:

- (i) about which personal advice may be required by the user in respect of their dosage, frequency of administration and general toxicity,
- (ii) with which excessive unsupervised medication is unlikely, or
- (iii) which may be required for use urgently so that their supply only on the prescription of a medical practitioner or veterinary surgeon would be likely to cause hardship.

**Schedule Four**

Substances which in the public interest should be supplied only upon the written prescription of a medical practitioner, nurse practitioner authorised to prescribe the substance under section 17A, dentist or veterinary surgeon.

**Schedule Five**

Poisonous substances of a dangerous nature commonly used for domestic purposes which should be readily available to the public but which require caution in their handling, use and storage.

**Schedule Six**

Substances which should be readily available to the public for agricultural, pastoral, horticultural, veterinary, photographic or industrial purposes or for the destruction of pests.

**Schedule Seven**

Substances of exceptional danger which require special precautions in their manufacture or use.

**Schedule Eight**

Substances which are addiction producing or potentially addiction producing.

(3)-(5) (Repealed)

(6) The Poisons List may be amended by proclamation made on the recommendation of the Minister.

(7) An amendment of the Poisons List may be made by applying, adopting or

incorporating, with or without modification, the current Poisons Standard (within the meaning of Part 5B of the Commonwealth Act) or any other published standard, as in force at a particular time or as in force from time to time.

**Editorial note—**

See Historical notes at the end of this Act for amendments to the Poisons List.

## **Part 3 Poisons and restricted substances**

### **Division 1 Restrictions on supply, possession, etc, of poisons and restricted substances**

#### **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.

#### **9A (Repealed)**

#### **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

(a1) by a nurse practitioner, who is authorised under section 17A to supply the substance, in the lawful practice of his or her profession as such, 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

(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

(a1) by a nurse practitioner, who is authorised under section 17A to supply the substance, in the lawful practice of his or her profession as such, or

(b) by a pharmacist in accordance with the prescription of a medical practitioner, nurse 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, nurse practitioner or a dentist, or

(c1) by a person who has the care of, or is assisting in the care of, another person (for or to whom the supply of the substance has been authorised by the prescription of a medical practitioner, nurse practitioner or dentist) and who administers the restricted substance to the other person in accordance with that prescription, 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:

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

(a) a medical practitioner, dentist, veterinary surgeon or pharmacist, or

(a1) a nurse practitioner authorised under section 17A to supply or use, or have possession of, the substance concerned, 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:

- (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
  - (a1) a nurse practitioner authorised under section 17A to supply or use, or have possession of, the substance concerned, 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.

## **13-15 (Repealed)**

## **16 Offences relating to prescribed restricted substances**

- (1) A person shall not have in his or her possession or attempt to obtain possession of a prescribed restricted substance unless:
- (a) the person is a medical practitioner, pharmacist, dentist or veterinary surgeon, and the person obtains possession or attempts to obtain possession of it in the lawful practice of the person's profession as such,
    - (a1) the person is a nurse practitioner who is authorised under section 17A to possess the substance and the person obtains possession or attempts to obtain possession of it in the lawful practice of his or her profession,
  - (b) the person obtains possession or attempts to obtain possession of it on and in

accordance with the prescription of a medical practitioner, nurse practitioner, dentist or veterinary surgeon for its supply to the person,

- (c) the person is a person or belongs to a class of persons authorised by the Director-General for the purposes of section 10 (4) (c),
- (d) the person is a person authorised in writing by the Director-General to obtain possession of the prescribed restricted substance for the purposes of the person's profession or employment and obtains, or attempts to obtain, as the case may be, possession of the prescribed restricted substance in accordance with any conditions subject to which the person is so authorised,
- (d1) the person is a person who has the care of, or is assisting in the care of, another person (for or to whom the supply of the substance has been authorised by the prescription of a medical practitioner, nurse practitioner or dentist) and has the prescribed restricted substance in his or her possession for the sole purpose of administering, or assisting in the self-administration of, the substance to the other person in accordance with that prescription, or
- (e) the person is licensed or otherwise authorised by this Act or the regulations to obtain possession of the substance for the purposes of his or her profession or employment.

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

- (2) A person shall not forge or fraudulently alter, or utter, knowing it to be forged or fraudulently altered, any prescription of a medical practitioner, nurse practitioner, dentist or veterinary surgeon including any prescribed restricted substance.

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

- (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, nurse 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.

- (4) Any prescribed restricted substance in the order or disposition of a person shall, for the purposes of subsection (1), be deemed to be in the person's possession.
- (5) A person shall not be guilty of an offence against subsection (1) by virtue of the person having in his or her possession, or attempting to obtain possession of, a prescribed restricted substance if the person proves that he or she had possession, or attempted to obtain possession, of the substance only for the purpose of delivering it:
  - (a) to a medical practitioner, nurse practitioner, pharmacist, dentist or veterinary surgeon, or
  - (b) to a person to whom its supply has been authorised by the prescription of a medical practitioner, nurse practitioner, dentist or veterinary surgeon.

### **17 Regulations under Part 3**

- (1) Without limiting the generality of section 45C, the Governor may make regulations under this Part for or with respect to:
  - (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,
    - (a1) fixing the fees to be paid in respect of any licence issued or renewed under this Part,
  - (b) the colouring of any poisons and restricted substances,
  - (c) the conditions under which poisons and restricted substances shall be supplied, disposed of, obtained, stored, kept or used,
  - (d) the shape, size, colour and materials of, and method of sealing, the container or package in which any poison or restricted substance shall or shall not be supplied,
  - (e) requiring the container or package in which any prescribed poison or restricted substance is cased, covered, enclosed, contained or packed for supply to have printed thereon or on the label affixed or attached thereto such particulars as may be prescribed,

- (f) the conditions under which any proprietary preparation for use as a sheep or cattle dip, or for agricultural, pastoral, veterinary, piscicultural or horticultural purposes or as a vermicide shall be exempt from the operation of the provisions of this Part or any regulations made under this Part,
- (g) requiring persons engaged in the supply of any poison or restricted substance to keep records and furnish to any prescribed person information (whether in writing or otherwise),
- (h) the issue of prescriptions or orders for any poison or restricted substance, the dispensing of such prescriptions and the supply of poisons and any such substance on such a prescription or order,
- (i) prohibiting or regulating the free distribution of any poison or restricted substance,
- (j) (Repealed)
- (j1) prohibiting or regulating the administering, otherwise than on the order of a medical practitioner, nurse practitioner or dentist, of any restricted substance prescribed for the purposes of section 16.
- (k) (Repealed)

(2) A regulation made under this Part may apply:

- (a) to all poisons and restricted substances, to any poison or restricted substance specified in the regulation or to all poisons and restricted substances other than those so specified, and
- (b) to all persons, to persons or classes of persons specified in the regulation, or to all persons other than persons or classes of persons so specified.

**17A Director-General may authorise nurse practitioners to possess, use, prescribe or supply substances**

- (1) The Director-General may, by means of a written authorisation, authorise a nurse practitioner, or class of nurse practitioners, to possess, use, supply or prescribe any poison or restricted substance for the purposes of the practice of a nurse practitioner's profession.
- (2) Such an authority is to be given only if the Director-General approves guidelines, under section 78A of the *Nurses Act 1991*, that provide for the possession, use, supply or prescription of poisons or restricted substances by nurse practitioners and is to be given in accordance with those guidelines.
- (3) The Director-General may amend or revoke any authorisation given under this section.

### **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, nurse 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.

## **Division 2**

### **19 (Repealed)**

## **Part 4 Drugs of addiction**

### **Division 1 Restrictions on possession, manufacture, supply, etc, of drugs of addiction**

#### **20-22 (Repealed)**

### **23 Possession and supply of drugs of addiction by carers**

Despite any other provision of or made under this or any other Act, a person who has the

care of, or is assisting in the care of, another person (for or to whom the supply of a drug of addiction has been authorised by the prescription of a medical practitioner or dentist) is not guilty of an offence in relation to the possession or supply of the drug if the person is in possession of the drug for the sole purpose of administering, or assisting in the self-administration of, the drug to the other person and does so in accordance with that prescription.

#### **24 Regulations under Division 1 of Part 4**

- (1) Without limiting the generality of section 45C, the Governor may, for the purpose of preventing the improper use of drugs of addiction, make regulations under this Division for or with respect to:
  - (a) prohibiting the manufacture of any drug of addiction except on premises licensed for the purpose and subject to the conditions specified in the licence,
  - (b) prohibiting the manufacture or supply of any such drug except by persons licensed or otherwise authorised under the regulations and subject to any conditions specified in the licence or authority,
  - (c) prohibiting the issue by persons other than medical practitioners, dentists or veterinary surgeons of prescriptions containing any such drug,
  - (d) prohibiting or regulating the issue by medical practitioners, dentists or veterinary surgeons of prescriptions containing any such drug, the dispensing of such prescriptions, and the supply of any such drugs thereunder,
  - (e) requiring persons engaged in the manufacture or supply of any such drug to keep such books and furnish such information either in writing or otherwise to such persons as may be prescribed, and making provision for the inspection of such books and records by prescribed persons,
  - (f) fixing the fees to be paid in respect of any licence, inspection, permit, or authority made or issued under the regulations,
  - (g) providing for the forfeiture of any such drug unlawfully in the possession of any person,
  - (h) providing that any specified breach of the regulations shall be regarded as “misconduct in a professional respect” within the meaning of any Act,
  - (h1) prohibiting or regulating the administering, otherwise than on the order of a medical practitioner or dentist, of any drug of addiction, and
  - (i) generally, regulating and controlling the manufacture, possession and supply of drugs of addiction.
  - (j) (Repealed)

- (2) Regulations shall be made under this Division making provision for or with respect to:
- (a) authorising pharmacists to be in possession of any drug of addiction for the purposes of:
    - (i) manufacturing at their respective shops in the ordinary course of their respective retail businesses any preparation, admixture, or extract of that drug, and
    - (ii) carrying on at their respective shops the business of supplying, dispensing, or compounding that drug,
  - (b) authorising medical practitioners, pharmacists employed in dispensing medicines at any public hospital or other institution, dentists and veterinary surgeons to be in possession of and to supply, in the lawful practice of their professions as such, any drug of addiction, subject to such conditions and restrictions as may be prescribed,
  - (c) authorising persons in charge of laboratories for the purpose of research or instruction, and such other persons as to the Minister may seem proper to be in possession of any drug of addiction for the purposes of their professions or employments, subject to such conditions and restrictions as may be prescribed,
  - (d) the issue, grant and renewal of licences or authorities for the purposes of this Division by the Director-General on such terms and subject to such conditions (including in the case of a licence the payment of a fee) as the Director-General thinks proper, and
  - (e) the withdrawal and suspension of any such licence or authority by the Director-General.
  - (f) (Repealed)
- (2A), (3) (Repealed)
- (4)
- (a) A general licence to manufacture drugs of addiction shall not be issued.
  - (b) A licence to manufacture drugs of addiction shall be limited to the manufacture of a particular drug or drugs specified in the licence.
  - (c) Several licences to manufacture drugs of addiction may be issued to the same person.
- (5) Subject to this Division, a regulation made under this Division may apply:
- (a) to all drugs of addiction, to any such drug specified in the regulation, or to all such drugs other than those so specified, and

- (b) to all persons, to persons or classes of persons specified in the regulations, or to all persons other than persons or classes of persons so specified.

## **25 Further offences against this Division**

Any person:

- (a) (Repealed)
- (b) who acts in contravention of or fails to comply with the conditions of any licence issued or authority granted under or in pursuance of this Division, or
- (c) who, for the purpose of obtaining, whether for himself or herself or for any other person, the issue, grant, or renewal of any such licence or authority as aforesaid, makes any declaration or statement which is false in any particular, or knowingly utters, produces, or makes use of any such declaration or statement or a document containing such a declaration or statement,

shall be guilty of an offence against this Division.

## **26 Penalties**

- (1) Every person guilty of an offence against this Division shall in respect of each offence be liable to a fine not exceeding 20 penalty units or to imprisonment for a term not exceeding 2 years, or to both such fine and imprisonment, and the court convicting any such person may order that any article in respect of which the offence was committed shall be forfeited to Her Majesty.
- (2) The court before which the offender was convicted of an offence against this Division may order any forfeited articles to be destroyed or otherwise disposed of as the court thinks fit.
- (3) No person shall, on conviction for any offence of contravening or failing to comply with the conditions of any licence issued or authority granted under the regulations made under this Division to supply a drug of addiction or any regulation relating to the keeping of books or the issuing or dispensing of prescriptions containing a drug of addiction, be sentenced to imprisonment without the option of a fine or to pay a fine exceeding 1 penalty unit, if the court dealing with the case is satisfied that the offence was committed through inadvertence and was not preparatory to or committed in the course of or in connection with the commission or intended commission of any other offence against this Division.
- (4) Any person who attempts to commit an offence against this Division, or solicits or incites another person to commit such an offence, shall, without prejudice to any other liability, be liable to the same punishment and forfeiture as if the person had committed an offence against this Division.
- (5) (Repealed)

- (6) In any proceedings against a person for an offence against this Division it shall not be necessary to negative by evidence any licence, authority, or other matter of exception or defence, and the burden of proving any such matter shall lie on the person seeking to avail himself or herself of the matter.

## **Division 2 Restrictions on prescribing drugs of addiction**

### **27 Definitions**

In this Division:

**approved prescriber** means a medical practitioner approved under section 28A as a prescriber of drugs of addiction.

**drug dependent person** means a person who has acquired, as a result of repeated administration of:

- (a) a drug of addiction, or
- (b) a prohibited drug within the meaning of the [Drug Misuse and Trafficking Act 1985](#),  
an overpowering desire for the continued administration of such a drug.

### **28 Prohibition on prescribing drugs of addiction in certain cases**

Except as may be authorised by the regulations, a medical practitioner shall not prescribe for or supply to:

- (a) any person a drug of addiction (not being a drug of addiction that may be prescribed or supplied in accordance with paragraph (c)) for continuous therapeutic use by that person for a period exceeding 2 months or for a period which, together with any other period for which he or she has prescribed that or any other such drug or, together with any other period for which that or any other such drug has, to his or her knowledge, been prescribed or supplied by any other medical practitioner, would result in that drug, or that drug together with any other such drug, being prescribed for continuous therapeutic use by that person for a period exceeding 2 months,
- (b) any person who in the medical practitioner's opinion is a drug dependent person any drug of addiction (not being a drug of addiction that may be prescribed or supplied in accordance with paragraph (c)), or
- (c) any person any drug of addiction prescribed for the purposes of this paragraph,

unless the medical practitioner so prescribes or supplies that drug in accordance with an authority in respect of that person given to the medical practitioner by the Director-General under section 29.

**28A Approval of prescribers of drugs of addiction**

- (1) The Director-General may, on the recommendation of the Medical Committee, approve a medical practitioner as a prescriber of drugs of addiction for the purposes of section 29 (2) (b).
- (2) Application for such an approval must be made to the Director-General in writing and must be referred by the Director-General to the Medical Committee for its recommendation.
- (3) An applicant must provide the Director-General:
  - (a) in the application, and
  - (b) before approval of the application,with such information relevant to the application as the Director-General requires.
- (4) The Director-General may give an unconditional approval or an approval subject to specified conditions.
- (5) An approval given subject to conditions is ineffective unless the conditions are complied with.
- (6) The Director-General may, on the recommendation of the Medical Committee:
  - (a) revoke an approval or a condition of an approval,
  - (b) amend a condition of an approval,
  - (c) impose a condition of an approval that was an unconditional approval, or
  - (d) impose an additional condition of an approval.
- (7) The Director-General may, pending receipt of a recommendation for the purposes of subsection (6):
  - (a) suspend an approval, or
  - (b) impose or amend a condition of an approval.
- (8) The Director-General may arrange for an approval to be referred from time to time to the Medical Committee for review and a report and recommendation to the Director-General as a result of the review.
- (9) Nothing in this section prevents the Director-General from refusing an application or from referring for report and recommendation by the Medical Committee any question arising under this section.

**29 Director-General may authorise prescription or supply of drugs of addiction**

- (1) An application for the authority of the Director-General referred to in section 28 shall:
  - (a) be in writing and be signed by the medical practitioner who proposes to prescribe or supply the drug of addiction,
  - (b) be made in or to the effect of the prescribed form,
  - (c) contain such information as is provided for by the prescribed form, and
  - (d) be enclosed in a sealed envelope, marked "confidential", and be lodged with, or forwarded by registered mail to, the Director-General.
- (2) Any such application may be referred by the Director-General to the Medical Committee.
- (3) The Director-General may give an authority for the medical practitioner by whom any such application is made to prescribe for or supply to the person to whom the application relates any drug of addiction specified in that authority for the purpose of the treatment of that person.
- (4) Where the Director-General refers an application to the Medical Committee, the Director-General shall take into consideration any report of that Committee relating to that application made before the authority is granted.
- (4A) If an application has been referred to the Medical Committee under subsection (2), the Director-General may issue a temporary authority to the applicant expiring on a specified date that is not later than 4 months after its issue.
- (5) An authority (whether or not a temporary authority):
  - (a) shall specify the quantity of the drug of addiction that may be so prescribed or supplied by the medical practitioner,
  - (b) shall specify the period for which any such drug may be so prescribed or supplied,
  - (c) may be given subject to such conditions as the Director-General thinks fit and specifies in the authority, and
  - (d) shall be in writing and be signed by the Director-General or by an officer of the Department of Health authorised generally or specially by the Director-General to do so unless, in a case of emergency, it is given verbally.
- (6) Any such authority given verbally shall be confirmed in writing as soon as practicable after it is given.
- (7) The Director-General may revoke an authority (including a temporary authority) given under this section.

### **30 Medical Committee**

- (1) The Minister shall constitute a Medical Committee for the purposes of this Division.
- (2) The Medical Committee shall consist of:
  - (a) a medical practitioner nominated by the Australian Medical Association (NSW) Limited,
  - (b) a medical practitioner nominated by the Royal Australasian College of Physicians, New South Wales State Committee, and
  - (c) a medical practitioner nominated by the Minister.
- (3) If within the time specified by the Minister in a notice in writing served on the Australian Medical Association (NSW) Limited, or the Royal Australasian College of Physicians, New South Wales State Committee, as the case may be, a medical practitioner is not nominated for the purpose of subsection (2) (a) or (b) the Minister may appoint any medical practitioner to be a member of the Medical Committee in the place of the member referred to in subsection (2) (a) or (b), as the case may be.
- (4) The Medical Committee shall consider every application referred to it under section 28A or 29 (2) and shall, as soon as practicable after the application is referred to it, furnish to the Director-General a report in writing containing a recommendation whether or not an approval or authority of the kind applied for should be given and whether, if given, it should be unconditional or subject to specified conditions.
- (5) A member of the Medical Committee is entitled to be paid such remuneration (including travelling and subsistence allowances) as the Minister may from time to time determine in respect of the member.

### **30A Subcommittees**

- (1) The Medical Committee may establish subcommittees to assist it in the exercise of its functions.
- (2) It does not matter that any or all of the members of a subcommittee are not members of the Medical Committee.
- (3) The procedure for the calling of meetings of a subcommittee and for the conduct of business at those meetings shall be as determined by the Medical Committee or (subject to any determination by the Medical Committee) by the subcommittee.

### **30B Delegation**

The Medical Committee may delegate to a subcommittee of the Medical Committee any of its functions other than:

- (a) this power of delegation, and

- (b) any function required by the regulations to be exercised only by the Medical Committee.

## **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.
- (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.
- (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.
- (4) Any provision of a Commonwealth administrative law applying because of this section that purports to confer jurisdiction on a federal court is taken not to have that effect.

### **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.

(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 (Repealed)**

**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.

**Part 5 General**

**Division 1 Offences**

### **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).
- (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, nurse practitioner authorised under section 17A, 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).

- (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.
- (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.

### **37 Prohibition on supply etc of any poison, restricted substance or drug of addiction**

- (1) Notwithstanding any other provision of this Act, the Director-General may, by order, prohibit the supply of any substance specified in the order which in his or her opinion should not be supplied pending the evaluation of its toxic or deleterious properties or of any substance containing any such substance.
- (2) Any person who contravenes an order made under subsection (1) shall be guilty of an offence against this Act.

## **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.

### **38 Calculation of percentages in case of liquid preparations**

For the purpose of the Poisons List, percentages in the case of liquid preparations shall (unless other provision in that behalf is made by regulations) be calculated on the basis that a preparation containing 1 per cent of any substance means a preparation in which:

- (a) 1 gramme of the substance, if a solid, or
- (b) 1 millilitre of the substance, if a liquid,

is contained in every 100 millilitres of the preparation, and so in proportion for any greater or less percentage.

## **Division 3 Evidentiary matters**

### **39 Certificate of Director-General prima facie evidence**

In any legal proceedings under this Act or the regulations a certificate purporting to be signed by the Director-General or by an officer of the Department of Health authorised generally or specially by the Director-General in that behalf to do so and to certify that any person is or is not a person who holds a licence, permit or authority under this Act or the regulations shall, without proof of the signature or of the official character or authority of the person purporting to have signed the certificate, be prima facie evidence of the fact stated in the certificate.

### **40 Proof of certificate of an analyst**

- (1) Any analyst analysing any substance submitted to him or her may give a certificate of the result of the analysis.
- (2) In any legal proceedings under this Act or the regulations, the production of a

certificate, purporting to be signed by an analyst, shall be prima facie evidence of the identity of the substance analysed, and of the result of the analysis, without proof of the signature, employment or appointment of the person appearing to have signed the certificate.

(3) (Repealed)

#### **41 Evidence in prosecutions under this Act**

In any prosecution for a contravention of or failure to comply with any provision of this Act or any regulation, whenever it is necessary or proper to prove in respect of any particular article or substance that it conforms to any of the following descriptions, namely:

- (a) that it is a poison or poisonous,
- (b) that it consists of or contains poison,
- (c) that it is a restricted substance, or
- (d) that it is a drug of addiction, or
- (d1) that is therapeutic goods,

then in every such case:

- (e) evidence that any substance commonly supplied under the same name or description as the said particular article or substance conforms to any of the descriptions contained in paragraph (a), (b), (c), (d) or (d1) is prima facie evidence that the particular article or substance also conforms to the same description accordingly,
- (f) evidence that any particular article or substance bears any inscription required by the regulations in respect of any substance or class of substances shall be prima facie evidence that that particular article or substance is a substance, or belongs to the class of substances, in respect of which that inscription is so required, and
- (g) evidence that the container in which any particular article or substance is contained is labelled as required, or bears any inscription required, by the regulations in respect of containers containing any substance or class of substances shall be prima facie evidence that that particular article or substance is a substance, or belongs to a class of substances, the containers of which are so required to be labelled or to bear that inscription.

### **Division 4 Enforcement**

#### **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,
  - (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).
- (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.

#### **43B Powers of detention and search**

(1) In this section:

**police vessel** means a vessel ordinarily used by members of the police force in the execution of their duty.

**prescribed restricted substance** means a restricted substance prescribed for the purposes of section 16.

- (2) A member of the police force of or above the rank of sergeant, or in charge of a police station or police vessel, may at any time with as many members of the police force as the member thinks necessary:
  - (a) enter into any part of any vessel or aircraft, and

(b) search and inspect the vessel or aircraft.

(3) A member of the police force of or above the rank of sergeant, or in charge of a police station or police vessel, may, for the purpose of enabling the powers conferred on members of the police force by subsection (2) to be exercised, stop and detain any vessel or aircraft in which the member reasonably suspects there is any prescribed restricted substance which is, in contravention of this Act, in the possession or under the control of any person.

(4) A member of the police force may stop, search and detain:

(a) any person in whose possession or under whose control the member reasonably suspects there is, in contravention of this Act, any prescribed restricted substance,  
or

(b) any vehicle in which the member reasonably suspects there is any prescribed restricted substance which is, in contravention of this Act, in the possession or under the control of any person.

#### **44 Penalty**

Every person who is guilty of an offence against any provision of this Act or acts in contravention of or fails to comply with any provision of this Act or any regulation for which no other penalty is expressly provided shall be liable to a penalty not exceeding 2 penalty units.

#### **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.

#### **45A-45B (Repealed)**

### **Division 5 Miscellaneous**

#### **45C Regulations**

(1) The Governor may make regulations, not inconsistent with this Act, for or with respect to any matter that by this Act is required or permitted to be prescribed or that is necessary or convenient to be prescribed for carrying out or giving effect to this Act.

(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,
- (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.

(2) Regulations may be made so as to apply differently according to such factors as may be specified in the regulations.

(3) The regulations may authorise any matter or thing to be from time to time determined, applied or regulated by any person specified therein, either generally or for any class of cases or in a particular case.

(4) The regulations may incorporate by reference, wholly or in part and with or without modification, any standards, rules, codes, specifications or methods, as in force at a particular time or as in force from time to time, prescribed or published by any

authority or body, whether or not it is a New South Wales authority or body.

- (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.

#### **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.

#### **46 Publication, commencement and disallowance of publications and orders**

Sections 39, 40 and 41 of the [Interpretation Act 1987](#) apply to:

- (a) a proclamation made under section 8, and
- (b) an order made under section 37,

in the same way as they apply to a statutory rule within the meaning of that Act.

#### **46A Savings and transitional provisions**

Schedule 3 has effect.

### **Part 6 Amendments to [Crimes Act 1900](#), as amended by subsequent Acts, and [Motor Traffic Act 1909](#), as amended by subsequent Acts**

#### **47, 48 (Repealed)**

### **Schedule 1 Provisions relating to the members of the Advisory Committee**

(Section 6)

#### **1 Definitions**

In this Schedule:

***appointed member*** means a member appointed by the Governor.

***member*** means a member of the Advisory Committee.

#### **2 Chairperson of the Advisory Committee**

The Chairperson of the Advisory Committee is the person nominated by the Minister under section 6 (2) as a member.

### **3 Acting appointed members**

- (1) The Governor may, from time to time, appoint a person to act in the office of an appointed member and the person, while so acting, has all the functions of a member and shall be deemed to be an appointed member.
- (2) The Governor may remove from office a person appointed under subclause (1).
- (3) A person while acting in the office of an appointed member is entitled to be paid such remuneration (including travelling and subsistence allowances) as the Minister may from time to time determine in respect of the person.

### **4 Term of office**

Subject to this Schedule, an appointed member holds office for such period not exceeding 3 years as is specified in the member's instrument of appointment, but is eligible (if otherwise qualified) for re-appointment.

### **5 Remuneration**

A member is entitled to be paid such remuneration (including travelling and subsistence allowances) as the Minister may from time to time determine in respect of the member.

### **6 Vacancy in office of appointed member**

- (1) The office of an appointed member becomes vacant if the member:
  - (a) dies,
  - (b) completes a term of office and is not re-appointed,
  - (c) resigns the office by instrument in writing addressed to the Minister,
  - (d) is removed from office by the Governor under this clause,
  - (e) is absent from 4 consecutive meetings of the Advisory Committee of which reasonable notice has been given to the member personally or by post, except on leave granted by the Director-General or unless, before the expiration of 4 weeks after the last of those meetings, the member is excused by the Director-General for having been absent from those meetings,
  - (f) becomes bankrupt, applies to take the benefit of any law for the relief of bankrupt or insolvent debtors, compounds with his or her creditors or makes an assignment of his or her remuneration for their benefit,
  - (g) becomes a temporary patient or a continued treatment patient within the meaning of the *Mental Health Act 1958*, a forensic patient within the meaning of the *Mental Health Act 1983* or a protected person within the meaning of the *Protected Estates Act 1983*, or

(h) is convicted in New South Wales of an offence that is punishable by imprisonment for 12 months or more or is convicted elsewhere than in New South Wales of an offence that, if committed in New South Wales, would be an offence so punishable.

(2) The Governor may remove an appointed member from office at any time.

## **7 Filling of vacancy in office of member**

If the office of an appointed member becomes vacant, a person shall, subject to this Act, be appointed to fill the vacancy.

## **8 Effect of certain other Acts**

(1) The *Public Service Act 1979* does not apply to the appointment of an appointed member and an appointed member is not, as a member, subject to that Act.

(2) If by or under any other Act provision is made:

(a) requiring a person who is the holder of a specified office to devote the whole of his or her time to the duties of that office,

(b) prohibiting the person from engaging in employment outside the duties of that office,

the provision does not operate to disqualify the person from holding that office and also the office of a member or from accepting and retaining any remuneration payable to the person under this Act as a member.

## **Schedule 2 Provisions relating to the procedure of the Advisory Committee**

(Section 6)

### **1 General procedure**

The procedure for the calling of meetings of the Advisory Committee and for the conduct of business at those meetings shall, subject to this Act and the regulations, be as determined by the Advisory Committee.

### **2 Quorum**

The quorum for a meeting of the Advisory Committee shall be as prescribed by the regulations.

### **3 Presiding member**

(1) The Chairperson of the Advisory Committee or, in the absence of the Chairperson, another member elected to chair the meeting by the members present shall preside at a meeting of the Advisory Committee.

- (2) The person presiding at a meeting of the Advisory Committee has a deliberative vote and, in the event of an equality of votes, a second or casting vote.

#### 4 Voting

A decision supported by a majority of the votes cast at a meeting of the Advisory Committee at which a quorum is present is a decision of the Advisory Committee.

#### 5 Minutes

The Advisory Committee must cause full and accurate minutes to be kept of the proceedings at each meeting of the Advisory Committee.

### 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*

*Nurses Amendment (Nurse Practitioners) Act 1998*

- (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:
- 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
  - 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 Definitions

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.