

[Act 1996 No 2]



New South Wales

Poisons Amendment (Therapeutic Goods) Bill 1995

Explanatory note

This explanatory note relates to this Bill as introduced into Parliament.

Overview of Bill

The object of the Bill is to amend the *Poisons Act 1966* (“the Principal Act”) so as:

- (a) to complement Commonwealth legislation for the regulation of manufacturing, importing and exporting therapeutic goods in accordance with an agreement between the relevant Commonwealth Minister and the relevant State and Territory Ministers, and
 - (b) to regulate the wholesale supply of those therapeutic goods that are poisons or restricted substances as defined in the Principal Act, and
 - (c) to merge certain provisions of the *Therapeutic Goods and Cosmetics Act 1972* with the Principal Act, and
 - (d) to repeal the *Therapeutic Goods and Cosmetics Act 1972* and the regulations in force under that Act, and
 - (e) to make other changes of a minor, consequential or ancillary nature.
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The manufacture and supply of cosmetics will no longer be regulated under New South Wales law on the repeal of the *Therapeutic Goods and Cosmetics Act 1972*. The manufacture of therapeutic goods will be regulated under Commonwealth therapeutic goods laws and the provisions of those laws that are to be applied as a law of New South Wales by proposed Part 4A of the Principal Act. The manufacture and supply of therapeutic devices in New South Wales will also cease to be regulated on the repeal of the *Therapeutic Goods and Cosmetics Act 1972*. However, despite the repeal of that Act, New South Wales consumer protection laws will continue to provide protection for consumers with respect to the manufacture and supply of defective therapeutic goods and therapeutic devices.

Outline of provisions

Clause 1 specifies the name (also called the short title) of the proposed Act.

Clause 2 provides for the proposed Act to commence on a day or days to be fixed by proclamation.

Clause 3 is a formal provision that gives effect to Schedule 1, which contains amendments to the Principal Act.

Clause 4 is a formal provision that gives effect to Schedule 2, which contains consequential amendments to other Acts.

Clause 5 provides for the repeal of the *Therapeutic Goods and Cosmetics Act 1972* and the *Therapeutic Goods and Cosmetics Regulations*.

Schedule 1 Amendment of Poisons Act 1966

Amendments to Part 1 (Preliminary)

One amendment changes the name (short title) of the Principal Act to the *Poisons and Therapeutic Goods Act 1966*. (See Schedule 1 [2].) Another amendment introduces definitions of *Analyst*, *Animal*, *Applied provisions*, *Authority*, *Commonwealth Act*, *Commonwealth administrative laws*, *Commonwealth Department*, *Commonwealth Minister*, *Commonwealth Secretary*, *Commonwealth therapeutic goods laws*, *Listed goods*, *Manufacturer's licence*, *Registered goods*, *Regulated goods*, *Representation*, *Supply by wholesale*, *Therapeutic device* and *Therapeutic goods*. (See Schedule 1 [3].) Schedule 1 [5] replaces the definition of *Supply*. The remaining amendments to Part 1 are of a minor or consequential nature. (See Schedule 1 [4] and [6]–[11].)

Amendments to Part 3 (Poisons and restricted substances)

Part 3 of the Principal Act imposes restrictions on the supply and possession of poisons specified in Schedules 1, 2 and 3 of the Poisons List and of restricted substances (Schedule 4 poisons). Section 9 (Supply of certain substances prohibited) and section 9A (Obtaining substances by false representation) are to be replaced by proposed sections 9–12. (See Schedule 1 [12].)

Proposed section 9 will prohibit the wholesale supply of poisons and restricted substances for therapeutic use in humans or animals, except under a wholesaler's licence or wholesaler's authority issued in accordance with regulations made under the Principal Act.

Proposed section 10 (which replaces the existing section 9) will prohibit the supply otherwise than by wholesale of substances specified in Schedules 1, 2 and 3 of the Poisons List, except under a general supplier's licence or general supplier's authority issued in accordance with regulations made under the Principal Act. The prohibition will not however apply to medical practitioners, dentists, veterinary surgeons and pharmacists who supply those substances in the course of practising their professions. That section will also prohibit the supply of restricted substances except by:

- medical practitioners, dentists and veterinary surgeons, and
- pharmacists who supply those substances in accordance with the prescription of a medical practitioner, dentist or veterinary surgeon, and
- "authorised persons" who supply those substances in accordance with the prescription of a medical practitioner and the substances are for patients or inmates of a designated hospital or institution, and
- other persons licensed or authorised by or under the Principal Act to supply those substances.

Proposed section 11 will prohibit holders of wholesalers' licences or wholesalers' authorities from supplying substances specified in Schedule 1, 2, 3 and 7 of the Poisons List and restricted substances to persons other than medical practitioners, dentists, veterinary surgeons, pharmacists and holders of manufacturers' licences, wholesalers' licences and wholesalers' authorities and others.

Proposed section 12 will make it an offence for a person to obtain or attempt to obtain a substance specified in Schedule 1, 2, 3 or 7 of the Poisons List, or a restricted substance, by means of a representation that the person knows or ought to know is false.

An amendment to section 17 (Regulations under Part 3) will make it clear that regulations can be made for the issue, renewal, refusal to issue or renew, suspension and cancellation of authorities for the purposes of Part 3. (See Schedule 1 [[17].)

Other amendments to Part 3 are consequential on the amendments to that Part mentioned above. (See Schedule 1 [[13]–[16] and [[18]–[22].)

Proposed Part 4A (Application in New South Wales of Commonwealth therapeutic goods laws)

The *Therapeutic Goods Act 1989* of the Commonwealth (“the Commonwealth Act”) currently provides for a nationwide system for the regulation of manufacturing, importing and exporting therapeutic goods. It also provides for standards for therapeutic goods, advertising therapeutic goods and for the Australian Register of Therapeutic Goods. Amendments to the Commonwealth Act in 1993 allowed the Commonwealth to exercise functions under complementary State or Territory legislation. An agreement between the Commonwealth Minister and the State and Territory Ministers provides for the Commonwealth to assume responsibility for regulating the manufacture, export and import of therapeutic goods and for the States and Territories to regulate the wholesaling of such goods.

Proposed Part 4A is intended to give effect to the agreement as regards New South Wales. The Part contains proposed sections 31–33L. The Part contains the following provisions:

- Proposed section 31 applies the Commonwealth therapeutic goods laws (which comprise the *Therapeutic Goods Act 1989* of the Commonwealth and regulations, orders and “manufacturing principles” in force under that Act), as in force for the time being, as a law of New South Wales. The clause will also allow the Commonwealth therapeutic goods laws to be modified by regulations made under the Principal Act.
- Proposed section 32 provides for the applied provisions to be interpreted in accordance with Commonwealth rather than New South Wales statutory interpretation legislation.
- Proposed section 33 will enable the relevant Commonwealth Minister to exercise the same functions and powers under the applied provisions as that Minister has under the Commonwealth therapeutic goods laws as they apply to the Commonwealth.

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- Proposed section 33A will enable the relevant Commonwealth Secretary to exercise the same functions and powers under the applied provisions as he or she has under the Commonwealth therapeutic goods laws as they apply to the Commonwealth.
- Proposed section 33B will enable certain officers of the Commonwealth to exercise the same functions and powers under the applied provisions as they have under the Commonwealth therapeutic goods laws.
- Proposed section 33C provides for delegations of the Commonwealth Minister or the Commonwealth Secretary under section 57 of the Commonwealth Act to extend to the applied provisions.
- Proposed section 33D provides for appointments of persons to positions under the Commonwealth therapeutic goods laws (including appointments made before the commencement of the proposed section) to extend to the applied provisions.
- Proposed section 33E will apply Commonwealth administrative laws in relation to the applied provisions. Those laws include the *Administrative Appeals Tribunal Act 1975*, *Administrative Decisions (Judicial Review) Act 1977*, *Freedom of Information Act 1982*, *Ombudsman Act 1976* and *Privacy Act 1988*. One of the consequences of this section is that the Commonwealth Administrative Appeals Tribunal will be able to review certain decisions of the Commonwealth Secretary under the applied provisions.
- Proposed section 33F deals with functions and powers conferred on Commonwealth officers and authorities under Commonwealth administrative laws applying because of proposed section 33E.
- Proposed section 33G provides that the object of Division 4 of the proposed new Part is to treat an offence against the applied provisions as if it were an offence against a law of the Commonwealth.
- Proposed section 33H provides for relevant Commonwealth laws to apply as laws of New South Wales in relation to offences against the applied provisions.

- Proposed section 33I provides that a Commonwealth officer (such as the Commonwealth Director of Public Prosecutions) or a Commonwealth authority will have the same functions and powers in relation to an offence against the applied provisions as that officer or authority has in relation to the corresponding offence against the Commonwealth therapeutic goods laws.
- Proposed section 33J will prevent a person from being punished for the same offence under both the applied provisions and the Commonwealth therapeutic goods laws.
- Proposed section 33K will confer jurisdiction on the Federal Court of Australia with regard to civil matters arising under the applied provisions.
- Proposed section 33L will allow the Commonwealth to retain fees paid to the Commonwealth Secretary under the applied provisions.

(See Schedule 1 [23].)

Amendments to Part 5 (General)

Proposed sections 34–36D will replace the existing sections 34–36. (See Schedule 1 [25].)

Proposed section 34 will prohibit the hawking of regulated goods from house to house and in public streets and other public places. (*Regulated goods* are substances listed in a Schedule of the Poisons List and those therapeutic goods that are not substances so listed.)

Proposed section 35 will enable the Director-General of the Department of Health to obtain information about regulated goods.

Proposed section 36 will prohibit the installation of an automatic machine for the supply of regulated goods and the supply of regulated goods by means of an automatic machine. The proposed section also provides that the occupier or person in control of premises is to be guilty of an offence if:

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

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Proposed section 36A will make it an offence to supply by retail therapeutic goods for use in or on humans unless the goods are registered or listed under the Commonwealth Act or the goods are exempt goods or are the subject of an approval or authority under section 19 of that Act.

Proposed section 36B will make it an offence to supply therapeutic goods by retail after the relevant expiry date.

Proposed section 36C will make it an offence to use a therapeutic device of a kind prescribed by regulations made under the Principal Act, except under a user's licence issued under those regulations.

Proposed section 36D replaces the existing section 42 (Offences by companies) with a new provision that provides that, if a body corporate contravenes the Principal Act, each person who is a director, or is concerned in the management, of the body corporate is also guilty of the offence if the person knowingly authorised or permitted the contravention.

Proposed sections 37A and 37B deal with the appointment of analysts and the conduct of analyses. (See Schedule 1 [26].)

Proposed section 42 provides for the appointment of inspectors for the purposes of the Principal Act. A police officer is, by virtue of his or her appointment, an inspector for the purposes of that Act. Proposed section 43 updates the existing section 43, which deals with inspectors' powers of entry, inspection and seizure. Proposed section 43A will enable an authorised justice to issue a search warrant where an inspector is refused admission to premises or an attempt to obtain admission has been or is likely to be unsuccessful. (See Schedule 1 [34].)

Proposed section 45 replaces the existing sections 45 and 45B, which respectively provide for how proceedings for offences are to be dealt with and prescribe the period within which proceedings for offences under the Principal Act may be brought. (See Schedule 1 [35] and [36].)

Amendments to section 45C (Regulations) specify further matters with which regulations under the Principal Act may deal and will enable regulations under that Act to create offences punishable by penalties not exceeding 20 penalty units (\$2,000) or imprisonment for a term not exceeding 6 months, or both. (See Schedule 1 [38] and [39].)

Proposed section 45D provides for the Principal Act to bind the Crown in all its capacities and proposed section 45E provides that notes in the text of that Act are explanatory notes only and do not form part of that Act. (See Schedule 1 [40].)

Schedule 1 [41] and [42] insert proposed section 46A and Schedule 3, which deal with savings and transitional matters.

Other amendments to Part 5 are of a minor or consequential nature. (See Schedule 1 [24], [27]–[33] and [37].)

Schedule 2 Consequential amendment of other Acts

The Schedule contains consequential amendments to the *Animal Research Act 1985*, the *Drug Misuse and Trafficking Act 1985*, the *Health Care Complaints Act 1993* and the *Traffic Act 1909*.