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THE LEGISLATIVE ASSEMBLY FOR THE AUSTRALIAN CAPITAL TERRITORY

POISONS AND DRUGS (AMENDMENT) BILL 1992

EXPLANATORY MEMORANDUM

Circulated by authority of the Minister for Health

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OUTLINE

This is an amending Bill, the first of a package of three. The Poisons (Amendment) Bill 1992 contains amendments consequential upon the Poisons and Drugs (Amendment) Bill 1992, and the Drugs of Dependence (Amendment) Bill (No. 5) 1992 facilitates the adoption of the recommendations of the National Health and Medical Research Council in regard to drugs of dependence.

This Bill amends the Poisons and Drugs Act 1978 (the Principal Act). The Principal Act lists poisons and drugs in eight schedules, sets out labelling and packaging requirements for all scheduled substances, and lists restricted substances which can be prescribed or supplied only by authorised medical specialists.

This Bill adopts by reference Schedules 1 to 8 of the National Health and Medical Research Council's Standard for the Uniform Scheduling of Drugs and Poisons. This will assist in fulfilling the ACT's commitment to the uniform scheduling of drugs and poisons throughout Australia given at the Australian Health Ministers' Conference in June 1990, and is the same as the approach adopted in NSW in August 1991.

The Bill also introduces controls over the most dangerous poisons, which are listed in Schedule 7. These controls have been transferred from the Poisons Act 1933 and updated by including provision for appeal to the Administrative Appeals Tribunal.

The Bill requires manufacturers and sellers of Schedule 7 poisons to be licensed, a Poisons Register to be kept by licensees, and researchers using Schedule 7 poisons to be authorised. Licences may be issued for a period of 12 months or less and are renewable. The fee for a licence or authorisation is to be set by the Minister, by notice in writing published in the Gazette.

FINANCIAL CONSIDERATIONS

This Bill has no financial implications. Minimal revenue is expected to be raised from the licence and authorisation fees. There are some sellers of Schedule 7 poisons in the ACT, but no known manufacturers of, or researchers using, these poisons.

There will be minimal costs involved as Schedule 7 licences and authorisations will be handled concurrently with the existing issue of licences and inspection program under the Poisons Act 1933 for less dangerous poisons in Schedules 5 and 6.

CLAUSE NOTES

Formal Clauses

Clauses 1, 2 and 3 are formal requirements. They refer to the short title and commencement of the Bill, and the definition of the Principal Act. Clauses 1, 2 and 3 will commence on the day the Bill is notified in the Gazette. The remaining clauses commence on a day or days to be fixed by the Minister by notice in the Gazette, or automatically after 6 months.

Clause 4: Interpretation

Subclause 4(a) omits the definition of "Scheduled substance" from subsection (1) of the Principal Act.

Subclause 4(b) defines certain terms for the purpose of the legislation. The more important ones are:

. "Drugs and Poisons Standard" means the latest Standard for the Uniform Scheduling of Drugs and Poisons recommended by the National Health and Medical Research Council, as amended from time to time, and as modified by the Board by instrument.

  Modification by the ACT Board of Health is intended only to provide for any unusual circumstance pertaining to the ACT where scheduling of a substance for a particular reason may need to differ to that in the Standard for the Uniform Scheduling of Drugs and Poisons. The new subsection 3(4) to be inserted in the Principal Act ensures that any modifications made in this way are scrutinised by the Assembly.

. "manufacture" of a scheduled substance means

  - carry out any process by which it is obtained
  - refine it
  - transform it into another scheduled substance
  - mix or compound it; or
  - pack or repack it for the purpose of sale or for use in connection with a profession, trade, business or industry.

. "poison" means a Schedule 7 substance.

Subclause 4(c) in effect adopts the Standard for the Uniform Scheduling of Drugs and Poisons by reference. Reference to a scheduled substance in the Act means reference to that substance as scheduled in the Standard.

Clause 5: Application to the Crown

The Crown in the right of the Territory will be bound by the Poisons and Drugs Act 1978.

Clause 6: Labelling of immediate container and primary pack

Clause 6 amends Section 37 of the Principal Act by substituting "Schedule 8 substance" for "drug of dependence". The clause also deals with table headings in Section 37 to achieve consistency.

Clause 7: deletion of statement of quantity or proportion of scheduled substances

Clause 7 omits subsection (3), which defines percentages, from Section 38 of the Principal Act. Percentages of substances and preparations are now defined in subclause 1.2 of the "Interpretation of Schedule Entries" in Part 4 of the Standard.

Clause 8: insertion of "PART IIIA - POISONS" in the Principal Act

Clause 8 of the amending Act inserts "PART IIIA - POISONS" in the Principal Act and provides for licences to manufacture and sell, and authorisations to possess or use for a program (for example, an approved research program), Schedule 7 poisons.

The following notes relate to the sections in "PART IIIA - POISONS".

DIVISION 1 - LICENSING FOR MANUFACTURE AND SALE

Section 47A - application for licence

This section provides that a person may apply for a licence to manufacture or sell a Schedule 7 poison and sets out the detail to be included in the application. The section requires that individuals be nominated as those personally responsible for supervising the operation. There is emphasis on security details. The application is to be accompanied by the appropriate fee.

Section 47B - Grant of licence

This section sets out the criteria that must be satisfied before a licence to manufacture or sell Schedule 7 poisons will be granted. It includes considerations such as the fitness of the applicant and those supervising the manufacture or sale of the poisons, their qualifications and competence, and the suitability of the premises at which the manufacture or sale is to be conducted. The details to be included on the licence are specified.

Section 47C - Conditions of licence

This section allows for conditions relevant to the licence that are specified in Appendix J to the Standard for the Uniform Scheduling of Drugs and Poisons to be attached to the licence. Othe conditions that can be attached to the licence concern proper manufacture, safekeeping, and supervision of that manufacture or sale.

Section 47D - Variation of conditions of licence

This section allows the Board to vary the conditions of a licence and also ensures that plenty of notice is given to the licensed manufacturer or vendor to adjust their affairs according to the varied notice issued under section 49.

Section 47E - Amendment of licence

This section requires the licensee to notify the Board of Health of a change of address or supervisor before the manufacturer or vendor commences to manufacture or sell at premises other than the premises referred to in the licence or the new supervisor commences duties.

Under section 47E(2) the Board must amend the address of premises specified in a licence in the case where the premises and security arrangements are satisfactory.

Ssection 47E(7) requires the Board to amend a licence where the qualifications of the new supervisor are satisfactory.

Section 47F - Cancellation of licence

This section outlines the circumstances when a licence may be cancelled. Where the Board has not issued directions for the manner of disposal of any poison held by a former licensee, the licensee shall dispose of the poison as soon as practicable. The penalty for failure to dispose of poisons is not more than $5,000 or imprisonment for six months, or both.

Section 47G - Return of licence and Poisons Register

This section requires a former licensee to return his or her licence and Poisons Register to the Board of Health as soon as possible after the cancellation takes effect. Penalty for non-compliance is $1,000.

Sections 47H and 47J - Duration and renewal of licence

These sections provide for annual expiration and renewal of a licence to manufacture or sell Schedule 7 poisons.

Section 47K - Poisons Register

47K(1) requires licensed manufacturers and vendors to keep a Poisons Register at the premises where Schedule 7 poisons are kept.

47K(2) specifies that the Register be in written or printed form or in a form readily convertible to written or printed form. This permits computerisation of the Poisons Register.

47K(3) requires a licensee to enter details of a sale into the Poisons Register within 24 hours of the sale.

47K(4) provides a defence to a prosecution under 47K(3) if it was not reasonably practicable to comply with 47K(3), and the licensee made such record as was reasonable in the circumstances and entered the appropriate particulars in the Poisons Register as soon as practicable.

47K(5) specifies the details of sale, including the name, address and signature of the purchaser, that licensees must enter into the Poisons Register.

47K(6) is a device to ensure that the name and address of the agent are obtained as well as the name and address of the principal. This is to prevent a person giving another person's name and address and not their own.

47K(7) requires a licensee to keep a Poisons Register and any signed orders for a period of 5 years from the date of the last entry. There is a penalty of $2,000 for a natural person or $10,000 for a company for failing to keep the Register.

Section 47L - Offences by licensee

This section creates a number of offences in relation to licensees. They are:

- the manufacture, possession or sale of a specified poison at a place other than the specified premises;
- the sale of a specified poison from a place other than the specified premises;
- the manufacture of a specified poison other than under the supervision of the person who is specified in the licence to supervise the manufacture;
- the storage, manufacture or sale of a specified poison except in accordance with any conditions of the licence.

A penalty of $10,000 or imprisonment for 1 year, or both, is provided.

Section 47M - Conditions for sale of poisons

This section creates a number of offences in relation to manufacturer and vendor licensees.

47M(1) requires a licensee not to sell a Schedule 7 poison:

- without the purchaser's signature in the Poisons Register or on an order; and
- unless the purchaser is 18 years or older.

47M(2) requires a licensee not to sell a Schedule 7 poison to a person who:

- does not supply his or her name and address;
- is an agent for another person and does not supply the name and address of that other person, or a signed order on which the other person's name and address is written;
- does not state the purpose for which the poison is required; or
- does not sign the Poisons Register or provide a signed order.

A penalty of $10,000 or imprisonment for 1 year, or both, for a natural person, or $50,000 for a company, is provided.

DIVISION 2 - AUTHORISATIONS

Section 47N - Application for authorisation

This section requires a person who proposes to conduct a program of education or research, which involves the possession or use by that person of a poison, to apply for an authorisation. It also sets out the details to be included in the application, such as the qualifications of the person supervising the program and the safe custody arrangements for the poison. The application is to be accompanied by the appropriate fee.

Section 47P - Grant of authorisation

This section sets out the criteria that must be satisfied before an authorisation will be granted. The Board must be satisfied that the program cannot be carried out satisfactorily without the use of the poison, the research is scientifically viable in a research program, and the program will be adequately supervised; and of the fitness of the applicant and those who may supervise the program. The details to be included on the authorisation are specified.

Section 47Q - Conditions of authorisation

This section enables the specification of conditions to an authorisation, such as measures required to ensure the safe keeping of the specified poison, and recording requirements relating to the receipt, use and disposal of that poison.

Section 47R - Variation of conditions of authorisation

This section allows the Board to vary the conditions of an authorisation and also ensures that at least 28 days are given to the authorised person to adjust his or her affairs according to the varied notice issued under section 49.

Section 47S - Cancellation of authorisation

This section outlines the circumstances when an authorisation may be cancelled. Where the Board has not issued directions for the manner of disposal of any poison held by a former authorised person, he or she shall dispose of the poison as soon as practicable. The penalty for failure to dispose of poisons is not more than $5,000 or imprisonment for six months, or both.

Sections 47T and 47U - Duration and renewal of authorisation

These sections provide for the expiration and renewal of an authorisation to possess or use a poison for the purpose of conducting a program.

Section 47V - Return of authorisation

This section requires a former authorised person to return the authorisation to the Board of Health as soon as possible after ceasing to be an authorised person. Penalty for non-compliance is $1,000.

Clause 9: Insertion of Sections 47W, 47X, 47Y and 47Z in PART IV of the Principal Act

Clause 9 of the amending Act inserts Sections 47W, 47X, 47Y and 47Z before Section 48 in Part IV of the Principal Act.

Section 47W - Possession of poison

This section provides that a person shall not have in his or her possession a poison unless that person is licensed or authorised to possess that poison, is a member of a prescribed class of persons and possesses the poison for a purpose prescribed in relation to that class, possesses a specified poison with the authority of the authorised person for the purpose of conducting the program specified in the authorisation, or is otherwise legally in possession of that poison. This latter provision under 47W(2)(d) provides for a person holding a licence or

authorisation to possess a poison under another Act in force in the Territory to be exempt. A penalty of $5,000 or imprisonment for 6 months, or both, for a natural person, or $25,000 for a company.

Section 47X - Manufacture of poison

This section provides that a person shall not, without reasonable excuse, manufacture a poison unless licensed to manufacture that poison, or authorised to possess or use the poison and manufacture it for the purpose of the program to which the authorisation relates. There is a penalty of $10,000 or imprisonment for 1 year, or both, for a natural person, or $50,000 for a company.

Section 47Y - Sale of poison

This section provides that, except where a person is licensed to supply a poison and the poison is supplied by way of sale, a person is prohibited from supplying a poison. There is a penalty of $10,000 or imprisonment for 1 year, or both, for a natural person, or $50,000 for a company.

Section 47Z - Directions for disposal

This section enables the Board of Health to give written directions regarding the disposal of a poison where such directions are necessary for the protection of human health and the environment. The penalty for failing to comply with a direction to dispose of a poison is $5,000 or imprisonment for 6 months, or both.

Clauses 10 and 11: Amendment of Section 49 and Repeal of Section 49A of the Principal Act

Notification of Decisions and Review by Administrative Appeals Tribunal

Clause 10 of the amending Act omits subsection (2) of Section 49 of the Principal Act and substitutes subsections (1A) and (2); and makes consequential amendments to subsection 49 (3) of the Principal Act.

Clause 11 of the amending Act repeals Section 49A of the Principal Act and substitutes Section 50.

Clauses 10 and 11 in effect provide for review by the Administrative Appeals Tribunal of decisions made by the Board of Health under the Act, such as refusing to grant a manufacturer's licence or the cancellation of an authorisation. The usual notification requirements are provided for.

Clause 12: Evidentiary Certificate, Fees, and Delegation

Clause 12 inserts the following sections in the Principal Act-

Section 53 - Evidentiary Certificate

This section provides for a certificate relating to the scheduling of a specified substance and signed by a drug inspector appointed under the Drugs of Dependence Act 1989 to be evidence of the matter stated in it. Until proven otherwise, a certificate purporting to be signed by an inspector will be assumed to have been signed by the inspector.

Section 54 - Fees

This section enables the Minister, by notice in writing published in the Gazette, to determine licence and authorisation fees.

Section 54A - Delegation of powers

This section enables powers held by the Board to be delegated to a member of the Board, and powers held by the Medical Officer of Health to be delegated to a public servant.

Clause 13 - Repeal of Schedules 1 to 7

Clause 13 repeals Schedules 1 to 7 (inclusive) to the Principal Act.