# ACT LEGISLATIVE ASSEMBLY

# HEALTH AND COMMUNITY CARE LEGISLATION AMENDMENT BILL 2000

# EXPLANATORY MEMORANDUM

**Circulated by the authority of**
**Michael Moore MLA**
**Minister for Health and Community Care**

*HEALTH AND COMMUNITY CARE LEGISLATION AMENDMENT BILL 2000*

**EXPLANATORY MEMORANDUM**

## OUTLINE

This Bill is primarily intended to make some minor adjustments to the system by which drugs and poisons are identified for the purpose of regulation under Territory law.

For more than twenty years arrangements have been in place between the Commonwealth, states and territories to classify into schedules the many hundreds of drugs and poisons that are available on the Australian market.

This task would involve an unreasonable duplication of effort if undertaken by each jurisdiction concerned and could lead to inconsistent treatment of the same substance in different parts of the country. Accordingly the task has been undertaken by the National Drugs and Poisons Schedule Committee (the Committee), which includes a representative from each jurisdiction affected, under the auspices of the Australian Health Ministers' Advisory Council (AHMAC).

The Standard for the Uniform Scheduling of Drugs and Poisons (the Standard) is the recommendation of the Committee. The Committee periodically revises the Standard, which is divided into parts and schedules and is given effect in the Territory under the *Poisons and Drugs Act 1978*. The people primarily affected by the Standard, the pharmaceutical industry and pharmacists, have ready access to the text of the Standard and are familiar with it.

Last year the *Therapeutic Goods Act 1989* of the Commonwealth and the Therapeutic Goods Regulations were amended to establish the National Drugs and Poisons Schedule Committee as a statutory body, and the first Standard to be made by the new body will be effective from 1 July 2000. The Standard is given legislative effect in the Territory through the *Poisons and Drugs Act 1978* and that Act will need to be amended in consequence of the changes made to the Commonwealth legislation. It will also be desirable to amend the *Poisons Act 1933* to make it clear that declarations under section 12 of that Act may apply provisions of the Standard.

In addition, the opportunity has been taken to make a number of minor amendments to the *Poisons and Drugs Act 1978*, the Poisons and Drugs Regulations, the *Poisons Act 1933* and the Poisons Regulations. These would bring the law into line with existing practice, especially as affected by the widespread computerisation of the pharmacy industry. Changes have also been made to bring the language of these laws into line with everyday language or plain English. Provisions which are obsolete or duplicate unnecessarily other laws would also be repealed. Simplification and tidying measures made possible by the *Interpretation Act 1967* and the *Subordinate Laws Act 1989* have also been implemented. These amendments do not change the substantive law of the Acts and Regulations to any significant extent, and will also enable these laws to be reprinted in an up to date form.

These amendments ensure that drugs and poisons legislation in the ACT remains up to date and assist in fulfilling the Territory's continuing commitment to harmonisation of such legislation between states and territories made at the Australian Health Ministers' Conference in June 1990.

The press release issued at the conference stated that all Health Ministers agreed to accept, by reference, the scheduling recommendations contained in the Standard. The effect of this historic decision was that for the first time in Australian history, the possession and sale of specific drugs and poisons would be on the same basis in each state and territory. This decision significantly assisted industry in the packaging of drugs and poisons, as well as simplifying consumer access to drugs throughout the country.

## FINANCIAL CONSIDERATIONS

This Bill has no revenue or cost implications.

## CLAUSE NOTES

### PART 1 - PRELIMINARY

**Formal Clauses**

Clauses 1 and 2 are formal requirements. They refer to the title and commencement of the *Health and Community Care Legislation Amendment Act 2000*. The amending Act commences on 1 July 2000 to ensure a smooth transition to the first Standard for the Uniform Scheduling of Drugs and Poisons made available by the statutory National Drugs and Poisons Schedule Committee established under the *Therapeutic Goods Act 1989* of the Commonwealth.

### PART 2 – AMENDMENTS OF POISONS ACT 1933

**Clause 3 – Act amended in pt 2 and sch 1**

This clause provides for the *Poisons Act 1933* to be amended by the Bill in two places In effect, the more significant amendments are set out in the body of the Bill (Part 2) with parallel but minor amendments provides for in Schedule 1 to the Bill. Some provisions of the *Poisons Act 1933* (for example, subsection 5(1)) are amended in both places.

**Clause 4 - Interpretation**

This clause adopts in the *Poisons Act 1933* the new definition of "drugs and poisons standard" that is being inserted in the *Poisons and Drugs Act 1978* by this Bill. In effect, this defines the drugs and poisons standard as the current Standard that is in effect. Although the definition merely takes the form of a "signpost" to the *Poisons and Drugs Act 1978*, it applies to the entire *Poisons Act 1933* as if the definition of "drugs and poisons standard" in subsection 3(1) of the *Poisons and Drugs Act 1978* had been set out in full in the *Poisons Act 1933*. (See example 2 to subsection 11F(2) of the *Interpretation Act 1967*.)

**Clause 5 – Declaration of substances by Minister**

Section 12 of the *Poisons Act 1933* enables the Minister to declare, by notice in the Gazette, what substances are, for example, poisons or restricted substances. The effect of clause 5 is that declarations would no longer be published in the Gazette but would become disallowable instruments under the *Subordinate Laws Act 1989*. At the same time new subsection 12(2) would enable a declaration to apply the provisions of the drugs and poisons standard.

## PART 3 – AMENDMENTS OF POISONS AND DRUGS ACT 1978

### Clause 6 – Act amended in pt 3 and sch 2

This clause provides for the *Poisons and Drugs Act 1978* to be amended by the Bill in two places In effect, the more significant amendments are set out in the body of the Bill (Part 3) with parallel but minor amendments provides for in Schedule 2 to the Bill. Some provisions of the *Poisons and Drugs Act 1978* (for example, subsection 3(1)) are amended in both places.

### Clause 7 – Interpretation

Clause 7 amends section 3 of the *Poisons and Drugs Act 1978* by substituting a new definition of "drugs and poisons standard". The new definition consists of two elements: first, the concept of "current poisons standard" (also defined by clause 7) and, second, a power of modification under proposed section 53A. Broadly speaking, the new definition is intended to have the same effect as the definition it replaces. The main difference (apart from the changes implicit in the concept of "current poisons standard" – see below) is that the power of modification would be based on an express statutory power rather than implied in a definition.

The definition of "current poisons standard" identifies the document prepared by the National Drugs and Poisons Schedule Committee under the Therapeutic Goods legislation of the Commonwealth. The document it refers to is the latest to have come into effect under the provisions of the *Therapeutic Goods Act 1989* mentioned in the definition.

The signpost definition of "scheduled substance" inserted by clause 7 applies the definition proposed in subsection 3(1) (see clause 8) to the entire *Poisons and Drugs Act 1978*. (See example 1 to subsection 11F(2) of the *Interpretation Act 1967*.)

### Clause 8 – Insertion

Section 4, which would be inserted by clause 8, broadly corresponds to existing subsections 3(2) and (3), taking into account changes in the structure of the drugs and poisons standard that will take effect on 1 July 2000. The section would continue the approach adopted by the Act of describing substances by reference to the latest drugs and poisons standard.

### Clause 9 – Substitution

New sections 29 and 30 would have the same broad effect as the sections they replace and would incorporate the effect of the penalties provided by section 47 (which would be repealed). The new sections differ from the old in that they impose obligations on identifiable persons to which the penalties formerly provided under section 47 can apply. In this regard see also section 33AA of the *Interpretation Act 1967*. This has enabled the statement of the penalty to be simplified and yet allows the existing

distinction provided for in the penalties under section 47 to be continued in the new provisions (a maximum fine of $5,000 for individuals and $25,000 for corporations).

New section 29 (Labels and Containers) provides, in effect, that a person must supply scheduled drugs and poisons in containers and with labels which comply with the packaging and labelling requirements specified in Part 2 of the current Standard.

New subsection 30(1) provides, in effect, that if a person supplies a substance mentioned in Appendix E at a concentration above the level specified in that Appendix, the container must have the appropriate first aid instructions on the label. For example, eucalyptus oil may, if swallowed by small children, be lethal, so containers must be labelled with the first aid instructions, "If poisoning occurs get to a doctor or hospital quickly." and "If swallowed, do NOT induce vomiting. Give a glass of water.".

New subsection 30(2) provides, in effect, that if a person supplies a substance mentioned in Appendix F , the container must have the appropriate warning statements and/or safety directions on the label. This is to ensure that the person supplying the drug or poison gives the purchaser or user of the product sufficient information to be able to use it correctly and safely. For example, hair dyes containing phenylenediamines must be labelled with the statement "WARNING – This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye."

New subsection 30(3) provides, in effect, that if a person supplies a dispensed medicine mentioned in Appendix K, the container must have the appropriate sedation warning specified in paragraph 45 of Part 3 of the current Standard; and that if a person supplies a dispensed medicine specified in paragraph 45 of Part 3 of the current Standard, the container must have the appropriate warning statement. For example, the antihistamine dexchlorpheniramine is listed in Appendix K, and paragraph 45 of Part 3 of the Standard specifies that when dispensed, the container must be labelled with the warning statement "This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol." or "This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.".

New subsection 30(4) provides that the requirements of the current Standard do not apply to a substance listed in Appendix G if the concentration of that substance is less than that specified in Appendix G for that substance. For example, a homoeopathic preparation may contain a scheduled poison, i.e. a poison listed in a schedule of the Standard; subsection 30(4) provides that if a preparation contains a substance in a concentration equal to or less than that specified in Appendix G, it is exempted from the requirements of the Standard.

**Clause 10 – Insertion**

Clause 10 would insert a new section 53A empowering the Minister to modify the current Standard. The effect of subsection 2 is that the modification is a disallowable instrument under section 10 of the *Subordinate Laws Act 1989*. See also the comment on the definition of "drugs and poisons standard" under clause 7 above.

**PART 4 – MINOR AMENDMENTS OF REGULATIONS**

**Clause 11 – Minor Amendments of the Poisons Regulations**

Clause 11 provides for the Poisons Regulations to be amended in accordance with Schedule 3 to the Bill.

**Clause 12 – Minor Amendments of the Poisons and Drugs Regulations**

Clause 12 provides for the Poisons and Drugs Regulations to be amended in accordance with Schedule 4 to the Bill.

**SCHEDULE 1 – MINOR AMENDMENTS OF POISONS ACT 1933**

Generally, the schedule provides for provisions to be amended in minor ways, or remade with minor changes, to bring them into line with current industry practice, to promote plain English and current drafting practice, to reflect the effect of the *Interpretation Act 1967* and the *Subordinate Laws Act 1989*, and to omit obsolete or unnecessary provisions.

Section 1 would be remade in accordance with current drafting practice.

Subsection 5(1) would be renumbered as Section 2 and include some revised definitions. Definitions no longer required would also be omitted.

Sections 11, 14, 19 and 43 would be remade to clarify their operation.

Sections 48 to 51, which either are obsolete or duplicate other laws, would be omitted.

Provision is also made for the sections and other provisions of the Act to be renumbered.

**SCHEDULE 2 – MINOR AMENDMENTS OF POISONS AND DRUGS ACT 1978**

Generally, the schedule provides for provisions to be amended in minor ways, or remade with minor changes, to bring them into line with current industry practice, to promote plain English and current drafting practice, to reflect the effect of the *Interpretation Act 1967* and the *Subordinate Laws Act 1989*, and to omit obsolete or unnecessary provisions.

Section 1 would be remade in accordance with current drafting practice.

Subsection 3(1) would be renumbered as Section 3 and omit definitions no longer required.

Section 28 would be remade to clarify its operation.

Provision is also made for the sections and other provisions of the Act to be renumbered.

**SCHEDULE 3 – MINOR AMENDMENTS OF POISONS REGULATIONS**

Generally, the schedule provides for provisions to be amended in minor ways, or remade with minor changes, to bring them into line with current industry practice, to promote plain English and current drafting practice, to reflect the effect of the *Interpretation Act 1967* and the *Subordinate Laws Act 1989*, and to omit obsolete or unnecessary provisions.

Regulation 2 would include new definitions of "prescriber" and "recipient" to clarify and simplify proposed amendments of regulations 12 and 13.

Regulation 3 would provide for licences to be in an improved form instead of the form in the schedule to the Regulations.

Provision is also made for the Regulations and other provisions of the Regulations to be renumbered.

**SCHEDULE 4 – MINOR AMENDMENTS OF POISONS AND DRUGS REGULATIONS**

Generally, the schedule provides for provisions to be amended in minor ways, or remade with minor changes, to bring them into line with current industry practice, to promote plain English and current drafting practice, to reflect the effect of the *Interpretation Act 1967* and the *Subordinate Laws Act 1989*, and to omit obsolete or unnecessary provisions.

Provision is also made for the Regulations and other provisions of the Regulations to be renumbered.