DEPARTMENT OF HEALTH

DISCUSSION PAPER

REVIEW OF

POISONS ACT 1964

January 2002

1. BACKGROUND TO REVIEW

The Department of Health is reviewing the Poisons Act 1964 ['the Act'] at a time, which coincides, with the Council of Australian Governments National Competition Review of Drugs, Poisons and Controlled Substances Legislation ("Galbally Review").

Those recommendations included in the Galbally Review that will require legislative amendment to the Act have been included in the discussion paper where possible.

Since the Act was considered by Parliament, a number of significant events have occurred which have a direct impact on the provisions of the Act. These are:

1.1. Mutual Recognition Scheme

In 1992 the Commonwealth, States and Territories signed an intergovernmental agreement by which they committed to introduce a mutual recognition scheme for goods and occupations. In December 1995, the Mutual Recognition (Western Australia) Act was proclaimed. The mutual recognition scheme overrides the provisions of health practitioner's legislation dealing with reciprocal recognition of health regulation bodies and health practitioners.

1.2. The Corporation Law

In 1995 The Corporation Law was amended to provide for one member "body corporate". Some of the health practitioner legislation in Western Australia permits the registration of "bodies corporate" but in some cases non-registered members may form part of the "body corporate".

1.3. National Competition policy

In 1995 the Commonwealth, States and Territories entered into the Competition Principles Agreement and the Conduct Code Agreement. Under the terms of this agreement the Act was reviewed and recommendations have been included in the Galbally Report.

1.4. Commonwealth Therapeutic Goods Act 1989

The Commonwealth introduced legislation to control safety and efficiency aspects of therapeutic goods and more recently poisons.

2. PURPOSE OF DISCUSSION PAPER

The purpose of this discussion paper is to alert interested parties to the fact that the Department of Health proposes to review the Poisons Act 1964, taking into account the recommendations of the Galbally Report.

Interested parties are asked to consider the proposed provisions set out in the discussion paper.

The aim of this review is to develop a comprehensive legislative framework that regulates medicines and poisons.

The Galbally Report recommended that the objectives of the legislation should be to promote and protect public health and safety by minimising the potential for:

- accidental or deliberate poisoning;
- medicinal misadventure; and
- diversion for abuse or manufacture of substances of abuse.

It is also desirable that the legislation is readily understandable and as far as possible achieves constancy of outcomes with other States and Territories.

SUBMISSIONS

All submissions and comments should be made by 5 pm Friday 19 April 2002 and addressed to:

Chief Pharmacist
Pharmaceutical Services
Department of Health
PO Box 8172
PBC Perth WA 6849.

LEGISLATION BY THE COMMONWEALTH AND IN OTHER STATES AND TERRITORIES

In considering this discussion paper it is useful to also consider the controls set out in similar legislation used by other States and Territories. These include:

New South Wales	Poisons and Therapeutic Goods Act 1966 Drugs Misuse and Trafficking Act 1985
Queensland	Health Act 1937 Health (Drugs and Poisons) Regulation 1966
South Australia	Controlled Substances Act 1984 Drugs of Dependence (General) Regulations 1985 Controlled Substances Act (Exemptions) Regulations 1989 Controlled Substances (Poisons) Regulations 1996 Controlled Substances (Volatile Solvents) Regulations 1996
Tasmania	Poisons Act 1971 Poisons Regulations 1975 Alcohol and Drug Dependency Act 1968
Victoria	Drugs, Poisons and Controlled Substances Act 1981 Drugs, Poisons and Controlled Substances Regulations 1995
Australian Capital Territory	Drugs of Dependence Act 1989 Drugs of Dependence Regulations 1993 Poisons Act 1933 Poisons Regulations 1933 Poisons and Drugs Act 1978 Poisons and Drugs Regulations 1933 Public Health (Sale of Food and Drugs) Regulations 1931
Northern Territory	Poisons and Dangerous Drugs Act 1993 Poisons and Dangerous Drugs Regulations 1985 Therapeutic Goods and Cosmetics Act 1986 Pharmacy Act 1979

In Western Australia, the *Poisons Act 1964* impacts upon other legislation including:

Misuse of Drugs Act 1981
Pharmacy Act 1964
Medical Act 1894
Nurses Act 1992
Agricultural and Veterinary Chemicals Act 1995
Podiatrist Registration Act 1984
Optometrist Act 1940
Veterinary Surgeons Act 1960
Dental Act 1939

3. PROPOSED AMENDMENTS TO THE POISONS ACT

3.1. Commissioner of Health

Consideration will be given to amending the title 'Commissioner of Health', where it occurs, to Director General.

3.2. Delegation of Authority

The *Health Legislation Administration Act 1984* provides authority for a delegation of powers and duties. However, it is proposed that there be a provision in the Act for a delegation of authority from the Commissioner of Health for any or all of the powers and duties set out in the Act and Regulations.

3.3. Interpretation Section 5(1)

Amend the following definitions:

3.3.1. "authorised officer" by deleting an environmental health officer as this category of person has not been used in administering the Act.

The Minister has under section 52A the ability to authorise any person to be an 'authorised officer' for the purposes of the Act.

3.3.2. "automatic machine" to ensure that an electronic device is captured by this definition.

Since the definition was initially written there have been developments in technology and it is desirable that the definition includes electronic devices.

3.3.3. The Act provides for registered health professionals to have access to and use poisons for the purpose of their profession. There is the potential for the registered health professional to be a body corporate following changes to the Corporation law in 1995. It is proposed that the definitions for dentist, medical practitioner, veterinary surgeon and pharmaceutical chemist are amended to clearly identify that an individual has the authority and not the body corporate. In addition, it is proposed to include provisions to ensure that where an individual person is authorised to access a poisons that it will mean a 'natural' person and not a body corporate unless otherwise stated.

3.4 Poisons Advisory Committee Part II Section 8

3.4.1 The membership of the Advisory Committee was determined at a time when the classification of poisons into the schedules was the primary function. The National Drugs and Poisons Scheduling Committee now performs this function and the membership of the committee should be

revised to reflect the new role. It is proposed to amend the membership of the Committee to consist of:

The Commissioner of Health or an employee of the Department of Health nominated by the Commissioner of Health.
One pharmacologist or clinical pharmacologist appointed by the Minister.
Two medical practitioners, one with expertise in general practice, appointed by the Minister.
Two pharmacists, one with expertise in community pharmacy, appointed by the Minister.
One person with expertise in the manufacturing and distribution of poisons which do not have a therapeutic use appointed by the Minister.
One person employed by the Department of Agriculture.
One person from the consumer movement appointed by the Minister.

A quorum would be made up of 5 members.

3.4.2 Some of the work of the Advisory Committee will require the consideration of experts not included in the membership of the Committee. For example, the Stimulants Committee. It is desirable that there be provision to establish sub-committees which are underpinned by legislation for some of these activities.

It is proposed to include a provision for sub-committees to be appointed with at least one member from the Advisory Committee. The establishment of a sub-committee and its functions are to be approved by the Advisory Committee and the Commissioner of Health and may include any function delegated to the Advisory Committee.

3.4.3 There is no public benefit in requiring the Governor to be involved in the administrative matters associated with this Act and it is proposed to substitute the word 'Governor' where it occurs with 'Minister'.

3.5 Part III - Poisons and Other Substances

Section 20
Schedule 1 of Appendix A to the Act is vacant. Victoria has implemented controls for Traditional Chinese Medicines using Schedule 1. It is proposed that provision should be made in the Act to accommodate this development. It is proposed to amend section 20(2)(a) Schedule 1, to poisons of plant, animal or mineral origin that in the public interest should only be available to a person holding a licence issued under section 24.

3.6 New Drug to be included in Schedule 4

There are often significant delays between when a new medicine is approved for marketing in Australia and its consideration for scheduling by the national committee. There are also many medicines imported for use in therapeutic drug trials and through the Special Access Scheme.

There is a requirement that any new medicine be included in Schedule 4 and require the authorisation of a medical practitioner or veterinary surgeon before it can be used until such time as the scheduling committee has considered the requirement for scheduling.

It is proposed that a new provision be included to ensure all new substances used for therapeutic, veterinary or agricultural use are included in Schedule 4 until they have been considered by the national scheduling committee.

3.7 Persons Authorised to Sell Poisons – Section 23

3.7.1 There is no longer a need to licence the manufacture and supply by wholesale or retail of poisons included in Schedules 5 and 6 provided they are labelled and packed in accordance with national standards.

It is proposed that there be a provision authorising the retail and wholesale supply of poisons included in Schedules 5 and 6 provided they conform to any prescribed conditions in the regulations or any notice issued by the Commissioner of Health.

This is a recommendation of the Galbally Report.

3.7.2 It is proposed that the substances which medical practitioners, dentists, pharmaceutical chemists and veterinary surgeons have access to and use for professional purposes be limited to those included in Schedules 2, 3, 4, and 8. Access to substances included in schedules 5 and 6 are proposed not to be restricted and those in schedule 7 are not generally used in these professional areas. In addition, it is proposed that the authorisation provided by this provision will be subject to any prescribed conditions and restrictions and any notice given by the Commissioner of Health. It is also proposed that the Commissioner of Health may also suspended or revoke the authority in accordance with the regulations.

3.7.3 It is proposed that there will be provision for the Commissioner of Health to authorise any person to purchase, possess, use and supply any poison included in Schedules 1, 2, 3, 4, 7 or 8 who has demonstrated achievement of prescribed competencies set out in the regulations. This authorisation will be subject to any prescribed conditions and restrictions and any notice given by the Commissioner of Health and may also be suspended or revoked by the Commissioner of Health in accordance with the regulations.

3.8 Licences – Section 24

3.8.1 Community pharmacies are registered under the Pharmacy Act 1964 and are also required to hold a licence to sell scheduled poisons by retail under the Poisons Act. Provided there is a registering system for pharmacies there does not appear to be any benefit in requiring pharmacies to hold a second licence under the Poisons Act. Particularly as the controls required regarding storage and record keep of scheduled poisons could be achieved through an alternative mechanism set out under section 3.7.2

It is proposed that a pharmacy registered under the Pharmacy Act 1964 would be exempted from the requirement under the Act to hold a licence to sell poisons included in Schedules 2, 3, 4 and 8 by retail.

3.8.2 It is proposed to include provision for the Commissioner of Health to issue a licence to sell those poisons included in Schedule 1 (see 3.5).

3.8.3 A number of substances included in Schedule 9 are required by laboratories as standards for the analytical analysis of samples. In addition, some substances included in Schedule 9 are used in research and the wholesale supply of these substances is prohibited under the current Act.

It is proposed that provision be made for a licence to be issued for the wholesale supply of substances included in Schedule 9 under certain conditions.

3.8.4 The Act allows for a licence application to be assessed on the basis that the premises are properly and hygienically equipped. It is proposed that there also be a requirement that the applicant to be able to demonstrate that they can comply with a standard prescribed by the regulations such as the Code of Good Wholesaling Practice.

3.8.5 The Commissioner of Health may issue a Notice under section 24 (5) to place conditions on the sale, supply or possession of poisons included in Schedule 7. It is proposed that this provision be extended to include Schedules 1, 2, 3, 5 and 6.

3.9 Duration of Licences and Permits – Section 26(B)

Section 26B provides for a licence or permit to expire on 30 June following the issue (up to one year) or the expiration of 2 years after the issue (up to three years). Experience with this system has found that many licences and permit holders who pay for a three year licence or permit forget they hold a licence or permit. In addition, applicants for a licence or permit pay the same fee regardless of the timing of the application. This results in a new licence or permit being valid for any period of time between a few weeks up to twelve months with the applicant paying the same fee.

Consequently, it is proposed that a licence and permit be valid for one year from the date of issue. This will result in licences becoming due throughout the year and overcome the issue of new applicants being charged the same fee for a licence with a duration of less than twelve months as a licence holder is charged for a full year.

3.9.1 There are occasions where a person has a valid claim for a single purchase of a poison which is either to be used immediately or over an extended period of time. However, a permit issued in the usual way is inappropriate in terms of the cost and the proposed 12-month life of the permit. Consequently, it is proposed that provision be made for a permit be issued for a single purchase of a poison.

3.10 Fees – Section 27

In addition to the requirement for an applicant to pay a fee as prescribed, it is proposed to include a provision for an application fee to be charged. This proposal is based upon the 'user pay' principal where resources are utilised in the assessment of applications. The application fee would not be refundable if an application was refused however, the licence or permit fee would be refundable.

3.10.1 It is also proposed that provision be made for a fee to be charged for any authorisation issued under the Act.

3.10.2 It is also proposed that provision be made for a fee to be charged for an urgent application to be processed within 24 hours of receipt and that the fee be five times the application fee.

3.11 Unauthorised sales of Poisons – Section 32

It is proposed to delete the exemption provided under section 32(c) referring to the Agriculture and Related Resources Protection Act 1976 and Agriculture Protection Board Act 1959 as this is no longer relevant.

3.12 Self Administration of a Drug of Addiction – Section 36

It is proposed to amend this section to clarify that a medical practitioner or dentist cannot use or prescribe a drug of addiction for themself to self-administer. However, it is acceptable for a medical practitioner or dentist to prescribe a drug of addiction for another medical practitioner or dentist to self-administer.

3.13 Needle Syringe Program – Section 36A

This provision dealing with the distribution of needles and syringes does not fit with the objectives of this Act.

It is proposed that the legislation for approving a needle and syringe program should be transferred to public health legislation. As a new Public Health Bill is being considered, it is proposed that it include this provision in the appropriate section of that Bill.

3.14 Use of Schedule 9 Poisons – Section 41

The process that has been developed to provide assess to poisons included in Schedule 9 is very involved and expensive. Access is required by laboratories for standards, by government entities for training and by researchers.

It is proposed that this provision be repealed and access to these substances be the same as all other poisons with the limitation that poisons in Schedule 9 cannot be sold by retail.

This approach will not weaken the current stringent controls over access to substances included in Schedule 9, but will provide a more efficient and considerably less expensive process for gaining access to these substances.

3.15 Prescribing of Drugs of Addiction – General

It is proposed that the primary controls over the prescribing of a drug of addiction be transferred from the Poisons Regulations to the Act. This will require provision in the Act to prohibit a medical practitioner, dentist, veterinary surgeon or any other authorized person being able to prescribe or supply a drug of addiction except as authorized by the regulations.

3.16 Prescribing of Drugs of Addiction – 'Drug Addicts"

It is well accepted that people with a drug addiction resort to pretences and deceits of an extraordinary nature to induce a medical practitioner to prescribe a drug of addiction. The intention of this legislation is to provide for an early identification of these people who exhibit a drug seeking behaviour to enable appropriate timely treatment.

Comment is sought on different models that could be used to provide for suitable controls to minimise inappropriate prescribing of drugs of addiction for non-therapeutic purposes.

It is intended to repeal the *Drugs of Addiction Notification Regulations 1981* and include all of the required controls in the Poisons Act. The basic premise of the controls is that a medical practitioner will not be able to write a prescription for a 'drug addict' except in accordance with the Regulations.

The definition of a 'drug addict' requires careful consideration, as does the name of the list or register of 'drug addicts'. For example it may be preferable to call the register a 'Drug Abuse Register'.

The current definition of a 'drug addict' in the *Drugs of Addiction Notification Regulations 1981* and the Poisons Regulations is a person who is:

- under a state of periodic or chronic intoxication produced by consumption of a drug of addiction or any substitute thereof;
- under a desire or craving to take a drug of addiction or any substitute therefore until he has so satisfied that desire or craving;
- under a psychic or physical dependence to take a drug of addiction or any substitute therefore;

The definition could also make reference to people who are participating in a drug treatment program for drug addiction as defined by the regulations. The regulations would be expected to include the methadone and buprenorphine treatment programs but not the naltrexone program.

The definition could also make reference to drug seeking behaviour such as three or more visits to a medical practitioner within seven days and obtaining a prescription for a drug of addiction at each visit.

To ensure a person can always gain access to appropriate pain relief a medical practitioner will always be authorised to administer or authorise the administration of a drug of addiction for any person.

Privacy issues will also require consideration. Provision will be required for a transparent process to enable a person who meets the definition of a 'drug addict' to be advised of their status; its meaning; and the appeal mechanism. Consideration will also be required to provide for a process which describes who will be able to gain access to the information, how access is achieved and how the information to be included in the register is verified.

3.17 Sale of Poisons in Inappropriate Container – Section 47

Section 47 prohibits the sale of a poison used internally when packaged in a container used for poisons used externally. However, it does not specifically prohibit a poison used externally to be packaged in a food container or a container usually used for a poison used internally.

There has been confusion regarding the packaging of propylene glycol in food containers and it is proposed to extend the provisions of Section 47 to prohibit the sale of poisons for external use in a food container or one usually used for poisons used internally.

3.18 Automatic Machines – Section 49

It is proposed to amend section 49 by including provision for the Minister to exempt any poison or class of poisons from the restrictions associated with being supplied by a vending machine at a particular place, facility or group of facilities. Any exemption would be published in the Government Gazette.

The intention of this amendment is to facilitate the development of automatic machines to supply medicines in hospitals or other facilities when the technology has been developed.

There may be consequential amendments in other Acts, such as the Pharmacy Act, to facilitate this provision.

3.19 Disposal of Poisons

It is proposed that there be a new provision that authorises the disposal of any poisons or poisons as prescribed in the regulations.

3.20 Proof of Certificate of Analysis – Section 60

It is proposed that section 60 (2) be amended and that the 'analyst' be an analyst employed at a laboratory approved by the Commissioner of Health.

3.21 Obtaining substances by false representation

3.21.1 It is proposed that there be a new provision prohibiting a person making representation which they know or ought to know, is false or misleading, to obtain any poison from an authorized person.

3.21.2 It is also proposed to include a new provision which would create an offence for a person to forge, alter, or utter a prescription or order of a medical practitioner, dentist, veterinary surgeon or authorised person for any poison included in schedule 4 or 8.

3.21.3 It is also proposed to include a new provision which would create an offence for a person to induce, or attempt to induce, a pharmacist to dispense a prescription that includes a substance included in schedules 4 or 8, knowing the prescription to be forged or altered.

3.21.4 It is also proposed to include a new provision which would create an offence for a person to be in possession of a fraudulent or altered prescription for a poison included in schedules 4 or 8 or an authorisation which has been obtained from uttering a fraudulent or altered prescription.

3.22 Possession and supply of drugs of addiction by carers

It is proposed to include a new provision which would authorise a parent, guardian or carer to be in possession of a specified drug or a drug of addiction when the drugs have been authorised by a medical practitioner, dentist, veterinary surgeon or other authorised person.

3.23 Use of Electronic Signatures

With the ongoing development of information technology it is proposed that provision will be made for the use of an electronic signature, such as an

access code and password, where a signature is required for the purposes of the Act.

It is also proposed that there will be provision that in any legal proceedings under the Act or the Misuse of Drugs Act 1981 that if it is proved that the electronic signature has been recorded in respect of an entry, then in the absence of proof to the contrary that person is taken to have made the entry.