



DEPARTMENT OF HEALTH

REVIEW OF POISONS ACT 1964

DISCUSSION PAPER 2

April 2004

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1. PURPOSE OF DISCUSSION PAPER

The Department of Health is conducting a review of the *Poisons Act 1964* (the Poisons Act). The review addresses two significant issues:

- Recommendations made by the National Competition Review of Drugs, Poisons and Controlled Substances Legislation undertaken by Rhonda Galbally for the Council of Australian Government (the Galbally Report); and
- A review of the legislative requirements for prescribing drugs of addiction that arose from the Community Drug Summit that was held in Perth in 2001 (Prescribing Drugs of Addiction).

The aim of the review is to develop a comprehensive legislative framework regulating medicines and poisons, including drugs of addiction, that is readily understandable and, as far as possible, achieves constancy of outcomes with other States and Territories.

Previous Discussion Papers

The “Discussion Paper – Review of *Poisons Act 1964*” (Discussion Paper 1) identifying proposed changes arising from the recommendations in the Galbally Report was circulated to interested parties in January 2001.

Another discussion paper entitled “Legislative requirements for Prescribing a Drug of Addiction – Proposed Reform” (DOA Discussion paper) was circulated to interested parties in July 2002.

This discussion paper sets out proposed amendments to the Poisons Act taking into account the input from stakeholders in addressing the issues raised in Discussion Paper 1 and the DOA Discussion Paper.

Interested parties are asked to consider and provide comment on the proposed provisions for the Poisons Act including the regulatory framework for the prescribing of drugs of addiction that are set out in this discussion paper.

SUBMISSIONS

All submissions and comments are required to be received by 5 pm Wednesday 30 June 2004 and should be sent to the Chief Pharmacist

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2. BACKGROUND TO REVIEW

The *Poisons Act 1964* (the Poisons Act) sets out the controls for the regulation of drugs, medicines and other controlled substances in Western Australia.

The Department of Health is reviewing the Poisons Act to coincide with the Council of Australian Governments National Competition Review of Drugs, Poisons and Controlled Substances Legislation (Galbally Report).

The Galbally Report concluded that the Australian community as a whole, benefited from the comprehensive legislative framework that regulates drugs, poisons and controlled substances. The recommendations were associated with improving national uniformity and efficiency, reducing levels of control where possible and improving benefit to the community as a whole.

The Galbally Report recommended that the objectives of drug, poisons and controlled substance 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.

As a parallel undertaking, the Department is also reviewing the legislative and administrative requirements for prescribing drugs of addiction following some issues being raised at the Community Drug summit.

The aim of the proposed reform to the legislation relating to prescribing drugs of addiction is to:

- minimise risk of diversion of drugs of addiction,
- ensure appropriate and effective use of drugs of addiction,
- facilitate early identification of persons who are exhibiting drug-seeking behaviour so that steps can be taken to encourage such people to seek appropriate treatment, and
- promote transparency and openness in the system.

Two discussion papers have been distributed to interested stakeholders. The “Discussion Paper – Review of *Poisons Act 1964*” (Discussion Paper 1) identified proposed changes arising from the recommendations in the Galbally Report and was circulated in January 2001. The discussion paper “Legislative requirements for Prescribing a Drug of Addiction – Proposed Reform” (DOA Discussion paper) was circulated in July 2002.

Public consultation on Discussion Paper 1 and the DOA Discussion paper attracted significant interest from medical and health consumer groups. There have also been meetings with stakeholders on specific issues. The outcomes of those meetings and the comments received on the initial discussion papers have been considered and recommendations incorporated, where possible, within Discussion Paper 2.

Additional amendments are proposed to incorporate some aspects of therapeutic goods legislation into the Poisons Act and to amend the penalty levels provided for in the Poisons Act.

Other issues reflected in the discussion paper arise from changes to the Commonwealth legislation relating to corporations, privacy and national competition policy.

3. 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 are set out in Attachment 1.

4. PROPOSED AMENDMENTS TO THE POISONS ACT

4.1. Commissioner of Health

Amendments to the Poisons Act to replace the title “Commissioner of Health” with “CEO” as defined in an amended *Health Legislation Administration Act 1984* are included in the *Machinery of Government (Miscellaneous Amendments) Bill 2003* that was introduced into the Legislative Assembly on 4 December 2003.

4.2. Delegation

For purposes of clarity it is proposed to insert a specific provision into the Poisons Act to provide that the CEO may delegate to a person any or all of the powers and duties set out in the Act and Regulations, except the power to delegate.

4.3. Definitions

A number of the terms need to be defined or definitions in section 5 of the Poisons Act require amendment. The following changes are proposed:

“*authorised officer*” – amend to remove reference to environmental health officer as environmental health officers are not involved in the administration of the Poisons Act

“*environmental health officer*” – delete as no longer required

“*automatic machine*” – amend to ensure that an electronic device is captured.

Amend the definitions of “*dentist*”, “*medical practitioner*”, “*nurse practitioner*”, “*pharmaceutical chemist*” and “*veterinary surgeon*” to make clear that these terms refer only to natural persons and not to incorporated bodies. This change follows changes to the corporations laws that allow bodies corporate to be registered as health professionals.

4.4. Poisons Advisory Committee

Discussion Paper 1 proposed changes to the composition of the Poisons Advisory Committee (the Committee) to reflect the changed nature of the Committee’s work as a result of the National Drugs and Poisons Scheduling Committee (NDPSC) taking over the role of classification of poisons.

Responses from various stakeholder groups representing health professionals, health regulators and consumer associations, all indicated a desire to have a representative on the Committee.

Restricting the composition of the advisory committee to certain professions created difficulties for those interest groups that are not represented on the Committee. It is not, however, feasible to have representation from all interested stakeholders who desire to be represented.

The area of medicines, poisons and controlled substances has become increasingly specific and complex. A large advisory committee with broad representation is not the most efficient and effective option to gain advice on a specific issue. It would be more efficient and effective to obtain advice on specific issues from a committee with representation and expertise in the areas under consideration.

It is therefore proposed that the provisions relating to the Poisons Advisory Committee be repealed and replaced with new provisions that allow the Minister to appoint committees or working groups as required. A committee or working group may be appointed to provide advice to the Minister and the CEO on specific issues relating to the manufacture, distribution, sale, supply, possession, use or labelling of poisons. It is proposed that the Minister would decide the composition and terms of reference of the committees or working groups and also on the terms and conditions of appointment of the members. This would allow the use of poisons in a particular area to be considered by a group with appropriate representation and expertise in that area rather than a 'one size fits all' approach.

4.5. New Drugs

As outlined in Discussion Paper 1 there are medicines that are imported for use in therapeutic drug trials and through the Special Access Scheme for individual patients which have not generally been considered by the NDPSC. There are also some drugs that have been registered under the Commonwealth's *Therapeutic Goods Act 1989* (TGA) or are subject to an approval under section 19 of the TGA. They are therefore not subject to the restrictions on import, export, manufacture and supply in section 20 of the TGA.

As these medicines are not scheduled or have not been through the scheduling process, they are not subject to access restrictions that apply to scheduled poisons under the Poisons Act. It is proposed that the Poisons Act be amended to allow these medicines to be treated as schedule 4 poisons until such time as they have been scheduled or considered for scheduling by the NDPSC.

It is proposed that Appendix A of the Poisons Act be amended to add to schedule 4:

- Substances intended for therapeutic application that have been registered under the *Therapeutic Goods Act 1989*, but not yet been considered by the NDPSC for inclusion in the SUSDP.
- Substances for which approval has been given under section 19 of the *Therapeutic Goods Act 1989*.

The inclusion of these substances in schedule 4 means that they will be subject to the same restrictions as all other schedule 4 poisons, that is they will only be available on prescription.

4.6. Persons Authorised to Sell Poisons – Section 23

Section 23(1) of the Poisons Act requires a person to hold a licence to manufacture, distribute, supply or sell by wholesale or retail any poison (other than a poison in schedule 5), subject to exemptions that are set out by way of authorisations in subsections (2), (3) and (4). Section 23(1a) provides for additional restrictions in relation to drugs of addiction and specified drugs.

The authorised supply of poisons without a licence is restricted to specified groups of health practitioner for use of poisons in connection with their professional practice. The authorised uses are:

- *Pharmaceutical chemists* – any preparation, admixture or extract containing any poison in the ordinary course of his/her retail business.
- *Medical practitioners, veterinary surgeons and dentists* – use, supply or sell any poison and prescribe the use, supply or sale of a drug of addiction in the lawful practice of his/her profession (although not to sell in an open shop).
- *Nurse practitioners* – use, supply or prescribe any poison in the lawful practice of his/her profession at a designated area.
- *A person who carries on a business* – sell by retail a poison in schedule 6 subject to restrictions in the regulations or ordered by the CEO.

It is proposed that section 23 be redrafted to more clearly set out the licensing requirements and exemptions and to reflect the use of poisons by health professionals in the practice of their profession. It is also proposed to introduce some flexibility in identifying health practitioners who are exempt from the licensing requirements.

4.6.1. Supply of Schedule 5 and 6 poisons

The Poisons Act currently authorises a person to manufacture, distribute, supply or sell by wholesale or retail poisons in schedule 5 (section 23(1)).

A person does not require a licence to sell a poison in schedule 6 by retail (Section 23(4)), but does require a licence to manufacture, distribute, supply or sell by wholesale a schedule 6 poison, subject to certain restrictions to be set out in the regulations (section 23(1)).

The National Drugs and Poisons Schedule Committee has developed national standards for the labelling and packaging of poisons in schedules 5 and 6.

It is proposed that with a view to simplifying the licensing requirements for Schedule 5 and 6 substances and in line with Recommendation 13 of the Galbally Report, poisons in these schedules be exempted from licensing requirements in Section 23 of the Poisons Act. The exemption is to provide that a person is authorised to manufacture, distribute, supply or sell by wholesale or retail any poisons in schedule 5 or 6 provided that:

- the poisons are labelled and packed in accordance with national standards to be prescribed in the Poisons Regulations;
- the person complies with any notice issued by the CEO; and
- provision is to be included to allow the CEO to withdraw the authorisation for a particular person to supply specific schedule 5 or 6 poisons.

4.6.2. Supply of Schedule 7 poisons

Section 23 of the Poisons Act currently provides that a person requires a licence to manufacture, distribute, supply or sell by wholesale or retail poisons in schedule 7 with general exceptions relating to a person who is a pharmaceutical chemist, medical practitioner, veterinary surgeon, dentist or nurse practitioner using the poison in the course of their professional practice.

Schedule 7 poisons are not generally used by medical practitioners, veterinary surgeons, dentists and nurse practitioners in the course of their professional practice.

Pharmaceutical chemists require access to some poisons included in schedule 7 for the purpose of preparation of extemporaneous products in the normal course of their profession.

It is proposed to amend section 23 to remove the automatic authorisation in respect of schedule 7 poisons for medical practitioners, veterinary surgeons, dentists and nurse practitioners. This would mean members of these professional groups would require a specific licence or authority (see Access to poisons for specific health professions below) in respect of schedule 7 poisons.

It is proposed that the exemption from the requirement to hold a licence for pharmaceutical chemists in relation to schedule 7 poisons be amended to make the exemption subject to any prescribed conditions and restrictions and any notice given by the CEO. This will allow a greater oversight of the use of schedule 7 poisons by the CEO.

4.6.3. Access to poisons for specific health professionals

As set out above, the Poisons Act currently provides that certain health professional groups are exempt from requirements to hold a licence in respect of the use of poisons in their professional practice.

The substances which medical practitioners, nurse practitioners, dentists, and veterinary surgeons would normally need to access and use for professional purposes are those included in schedules 2, 3, 4, and 8. It is therefore proposed to amend the Poisons Act to provide that authority (that provides an exception from the requirement to hold a licence for these health professional groups) should be limited to poisons in schedules 2, 3, 4 and 8.

It is also proposed that, in the interest of safety, the Poisons Act be amended to provide for a greater degree of oversight of the use of poisons by providing the capacity for the CEO to limit the use of poisons by those specified health professional groups. This would allow the CEO to put restrictions on individual members of a health professional group in respect of their use of particular poisons. It is also proposed that the Poisons Act be amended to provide that the CEO may suspend or revoke the authority of any medical practitioner, nurse practitioner, dentist, pharmaceutical chemist or veterinary surgeon to access and use any poisons in schedules 2, 3, 4, and 8 in accordance with the Regulations. A decision to restrict, or suspend, or revoke the authority of a health professional would be reviewable by the new State Administrative Tribunal.

4.6.4. Access to poisons for other health professionals

There have been strong arguments by stakeholder groups (for example, those representing optometrists, podiatrists and Aboriginal health workers) in many submissions on Discussion Paper 1 seeking access for health professionals to various poisons.

It is difficult to determine or define all of the relevant health professional groups that should have access to various poisons, or to determine to which poisons or group of poisons access should be given. In addition, not all members of a health professional group may have the expertise or the need to use particular poisons in the course of their clinical practice. Because of these difficulties, it would be cumbersome to include specific provisions relating to other health practitioner groups in the Poisons Act itself.

It is proposed to amend the Poisons Act to provide that the CEO may authorise a person or class of persons to purchase, possess, use and supply specified poisons included in schedules 2, 3, 4, 7 or 8 in accordance with the Regulations, if the person has demonstrated achievement of competencies that are prescribed in the Regulations.

The prescribed competencies will be determined following extensive consultation with the appropriate stakeholder group of health professionals. This provision will address the requirement for medicines in rural areas where there is no pharmacy or hospital by allowing other health professionals to provide some medicines. It will also enable other health professionals to have authority to possess, use and supply poisons required in the course of their practice where appropriate.

The authorisation will be subject to any prescribed conditions and restrictions and any notice given by the CEO. It may also be suspended or revoked by the CEO in accordance with the regulations. A decision to suspend or revoke an authorisation would be reviewable by the new State Administrative Tribunal.

4.6.5. Pharmacies

As outlined in Discussion Paper 1, there are currently a range of overlapping procedures and requirements in relation to licensing and registration of pharmacies and pharmaceutical chemists.

There are requirements in the *Pharmacy Act 1964* (the Pharmacy Act) for licensing of pharmaceutical chemists and requirements that a pharmaceutical chemist must be on the premises at all times that the pharmacy is open. The Pharmacy Act also contains provisions relating to the minimum standards for pharmacy premises and a registration process for pharmacies.

Registered pharmacies are currently also required to hold a licence to sell scheduled poisons by retail under the Poisons Act. The licensing requirements include consideration of premises standards. This is in addition to the authorisation under the Poisons Act for a pharmaceutical chemist to sell by retail, at his pharmacy in the ordinary course of his retail business, any poison.

The overlapping control of pharmacies is unnecessary and confusing.

The Pharmacy Act is currently being reviewed, including the premises registration provisions. It is appropriate for issues relating to minimum premises standards for pharmacies to be addressed in that legislation.

It is therefore proposed to amend the Poisons Act to remove the licensing requirements for pharmacies, as there are other legislative mechanisms available to exercise the same level of control. Pharmaceutical chemists will continue to be authorised to sell poisons included in schedules 2, 3, 4 and 8, by retail, in a pharmacy, but they will not be required to hold a licence.

4.7. Licences to sell poisons – Section 24

Section 24 of the Poisons Act provides the authority for the CEO to grant a licence for the manufacture and sale of poisons. The section is unclear, in that the initial broad authority in section 24(1) seems to be qualified by restrictions on the sale of poisons in section 24(4)(d). It is proposed that section 24 be redrafted to clarify that the circumstances in which a licence may be issued.

4.7.1. Schedule 2, 3, 4, 7 and 8 poisons

The CEO may issue a licence to any person (including a body corporate) to manufacture or sell by wholesale or retail a poison in schedules 2, 3, 4, 7 or 8 at a place specified in the licence.

The applicant must be a fit and proper person to hold a licence.

Section 24(3) of the Poisons Act provides that the CEO must not grant a licence unless he/she is satisfied that the premises are fit for the proposed purpose and are properly and hygienically equipped. The TGA has developed the “Australian Code of Good Manufacturing Practice for Medicinal Products” and the “Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use”. Other codes or standards may be developed in the future that impact on the manufacture and sale of poisons. It is proposed to amend the Poisons Act to ensure that applicants for licences comply with any relevant codes or standards.

It is proposed that section 24(3) be replaced with a requirement that the CEO must not issue a licence unless he/she is satisfied that the applicant can comply with a standard prescribed by the regulations for that type of licence.

It is proposed that it be made a required condition of each licence that the licence holder continue to comply with any prescribed standards.

Currently, 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 for the safeguarding of public health. It is proposed that this provision be extended to include schedules 2, 3, 4 and 8.

4.7.2. Schedule 9 poisons

As outlined in Discussion Paper 1, a number of substances included in schedule 9 are required as standards for the analytical analysis of samples in laboratories or for research. Section 41 of the Act requires that access to schedule 9 poisons can only

be authorised by an order of the Governor. As outlined in the discussion on section 41, it is proposed to amend section 24 of the Poisons Act to provide that the CEO may issue a licence for the manufacture or wholesale supply of schedule 9 substances under prescribed conditions.

There will be no provision to allow a licence to be issued for the retail sale of schedule 9 poisons. This licensing system will replace the existing process for authorisation in respect of schedule 9 poisons set out in section 41 of the Act (see below).

4.8. Duration of Licences and Permits – Section 26(B)

The Poisons Act was amended in 1995 to insert section 26B, which 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 of licence and permit renewal has been that many licence and permit holders who pay for a three year licence or permit forget they hold a licence or permit and do not apply for renewal before the expiry of the existing licence or permit.

Applicants for a licence or permit pay the same fee regardless of the timing of the application. This means that the same fee may cover a period of weeks or up to twelve months depending on when in a calendar year the application is made.

There are occasions where a person has a valid reason for a single purchase of a poison, which is either to be used immediately or over an extended period of time. A permit issued for a twelve month period may be inappropriate in such circumstances, and it may be unreasonable to charge fees for a full year for a limited purpose.

To address these concerns, it is proposed that section 26B be amended to provide that a licence or permit may be:

- valid for one year from the date of issue, or
- for a single purchase of a named poison.

Licences and permits would need to be renewed on an annual basis on the anniversary of the date of issue, rather than on 30 June.

The fee paid by each applicant will cover a full year unless the licence or permit is for a single purchase. A separate fee for a single purchase permit or licence may be prescribed under section 27 of the Poisons Act.

4.9. List of Licence and Permit Holders

Section 59 of the Poisons Act requires the Commissioner of Health to publish in the Government Gazette the names and places of business of all persons who hold a permit or licence in August of each year. The list is *prima facie* proof for legal purposes that a person on the list is a license or permit holder.

The publication of the list allows public access to information about licence and permit holders. It is also used for evidentiary purposes. With the move to variable commencement and conclusion dates for licences and permits, the August publication date will not necessarily provide current information about licence and permit holders.

It is proposed that section 59 be amended to require that the CEO maintain a list of licensees and permit holders. The list would be made available to wholesalers to ensure they only supply authorised persons. It is also proposed that a list of licence and permit holders be available to view at a site specified in the regulations and a copy of the list can be made available on the payment of a fee prescribed by the regulations.

For evidentiary purposes, it is proposed that a copy or extract from the list, certified by the CEO, be evidence that a person was a licence or permit holder at a specified time.

4.10. Fees – Section 27

The ‘user pay’ principle has been in use for a number of years when establishing the fee structure for the licences and permits issued under the Poisons Act. A substantial proportion of the cost associated with issuing a licence or permit is directly related to the complexity of assessing the application. The Poisons Act does not provide for an application fee to be charged and the cost of assessing new applications is amortised across each licence or permit category.

It is proposed to amend section 27 to provide that an application fee may be charged for each new application. There would be no application fee for an application to renew a licence or permit. The application fee would not be refundable if an application was refused. Licence or permit fees would only be charged where an application was successful. This will enable the annual fee for each licence or permit to be reduced as the costs associated with assessing applications would be charged directly to the applicant.

It is also proposed that provision be made for an additional prescribed fee to be charged for the assessment of an application on an urgent basis. The application fee for a licence or permit that is required on an urgent basis is to be prescribed in the regulations and may be up to 5 times the ordinary application fee, depending on the degree of urgency.

It is also proposed to amend section 27 to allow for prescribed fees to be charged for an authorisation issued by the CEO in accordance with the Poisons Act, or for copies of licences or permits that have been issued.

4.11. Self Administration of a Drug of Addiction – Section 36

The intent of section 36 of the Poisons Act is to prevent any person prescribing a drug of addiction for their own use. If a drug of addiction has been prescribed by another person, it can be self-administered if the patient for whom it was prescribed is authorised to possess drugs of addiction.

The wording of the prohibition in section 36 has caused some difficulties of interpretation for doctors, and it is proposed to redraft the section to make the intent clearer. It is proposed to amend this section to prohibit any person from prescribing a drug of addiction for his/her own use. However, it is acceptable for a person to self-administer a drug of addiction in accordance with a prescription provided by another person.

4.12. Use of Schedule 9 Poisons – Section 41

The process set out in the Act to provide access to poisons included in schedule 9 requires the Governor to make an order authorising a specific person to manufacture, prepare, possess or use a specified substance included in schedule 9. The formal requirements for an order to be prepared for the Governor to consider are involved and expensive. Access is required by laboratories for standards, by government entities for training and by researchers. Experience with administration of section 41 has indicated that appropriate oversight of access to schedule 9 poisons for legitimate purposes could be achieved through the normal licensing system that applies for other poisons.

It is proposed that section 41 be repealed and access to schedule 9 poisons be regulated by way of a licence issued under section 24. The licence requirements would be similar to licence requirements for other poisons except that a licence could not allow the retail sale of schedule 9 poisons.

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 allowing access to these substances.

4.13. Sale of Poisons in inappropriate Container – Section 47

Section 47 of the Poisons Act prohibits the sale of food, drink, drugs or medicines for internal use in a package or container like containers used for poisons that are intended for external use. There is no equivalent restriction prohibiting poisons that are intended for external use from being packaged in containers like those normally associated with packaging of food. It is a dangerous practice for a poison to be packaged in a food container or a container likely to be taken as a food container, for example, the packaging of cleaning products in containers that are like cordial bottles.

It is proposed that the Poisons Act be amended to include a provision prohibiting the sale of a poison used externally if it is packaged in a package or container like a food container or a container usually associated with contents for internal use.

4.14. Automatic Machines – Section 49

Section 49 of the Poisons Act prohibits the sale of any poisons (defined as any substance included in a schedule) from an automatic vending machine. Section 40 of the *Pharmacy Act 1964* also prohibits the use of an automatic machine for the sale or supply of any drug or medicine. The Galbally Report considered the legislative provisions relating to the supply of scheduled and unscheduled medicines from vending machines. The Report concluded that there should be a prohibition on the sale of scheduled medicines from automatic vending machines. In respect of unscheduled medicines the recommendation was that uniform legislation that allows the supply from vending machines in limited circumstances be introduced.

New South Wales and Victoria have legislation that contains provisions to allow the sale of scheduled and unscheduled medicines from vending machines.

In New South Wales, the *Poisons and Therapeutic Goods Act 1966* provides that the Minister may, by order published in the Gazette, exempt regulated goods from the general prohibition on sale by means of an automatic machine. Regulated goods are defined to include both scheduled poisons and unscheduled therapeutic goods.

In Victoria, the *Therapeutic Goods (Victoria) Act 1994* prohibits the supply of therapeutic goods (both scheduled and unscheduled) by means of a vending machine without the written consent of the Secretary of the Department of Human Services.

It is proposed to amend section 49 by including provision for the Minister, by order published in the Government Gazette, to exempt any therapeutic good (see Section 6 Therapeutic Goods), poison or class of therapeutic good or poison from the restrictions associated with being supplied by an automatic machine at a particular place, facility or group of facilities. It is also proposed to amend section 64 to allow regulations to be made regulating the circumstances in which a machine may be operated.

An exemption may be subject to conditions. This will allow strict controls to be put in place making access to unscheduled medication by children unlikely.

This amendment would achieve the outcome of allowing supply of unscheduled poisons from vending machines in limited circumstances as recommended in the Galbally Report.

The form of the amendment would also facilitate the use of security protected machines to allow scheduled medicines to be stored and accessed by suitably qualified staff in hospitals or other facilities when appropriate technology has been developed. The provision of scheduled medicines through security protected machines is not intended to involve sale of the medicines, or direct access to the public, but rather a secure means of storage and access by qualified persons.

Consequential amendments will also be required to the Pharmacy Act, which also contains a prohibition on sale or supply from automatic machines.

4.15. Obtaining substances by false representation

Abuse of prescription drugs has been described as Australia's third most significant drug problem (after alcohol and tobacco). Prescription drug fraud can result from doctor or pharmacy shopping, forging prescriptions and stealing from pharmacies and surgeries. In keeping with the objective of the Act to minimise the potential for diversion and abuse, it is proposed that specific provision be included in the Poisons Act to create offences relating to obtaining poisons by false pretences. The particular offences that are proposed to be included are:

- an offence for a person to obtain, or attempt to obtain any poison by making representations which they know, or ought to know are false or misleading;
- an offence for a person to forge, alter, or utter a prescription or order of a medical practitioner, dentist, veterinary surgeon, nurse practitioner or an authorised person for any poison included in schedule 4 or 8;

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- an offence for a person to induce, or attempt to induce, a pharmacist to dispense a prescription known to be forged or altered;
 - 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.

It is proposed that penalties be in line with the general penalty levels in section 62 (see below under section on penalties).

4.16. Possession and supply of drugs of addiction by “carers”

Drugs classified as specified drugs (section 22A) and drugs of addiction are subject to the *Misuse of Drugs Act 1981* (Misuse of Drugs Act) where possession without authority is prohibited. Concern has been expressed by consumer advocates that carers could potentially be caught up by the provisions of the Misuse of Drugs Act during the normal course of their activities as a carer of a patient who has been prescribed a specified drug or a drug of addiction.

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 persons. Clear consent will have to be given by the patient to the possession of the drug by the carer.

It is suggested that a ‘Carer’ be defined as ‘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 or specified drug has been authorised by the prescription of a medical practitioner or dentist) 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’.

4.17. Use of Electronic Signatures

The ongoing development of information technology has resulted in increased use of electronic signatures, such as an access code and password. The use of electronic signatures was not specifically provided for in the Poisons Act. To avoid any uncertainty, it is proposed to amend the Poisons Act to provide that the regulation making powers set out in section 64 includes the power to make regulations about the form of signature, where a signature is required for the purposes of the Poisons Act.

Amendments to the Poisons Act and the Misuse of Drugs Act will also be made to deal with evidentiary aspects of electronic signatures. It is proposed that the person whose electronic signature is recorded on an entry will be deemed to have made the entry, unless it is proved otherwise.

4.18. Time limit within which a charge for an offence can be laid

The *Criminal Code* provides that a prosecution for a summary offence must be commenced within 12 months unless otherwise expressly provided. The offences under the Poisons Act are summary offences, and there is no express provision

about the time when offences can be brought. Prosecution for offences under the Poisons Act must therefore be brought within 12 months. This has caused difficulties in the administration of the Act as the time-frame has on occasions been too short to allow evidence to be obtained.

It is proposed to amend the Poisons Act to expressly provide the following time limits for the commencement of a prosecution under the Act:

- 7 years for offences relating to drugs of addiction
- 2 years for all other offences.

4.19. Sanctions and Offences

The Poisons Act contains a number of offences with specific penalties but otherwise contains general provisions dealing with penalties for offences. The penalty provisions and levels of penalties are set out in the section on Penalty Levels below. Other sanctions that are available to the CEO are to revoke or place conditions or restrictions on a licence, permit or authority (sections 23(2) and 26A). Section 24(4) contains a specific provision in respect of schedule 7 poisons that allows the CEO to issue a notice imposing conditions and restrictions on the sale, supply, use and possession of such poisons.

Experience since the commencement of the Poisons Act indicates that, generally, breaches of the poisons legislation tend to be associated with inadequate knowledge of the legislative requirements. In these situations, the issue can be resolved by requiring corrective action within a reasonable time of a breach being identified. If an individual fails to take corrective action within a reasonable time, the options available to the Department are limited to placing restrictions on a permit or licence holder or initiating prosecution proceedings. These actions take considerable time and resources to implement and are often not commensurate with the initial breach.

For example, breaches relating to the storage of poisons, including the storage of poisons included in schedule 8, and record keeping do not generally necessitate action in court.

It is proposed to amend the Poisons Act to provide for an alternative form of action in circumstances where it appears to the CEO that there may have been a breach of the regulations. It is proposed to amend the Act to provide for the issue of an Improvement Notice. An Improvement Notice may be issued by the CEO (or a person to whom the CEO has delegated this power) to a licence or permit holder and would require rectification of activities specified in the Notice. It is intended that the Improvement Notice would be limited to activities prohibited under the Poisons Regulations and would not be available for offences specified in the Poisons Act.

It is intended that the failure to comply with an Improvement Notice would be an offence under the Poisons Act with penalty levels set in accordance with the general provisions in section 62. The other sanctions that would be available to the CEO for failure to comply with an Improvement Notice within the specified time would be the same as are currently available under the Poisons Act, including revoking, or placing conditions on authorities, licences or permits, or prosecuting for breach of the Act or regulations.

This proposed scheme would achieve the objective of the Act without the unnecessary expense of instigating action in court in most cases.

4.20. Penalty Levels

Many of the financial penalties specified in the Poisons Act no longer reflect appropriate penalties for the offences specified. It is proposed to make the following changes to the penalty levels to bring them more into line with current values. (Note that section 40(5) of the *Sentencing Act 1995* mean that the fine for a body corporate may be 5 times the maximum fines specified below.)

<i>Section of the Poisons Act</i>	<i>Existing maximum penalty for a natural person</i>	<i>Proposed maximum penalty for a natural person</i>
24(7) – failure to comply with a notice in respect of a schedule 7 poison	\$10,000 and daily penalty of \$1,000 for continuing offence	\$24,000 and daily penalty of \$2,400 for continuing offence
40 – offences against Part III – Poisons and other substances	\$5,000 for first offence and \$15,000 for subsequent offences	\$12,000 for first offence and \$36,000 for subsequent offences
44 – offences against Part IV – Drugs of addiction	\$15,000 and/or a period of imprisonment of 3 years	\$36,000 and/or a period of imprisonment of 3 years
48 – Prohibition against hawking	\$5,000 and daily penalty of \$500 for continuing offence	\$12,000 and daily penalty of \$1,200 for continuing offence
49(2) – Prohibition against selling by automatic machines	\$5,000 and daily penalty of \$500 for continuing offence	\$12,000 and daily penalty of \$1,200 for continuing offence
50(1) – Leaving poisons unlabelled	\$5,000 and daily penalty of \$500 for continuing offence	\$12,000 and daily penalty of \$1,200 for continuing offence
55B – Hindering or obstructing an authorised officer	\$5,000	\$12,000
55E(4) – failure to comply with a direction to quarantine or destroy poisons	\$10,000	\$24,000
62 – Failure to comply with the Act (unless otherwise specified)	\$5,000 and daily penalty of \$500 for continuing offence	\$12,000 and daily penalty of \$1,200 for continuing offence
64(2)(x) – maximum penalty that may be imposed in Regulations	\$5,000 and daily penalty of \$500 for continuing offence	\$12,000 and daily penalty of \$1,200 for continuing offence

5. PRESCRIBING DRUGS OF ADDICTION

5.1. Background

The Poisons Act defines drugs of addiction as those substances included in schedule 8 and schedule 9 of the Act. Substances included in schedule 8 are used for therapeutic purposes and those in schedule 9 are considered illicit substances that do not have any valid use (other than some limited uses in laboratories and research).

Historically, prescribers, law makers and the public have had concerns about the addiction potential of schedule 8 substances and the potential for diversion or abuse to occur. The legislation relating to regulation of schedule 8 substances in Western Australia was introduced over 30 years ago. Since then, drugs listed in schedule 8 have become much more widely used in the treatment of chronic pain and are more frequently prescribed by medical practitioners in the course of treatment. Also, new dosage forms, such as the long-acting preparations, which may be less likely to cause addiction, have been developed.

The Community Drug Summit held in Perth in 2001 provided an opportunity for the community to discuss, formulate and recommend strategies to tackle the illicit drug problem in Western Australia. One of the recommendations to come out of the Drug Summit was that existing legislation relating to the “Drugs of Addiction Notification Regulations” be reviewed and, in particular, the requirement to maintain a Register of Drug Addicts’. This legislation was perceived as a barrier to appropriate and effective treatment.

The Department of Health commenced a review of the legislation associated with the prescribing of drugs of addiction in 2002. A reform proposal for prescribing a drug of addiction in WA was distributed to the medical profession and stakeholders for comments in July 2002 following a consultation process with specialist physicians, general medical practitioners and consumers.

Section IV of the Poisons Act relates to “Drugs of Addiction”. Only four sections still remain in the Act, all of which specifically deal with schedule 9 drugs. These sections relate to use of poisons included in schedule 9, licences for access to a prohibited plant, penalties and a definition of a ‘corresponding law’. Regulations governing the use, sale and supply of schedule 8 drugs are provided for in the *Poisons Regulations 1965* (the Poisons Regulations). These regulations provide the framework and mechanics of the use, sale and supply of schedule 8 drugs for medical use, based upon the regulation-making powers set out in section 64 of the Act.

It is proposed that the Poisons Act be amended to provide a framework for regulating the prescribing of substances in schedule 8, while the mechanics of the controls continue be retained in the Regulations.

Further consultation will be undertaken in relation to the form of the regulations.

5.2. Current regulatory controls for the prescribing of Schedule 8 drugs

The Poisons Regulations require a medical practitioner to obtain authorisation from the Commissioner of Health, before prescribing a schedule 8 drug if a person is addicted to drugs (Reg 51B) or if treatment is required for a period longer than 60 days (Reg 51F).

The *Drugs of Addiction Notification Regulations 1980* (the Notification Regulations) require a medical practitioner who in the course of his/her practice becomes aware of or suspects a person of being addicted to drugs, to inform the Executive Director of Public Health (EDPH). A register of Notified Drug Addicts (the Register) is required to be maintained by the EDPH.

The Poisons Regulations requires every pharmacy to complete a report at the end of each month that sets out the details of prescriptions for schedule 8 drugs that have been dispensed and to forward the report to the Department of Health (Reg 52C).

5.3. Concerns with current regulatory controls for the prescribing of Schedule 8 drugs

Lack of transparency and openness:

Many medical practitioners are reluctant to notify the EDPH about patients whom they suspect may be addicted to drugs. This reluctance may stem from reasons such as: a fear of retribution from the patient, patient's family or elsewhere, or concern about casting judgement on a patient with whom they have had limited contact. In other cases, patients who are not addicted to drugs may be notified inappropriately. A medical practitioner who is willing to treat a notified addict is significantly constrained in his/her capability to do so by the authorisation process required under the current legislation. The present system may also act as a perceived barrier to the legitimate use of schedule 8 drugs for a registered addict.

Under the existing system, patients can be 'notified' without their knowledge. Inaccurate information, the stigma attached to the label of a 'drug addict' and the lack of any appeal provisions when a name is added to the Register, all contribute to a lack of confidence in the use and maintenance of the Register. The growing awareness of consumer rights associated with privacy of information need to be addressed in the legislative framework.

System is becoming unworkable:

In 2003, 323,862 prescriptions were dispensed in Western Australia for a schedule 8 drug and this is increasing at a rate of approximately 8% each year. 85% of these prescriptions are for the treatment of short term acute pain. Long term use of schedule 8 drugs for therapeutic purposes such as pain relief results in 9000 authorisations being issued each year with a current growth rate of 16%. An additional 3000 authorisations are also issued each year for the treatment of drug addiction with a growth rate of 19%. Each application for an authorisation requires an officer in the Department to make a decision as to whether a particular medical treatment is reasonable or within accepted medical standards.

The existing approach regulating the use of schedule 8 drugs is not sustainable with the current growth rate in the use of schedule 8 drugs. It is not anticipated that the growth rate will decrease as improved treatments for palliative care and pain associated with malignancies are likely to result in more rather than less use of schedule 8 drugs.

5.4. Reform Proposal

The key objectives of the reform are to develop a system that:

- Ensures appropriate, effective and timely treatment with schedule 8 drugs.
- Is open and transparent.
- Minimises the potential of abuse and diversion of schedule 8 drugs.

5.4.1 Definition of drug addict

The current definition of a ‘drug addict’ in the *Drugs of Addiction Notification Regulations 1980* and the *Poisons Regulations 1965* is a person who is:

“under the 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;”

It is proposed that the term ‘drug addict’ be replaced with a new definition which is generally more acceptable to the community and in line with the terminology used by other legislation. It is proposed that the new definition of a ‘drug dependent person’ be inserted into the Poisons Act itself and not the regulations.

The new definition of a ‘drug dependent person’ is proposed as:

‘being a person who has acquired as a result of repeated administration of a drug of addiction, an overpowering desire for the continued administration of such a drug’.

The definition encompasses people who are participating in a drug treatment program for drug addiction as well as people exhibiting drug-seeking behaviour.

It is proposed to insert new provisions in the Act requiring a medical practitioner, dentist, veterinary surgeon or other authorised person to administer, prescribe or supply a drug of addiction only in accordance with the current regulations. In addition, a medical practitioner, dentist or authorised person will be able to prescribe or supply a drug of addiction to a drug dependent person only in accordance with the regulations.

5.4.2 Drug Addict Register

In response to the recommendation of the Community Drug Summit, it is proposed that the Drugs of Addiction Notification Regulations be repealed. There will not be a register.

5.4.3 Collection of data by the Department and Patient Consent

Data collected by the Department should only be used in accordance with the Privacy Principles set out in the Commonwealth's *Privacy Act 1988*.

Under the current system the Poisons Regulations require pharmacists to advise details of prescriptions dispensed at a pharmacy to the Department. These details are entered into the 'Monitoring of Drugs of Dependence System (MODDS) computer database. The information provided include details of the person for whom the medication was prescribed and essentially provide a patient's prescription history of schedule 8 drugs.

One of the concerns expressed by patients and consumer groups is that the present system lacks transparency. There is no requirement for a patient to be made aware that the Department is holding this information. Currently, the Act does not contain provisions that deal specifically with circumstances in which medical prescribers, hospital personnel or researchers may access information in the database.

It is intended that the collection of data on the prescription of schedule 8 drugs by the Department of Health be provided for in the Poisons Act, rather than in regulations. The Poisons Act will also deal with the circumstances in which information on the MODDS database can be accessed. The administrative details for the collection of the data will be covered in the regulations.

Access to identifying information

Identifying information relating to a person would only be available with the consent of that person for whom the schedule 8 drug was prescribed.

The administration of obtaining and recording of consent may be difficult as technology develops and greater use is made of remote access to electronic databases.

Patient consent for a prescriber to access the patient's prescription records held by the Department may be explicit or implicit. For example, consent may be implied by a procedure where the patient is simply made aware that before a prescription for a schedule 8 drug can be provided the prescriber may need to access the patient's prescription records.

The preferred option is for the patient to give explicit consent. Therefore, it is proposed that amendments to the Poisons Act would authorise a medical practitioner, dentist or other authorised prescriber to access a patient's prescription history when treating a patient where the patient has provided informed consent as set out in the regulations.

It is envisaged that there will be circumstances where a patient may refuse to give consent to access his/her prescription history. In these circumstances, the prescriber may wish to consider the reasons for the refusal in making a decision about whether to prescribe a drug of addiction for the patient.

Access to personal information by a person whose details are on the database would be provided for in the regulations.

Access to de-identified information

Access to de-identified information on a database for any other purposes such as research would be governed by a strict protocol to be prescribed in the regulations.

5.4.4 Monitoring – ‘Dr Shopping’

The proposal to repeal of the Drug of Addiction Notification Regulations means that a “register of addicts” would no longer be maintained. It is expected that this will encourage drug-dependent persons to seek timely and appropriate treatment without fear and stigma of being notified as addicts.

However, the repeal of the Drugs of Addiction Notification Regulations means the Department will lose a mechanism of controlling the abuse of schedule 8 drugs by patients who attempt to access these drugs for diversion into the illicit drug market or for self use for non-therapeutic purposes. A new system will need to address this issue. The new system will be provided for in new regulations, which will replace the Drugs of Addiction Notification Regulations.

In summary, under the proposed regulatory system, the prescriber will have access to a patient’s prescription history when the patient provides informed consent. The Department will continue to monitor patient’s prescriptions for schedule 8 drugs dispensed at pharmacies. It is proposed that feedback will be provided to patients and prescribers where inappropriate trends of drug-usage or prescribing emerge. Further consultation with stakeholders will be required to develop the details of this concept.

5.4.5 Proposed Regulatory Scheme

It is proposed that the Poisons Act will be amended to provide that authorised health professionals will only be able to prescribe schedule 8 drugs in accordance with the requirements to be specified in regulations.

A practitioner prescribing a schedule 8 drug will be required to make a judgement based on the clinical assessment of the patient’s condition and other information available such as the patient’s prescription history that would be available (with patient consent) from the Department’s database. It is envisaged that this will encourage appropriate and timely treatment of all patients based on the medical practitioner’s assessment.

5.4.6 Authorisation for patients in a drug treatment program

Currently, authorised prescribers seeking to treat patients for drug addiction through the Community Program for Opioid Pharmacotherapy (C-POP), are required to obtain authorisation from the CEO.

The patient group being treated for drug addiction is a relatively small group when compared to the total number of patients being prescribed schedule 8 drugs. This group also has the greatest potential to abuse or divert schedule 8 drugs if adequate controls are not implemented. Consequently, there will not be a change to the requirement to obtain authorisation from the CEO before initiating treatment of a patient within the C-POP. However, the administration arrangements relating to the authorisation process will be streamlined to facilitate the process.

6 THERAPEUTIC GOODS

On 10 December 2003, the Australian and New Zealand Governments signed a Treaty to establish a joint scheme for the regulation of therapeutic products in both Australia and New Zealand, to be administered by a single agency. The joint regulatory agency will replace the Australian Therapeutic Goods Administration and the New Zealand Medicines and Medical Devices Safety Authority and will be accountable to both the Australian and the New Zealand governments. It is expected to commence operation in 2005.

The role of the Joint Agency will be to safeguard public health and safety through regulation of quality, safety and efficacy of therapeutic goods in both the countries. The regulatory activities of the agency will include:

- pre-market evaluation and assessment;
- product licensing;
- controls on manufacture;
- post-market monitoring and surveillance; and
- setting standards.

The Treaty provides that each government will enact legislation to give effect to the scheme. The Australian Implementing Legislation will replace the *Therapeutic Goods Act 1989*.

As the enactment of the Commonwealth legislation will be pursuant to the Treaty, the Commonwealth's external affairs power should allow the legislation to have complete coverage in Australia. This means that Western Australia should not have to enact its own separate complementary therapeutic goods legislation as was previously considered necessary.

The State will continue to maintain the jurisdictional responsibility for the implementation of scheduling decisions and regulation relating to access to therapeutic goods by consumers.

The *Health Act 1911* (the Health Act) currently contains a number of provisions relating to manufacture and sale of drugs and therapeutic substances (Part VII, Divisions 1, 5, 6, and

7). There is now a considerable degree of overlap between Part VII of the Health Act and the Commonwealth Therapeutic Goods Act. It is therefore proposed that section 203 of the Health Act (dealing with registration of analysts) be retained, whilst section 202 and the remainder of Part VII/A of the Health Act pertaining to drugs, medicines and disinfectants, and manufacture of therapeutic substances (Divisions 5, 6 and 7) be repealed.

It is proposed to include a new part to the Poisons Act that deals specifically with therapeutic goods. This part of the Poisons Act would provide for regulation-making powers to control the labeling, packaging, supply and use of therapeutic goods.

It is intended that there be a provision to prohibit the hawking of a therapeutic good in a street, by mail or from house to house unless authorised by the CEO in accordance criteria to be set out in the Regulations. There would be certain exemptions for samples supplied to particular classes of health professionals, but the supply of samples from representatives of manufacturers would not be permitted.

It is proposed that provision is made to enable the licensing of wholesaling of prescribed therapeutic goods and the wholesaling of all therapeutic goods be subject to compliance with the Code of Good Wholesaling Practice.

With the addition of this new part it is proposed that the title of the Poisons Act be amended to the 'Poisons and Therapeutic Goods Act'.

Attachment 1

Legislation by the Commonwealth and in Other States and Territories

New South Wales	<i>Drug Misuse and Trafficking Act 1985</i> <i>Drug Misuse and Trafficking Regulation 2000</i> <i>Drug Summit Legislative Response Act 1999</i> <i>Poisons and Therapeutic Goods Act 1966</i> <i>Poisons and Therapeutic Goods Regulation 2002</i>
Queensland	<i>Drugs Misuse Act 1986</i> <i>Drugs Misuse Regulation 1987</i> <i>Drugs Standard Adopting Act 1976</i> <i>Drugs Standard Adopting Regulation 1996</i> <i>Health Act 1937</i> <i>Health (Drugs and Poisons) Regulations 1966</i>
South Australia	<i>Controlled Substances Act 1984</i> <i>Controlled Substances (Expiation of Simple Cannabis Offences) Regulations 2002</i> <i>Controlled Substances Act (Exemptions) Regulations 1989</i> <i>Controlled Substances (Poisons) Regulations 1996</i> <i>Controlled Substances (Prohibited Substances) Regulations 2000</i> <i>Controlled Substances (Volatile Solvents) Regulations 1996</i> <i>Drugs Act 1908</i>
Tasmania	<i>Alcohol and Drug Dependency Act 1968</i> <i>Poisons Act 1971</i> <i>Poisons Regulations 2002</i>
Victoria	<i>Drugs, Poisons and Controlled Substances Act 1981</i> <i>Drugs, Poisons and Controlled Substances Regulations 1995</i> <i>Drugs, Poisons and Controlled Substances (Drugs of Dependence) Regulations 1999</i> <i>Drugs, Poisons and Controlled Substances (Drugs of Dependence) Regulations 2000</i> <i>Drugs, Poisons and Controlled Substances (Volatile Substances) Act 2003</i> <i>Poisons and Controlled Substances (Commonwealth Standard) Regulations 2001</i> <i>Therapeutic Goods (Victoria) Act 1994</i>
Australian Capital Territory	<i>Drugs in Sport Act 1999</i> <i>Drugs of Dependence Act 1989</i> <i>Drugs of Dependence Regulations</i> <i>Poisons Act 1933</i> <i>Poisons Regulations 1933</i> <i>Poisons and Drugs Act 1978</i> <i>Poisons and Drugs Regulations 1993</i> <i>Public Health (Prohibited Drugs) Act 1957</i>

**Northern
Territory***Pharmacy Act 1979**Pharmacy Regulations 1985**Poisons and Dangerous Drugs Act 1993**Poisons and Dangerous Drugs Regulations 1985**Therapeutic Goods and Cosmetics Act 1986***Commonwealth***Therapeutic Goods Act 1989**Therapeutic Goods Regulations 1990*