SECOND READING SPEECH

Poisons Amendment Bill 2012

Mr Speaker

The purpose of this Bill is to make a number of minor amendments to the *Poisons Act 1971* to strengthen the Act's scheme of regulation and control of the importation, making, refining, preparation, sale, supply, use, possession and prescription of substances known as scheduled substances.

Scheduled substances include domestic poisons, pharmacy medicines, prescription medicines, narcotics and prohibited substances.

The Act controls over three thousand substances or groups of substances by including them in the eight schedules to the *Poisons List Order 2001* and in the *Poisons (Prohibited Substances) Order 1990*.

These ministerial Orders are regularly updated by amendment Orders.

The substances listed in the Orders are based on the Standard for the Uniform Scheduling of Medicines and Poisons, or the 'Poisons Standard', which is established under section 52D of the Commonwealth *Therapeutic Goods Act 1989*.

The Standard is made by the Secretary of the Department of Health and Ageing (or his or her delegate) on advice from the scheduling committees which comprise representatives from all states and territories, appointed by their respective Ministers, expert pharmacology and toxicology members, other external expert committees and others appointed by the Commonwealth.

The Standard is registered on the Federal Register of Legislative Instruments as the *Poisons Standard 2010* and is administered by the Therapeutic Goods Administration.

The Standard is a record of decisions regarding the classification of medicines and chemicals into Schedules for inclusion in relevant legislation of the states and territories. It includes model provisions about containers and labels, and recommendations about other controls on medicines and chemicals.

The Bill implements recommendation 4 of the Galbally Review for jurisdictions to adopt by reference all the scheduling decisions covered in the Standard for the Uniform Scheduling of Drugs and Poisons Schedules – now the Standard for the Uniform Scheduling of Medicines and Poisons.

Other recommendations of the Galbally Review have been implemented through amendments to the current Act and changes at Commonwealth level.

This outstanding recommendation was to have been included in a new Poisons Act, which was under development for some time. This has now been overtaken by a national review of poisons legislation across jurisdictions resulting from the Council of Australian Governments' Productivity Commission review of chemicals and plastics legislation.

The national review is being funded under the Australian Health Minister's Advisory Council model through the National Coordinating Committee on Therapeutic Goods. Queensland is the lead jurisdiction with the resulting review aimed at delivering uniform regulatory controls over poisons.

Adoption of the Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)

The purpose of the Standard is to promote uniform scheduling of poisons throughout Australia; uniform headings on labels for poisons throughout Australia; uniform labelling and packaging requirements for poisons throughout Australia; and additional controls on the availability and use of poisons in Australia.

Tasmania has followed the Standard and its predecessor for many years through the Poisons List Orders.

Every time the Standard is updated at a national level by adding a new substance or deleting a substance, there is a time delay in Tasmania before the appropriate amendments are made to the Orders.

The process of making an amendment Order is often laborious, sometimes involving amendments to entries for 100 or more substances.

The delay in amending an Order may have consequences for the manufacturing and wholesale pharmaceutical industry for the uniform application of scheduling for substances and hence labelling, packaging and supply restrictions if Tasmania lags behind other jurisdictions in changing the Orders.

Similarly there could be inconvenience for patients who are unable to obtain a substance that is moved to a less restrictive schedule if they are required to obtain a prescription for that substance pending the change.

Conversely, if a public health risk is identified, and a more restrictive schedule is applied under the SUSMP, in the short term there may be additional risk to Tasmanian consumers if the drug is more easily available pending the changes to the Orders.

The Bill provides for the adoption of the Standard into the Act by reference. This will mean that the list of scheduled poisons will always be current in Tasmania and in line with the other states and territories and will remove the need for regular updates and amendments to the *Poisons List* and *Poisons (Prohibited Substances) Order*.

The Bill allows the Minister discretion to make any variations to the Standard considered appropriate in Tasmania by an amending Order. This retains the current ministerial authority over the contents of the schedules but introduces administrative efficiencies to the process.

The Bill makes a number of consequential amendments to other legislation which refers to the Poisons List.

Interstate visitors bringing in legally prescribed narcotics and declared restricted substances

The Act places restrictions upon the dispensing of narcotics and declared restricted substances so that a pharmacist in Tasmania may only dispense those substances if the prescription has been written by a locally based medical practitioner or other authorised prescribing health practitioner.

This mechanism for regulating the supply of drugs of dependence and other medications means that an interstate visitor who needs one of those substances has to attend a local practitioner to obtain a prescription as a pharmacist will not be able to dispense an interstate prescription.

Narcotic and declared restricted substances are medications which are often subject to abuse and misuse and as such the availability of these medications must be strictly controlled in the interests of patient and public safety.

Tasmania has a significant problem with the misuse and abuse of opioids and other drugs of dependence. There is an unacceptable level of morbidity and mortality associated with this misuse.

Prior to the national registration of health practitioners on 1 July 2010, prescriptions for declared restricted substances and narcotic substances were required to be written by medical practitioners registered in Tasmania.

This requirement was continued when the *Poisons Act* was amended in 2010 to reflect changes resulting from the national registration scheme.

An unintended effect of the way the provisions are worded is that it makes it an offence for a person to bring into Tasmania their own legally prescribed and dispensed narcotics or declared restricted substances. This deficiency was identified by the Ombudsman after a complaint from an interstate visitor.

The Bill clarifies that it will not be an offence for a person to bring into Tasmania these substances for their own use, or for the use of a family member, if the substance has been legally prescribed and dispensed for them in another state or territory.

Manufacturing chemists and wholesale chemists licences

The Act at section 16 provides that the Minister may grant a licence to carry on business as a manufacturing chemist or a wholesale chemist.

The Bill enhances the prospects of effective prosecution for breach of licence by assigning responsibility for compliance with the Act to individual persons.

In most cases licence holders are manufacturing or wholesaling companies rather than individuals. In order to assign responsibility for compliance with the Act and terms of a licence to an individual, the Bill creates a 'two level' regulatory process.

The Bill amends the Act so that a licence holder who is not a natural person is required to appoint a responsible officer for each workplace at which the licence holder carries on business as a manufacturing or wholesale chemist. The responsible officer is required to perform the duties of the licence holder under the terms of the licence, but without relieving the licence holder of performing his or her duties.

A responsible officer may be proceeded against and convicted of failing to perform the duties of the licence holder whether or not the licence holder has also been proceeded against or convicted.

The Bill also makes a minor amendment to section 16 to provide that licences continue in force for 12 months from the date of issue, rather than the current stated date of 31 December next following.

I commend the Bill to the House.