MEDICINES, POISONS AND THERAPEUTIC GOODS BILL 2013

Receipt and First Reading

Bill received from the Assembly; and, on motion by **Hon Alyssa Hayden (Parliamentary Secretary)**, read a first time.

Second Reading

HON ALYSSA HAYDEN (East Metropolitan — Parliamentary Secretary) [5.14 pm]: I move —

That the bill be now read a second time.

The present regulatory regime for medicines, poisons and therapeutic goods in Western Australia is the Poisons Act 1964 and its associated Poisons Regulations 1965. This legislation is outdated and confusing and lacks the flexibility to address emerging trends and issues in the regulation and control of and access to medicines and related therapeutic agents, as well as domestic, agricultural and veterinary and some industrial poisons. For example, the current legislation is limited in its powers to authorise new groups of suitably qualified health professionals to handle medicines and improve consumer access to care in response to current health workforce issues. Similarly, there is inadequate regulatory support for new initiatives to reduce diversion and misuse of drugs of addiction. Current legislation does not allow ready alignment of controls over poisons with nationally accepted best practice, which results in added compliance costs to industry. It does not support the timely prohibition of chemicals of unacceptably high risk to the public.

This government approved the drafting of a replacement bill in 2009. Since that time we have embarked on an extensive consultation process of major stakeholders, culminating in an exposure draft being circulated in September 2011. The stakeholders consulted included health professional registration boards, health professional organisations, consumer groups, other government departments, chemical and poisons industry organisations, and areas of the state public health system. The bill as presented today reflects that broad consultation and builds on the work done by the previous Minister for Health, who undertook a review of the act that made recommendations for achieving an important national approach to the manufacture, supply, use and prescribing of medicines and poisons. We believe the bill has been drafted in a way that will assist those persons handling medicines and poisons to better understand their rights and responsibilities.

Part 2 of the bill sets out the offences that stakeholders need to be aware of. Parts 3, 4 and 5 provide a high-level framework of controls over medicines and poisons designed to protect public health and safety. The finer detail of the controls of the manufacture, use, sale or supply of medicines and poisons will be developed in subsidiary legislation. The bill retains the majority of the controls associated with the present act. Substances controlled through the current poisons legislation are classified into a set of nine schedules. A substance is included in a particular schedule based on its risk to human health and the need for expert oversight. These schedules are consistent with the national approach to regulating medicines and poisons under the Standard for the Uniform Scheduling of Medicines and Poisons, known as the SUSMP. The controls that are applied to a particular substance are related to the schedule it resides in. These controls vary commensurate with the risk posed. For example, some medicines are available over the counter at pharmacies (schedules 2 and 3), whilst other medicines must be prescribed (schedule 4). The new bill will retain these schedules.

The main controls for handling medicines and poisons will continue to be through the authority afforded to defined groups of health practitioners, the issuing of licences and permits to supply or use, and controls on the labelling, packaging, storage and recording of such substances. The key reforms this bill will make include the simplification of the procedures for licences and permits; an ability to recognise new roles for a wider range of health professionals in handling medicines supporting a broader rollout of health programs, particularly in rural and remote areas; improved control of drugs of addiction, with greater transparency and protections for those affected by drug dependence; clarification of the rights of employers and employees who handle medicines and poisons, including protection for carers; and a more modern approach to the use of automated medicine systems that will increase the accountability, safety and efficiency of medicine supply.

When the Poisons Act was drafted in the 1960s, it did not take into account the part that technology would play in the purchasing, recording, storing, monitoring and dispensing of medicines and poisons in industry and, more importantly, in the hospital system. The Medicines, Poisons and Therapeutic Goods Bill will accommodate and facilitate electronic transactions and automated dispensing systems in hospitals and other healthcare settings.

The structure of the health workforce has changed much since the 1960s. The skills and scope of practice of various health practitioner groups have expanded to include many aspects of the prescribing and handling of medicines. The ability to provide vital medications is a key need for health professionals in providing timely treatment to patients. Part 3 of the bill recognises these new roles for a wider range of health professionals in handling medicines, which should facilitate a broader rollout of health programs, particularly in rural and remote

areas where access to treatment is limited by workforce issues and the restrictions of the current legislation. This might, for example, include public health initiatives such as vaccination programs or sexual health treatment. It would support changes to the delivery of emergency first aid medicines or primary care in remote communities where medicines are necessary. The new bill will enable suitably qualified health professionals to undertake such work.

Part 4 of the bill simplifies the procedures for the issuing of licences and permits to persons and businesses handling poisons. This includes the flexibility to procure authority for a shorter time than 12 months, with the issuing of licences being spread throughout the year, instead of all falling due on a specific date. In addition, the bill facilitates better consistency with corresponding controls in other states and territories and the recognition of licences issued by other competent authorities.

Feedback from stakeholders has led to the drafting of the bill in such a way as to clarify the rights of authorised employers and their employees, including the protection for carers in their handling of drugs of addiction. In the past, the legitimate role played by carers, aged-care workers and agents handling highly addictive substances has not been clearly described, leaving them in potential legal limbo. The bill will clearly regulate their authority to transport, administer or supply medicines and poisons. The bill will close a loophole that allows an individual to manufacture and supply a therapeutic good without being subject to the rigours of the scientific examination of an appropriate regulator. Corporations that produce therapeutic goods are subject to the controls of the commonwealth Therapeutic Goods Administration. At present, there is no regulatory framework preventing an individual from promoting an untested, ineffective or unsafe good for medical purposes within Australia. Part 6 of the bill seeks to adopt as Western Australian law the commonwealth legislation in this area. This will ensure that Western Australian consumers will have protection from substandard therapeutic goods equal to that anywhere else in Australia.

In the area of controlling the potential for the misuse of hard drugs, part 7 of the bill includes an Australian first in implementing a system to identify and regulate doctor shopping, a system whereby persons present at a number of different medical practitioners seeking medication for their personal addiction or for resale to others. The bill sets up a record of persons who are legitimately prescribed drugs of addiction—schedule 4 reportable poisons and schedule 8 poisons. A registered health professional will be able to check the record before prescribing to determine whether the patient has been recently prescribed the same or a similar substance. In circumstances in which Department of Health monitoring of the record identifies persons doctor shopping, there is a responsibility to intervene and warn those persons of the risk of such behaviour, as well as inform particular health practitioners when it is in the person's best interests.

The development of the bill has been undertaken against a background of balancing the control of medicines and poisons to protect the health of individuals and the role of the police service in preventing the misuse of drugs of addiction.

Pursuant to Legislative Council standing order 126(1), I advise that this bill is a uniform legislation bill. It is a bill that introduces a uniform law between the commonwealth and the government of this state to the extent that natural persons trading therapeutic goods exclusively within this jurisdiction are subject to the same regulatory framework as corporations under the authority of the commonwealth Therapeutic Goods Act 1989.

I commend the bill to the house and table the explanatory memorandum.

[See paper 886.]

Debate adjourned and bill referred to the Standing Committee on Uniform Legislation and Statutes Review, pursuant to standing orders.