Speech By

Hon. Dr Steven Miles

MEMBER FOR MURRUMBA

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MEDICINES AND POISONS BILL

THERAPEUTIC GOODS BILL

Second Reading (Cognate Debate)

Hon. SJ MILES (Murrumba—ALP) (Minister for Health and Minister for Ambulance Services) (3.52 pm): I move—

That the bills be now read a second time.

I want to thank the State Development, Natural Resources and Agricultural Industry Development Committee for its thorough examination of the bills. I also want to thank the stakeholders—stakeholders who made written submissions to the committee, who attended the public hearing and participated in the extensive consultation process during the development of the bills and draft regulations. Their involvement and ongoing engagement in this process will ensure the success of the scheme.

The committee's report on the Medicines and Poisons Bill 2019 made 10 recommendations. The first recommendation was that the Medicines and Poisons Bill be passed, and I appreciate the committee's support for the new legislative framework. I table the government's response to the report of the committee on the Medicines and Poisons Bill.

Tabled paper: State Development, Natural Resources and Agricultural Industry Development Committee: Report No. 32, 56th Parliament, July 2019, Medicines and Poisons Bill 2019, government response 1433.

I will address the other nine recommendations of the committee in a moment. For the Therapeutic Goods Bill 2019, the committee made only one recommendation—that the bill be passed. I thank the committee for its support.

As I outlined in my explanatory speech for the Medicines and Poisons Bill 2019, Queensland's current legislation that regulates medicines and poisons is outdated and difficult to apply in practice. It is full of prescriptive rules that are not responsive to industry practices and new technologies. The legislation is no longer fit for purpose. Queensland needs laws that are easier for industry to understand and apply. We need laws that are flexible and futureproof.

The Medicines and Poisons Bill reforms and modernises the regulatory framework for medicines and poisons in Queensland. The Therapeutic Goods Bill supports this framework by improving the regulation of the safety and quality of medicines for human use and enhancing national uniformity. The bills will be supported by four regulations for medicines, poisons, pest management and therapeutic goods. Collectively, they will give Queensland a comprehensive regulatory framework that is modern and streamlined. The framework removes regulatory cost and burden while enhancing public health and safety. Subject to the passage of the bills, the making of the regulations and a range of implementation activities to support stakeholders, the scheme is proposed to commence from 1 July 2020.

The Commonwealth Therapeutic Goods Act 1989 regulates the majority of manufacturers of medicines for human use. That act places standardised controls on the manufacture, import, export, supply and use of safe and effective therapeutic goods in Australia. It applies to Queensland based

manufacturers except those that do not trade as corporations and are not engaged in trade outside Queensland. Constitutional limitations mean this group is not regulated under the Commonwealth act. The bill adopts the Commonwealth act as a law of Queensland. In doing so, it means that all commercially manufactured therapeutic goods in Queensland must be manufactured to the same high standard. It supports a COAG commitment to adopt a nationally consistent approach to the management of medicines, poisons and therapeutic goods, bringing Queensland into line with other jurisdictions.

The Medicines and Poisons Bill will establish a modern framework for regulating substances. It enhances public health and safety and simplifies requirements for clinicians, pharmacists, industry and the community. While some aspects of the scheme will come into effect on commencement, there will be a one-year transition period before industry needs to comply with certain new obligations such as the requirement to develop a substance management plan. This will provide time for industry to become familiar with the new scheme and make any necessary changes.

This bill establishes a head of power to implement a real-time prescription monitoring system to be known as the monitored medicines database. The database will monitor prescribing and dispensing of certain dependence-forming medicines such as pharmaceutical opioids and other prescription-only medicines that may cause harm. The bill replaces prescriptive rules with a new requirement for certain authority holders to develop a substance management plan that deals with known and foreseeable risks from their activities. The bill also further streamlines the process for prescribing medicinal cannabis in Queensland by enabling non-specialist medical practitioners to prescribe without the need for approval from Queensland Health.

I will now address the committee's report on the Medicines and Poisons Bill. Three recommendations related to the need for ongoing consultation with affected industries and professions. The government accepts these recommendations. Queensland Health has consulted extensively throughout the development of the bill and will continue to consult during finalisation of the regulations and implementation of the new scheme. The remaining six recommendations ask that I comment on implementation of certain aspects of the medicines and poisons scheme in my second reading speech. The government accepts these recommendations.

Recommendation 3 asks that I report on the development and rollout of Queensland Health's comprehensive communications strategy to support the implementation of the new scheme. Communication, education and targeted support are integral to the successful implementation of this new framework. A range of materials such as fact sheets, guidelines and sample documents will be adapted to particular stakeholder groups so every profession and industry sector has resources that reflect its needs. Queensland Health will provide information through a range of channels.

Queensland Health is already working in partnership with key stakeholders to develop communication and training materials and to educate stakeholders about the changes. However, communication activities will ramp up even further in the lead-up to commencement of the scheme in mid-2020. This will ensure information is being provided at the time industry will be focusing on adjusting to the new framework.

Queensland Health's communications strategy will include templates and sample substance management plans to support industry in complying with their new requirements. These resources are currently being developed in consultation with key industry groups. Queensland Health will also help stakeholders identify how they can use existing resources such as workplace health and safety management plans or resources for quality and safety accreditation schemes to develop a substance management plan. Recommendation 4 asked how Queensland Health will ensure oversight and compliance of all substance management plans. Substance management plans provide flexibility to industry to manage risks in a way that is suited to the unique circumstances of each particular business.

Penalties apply if substance management plans are not developed or if they do not meet minimum requirements, such as being written in a way that staff can understand their responsibilities. Queensland Health will assess substance management plans through random audits, or when considering whether to grant or renew a substance authority, or in response to an incident or complaint. Accreditation agencies will also be supported to report any noncompliance to Queensland Health if this is identified during an accreditation assessment.

Recommendation 7 asked that I outline measures to ensure that the rural sector has sufficient time to comply with new departmental standards about pest management and poisons. The government recognises that the rural sector needs adequate time to adjust to the new regime. Queensland Health is working closely with key stakeholders to ensure that the rural and agricultural sectors are supported in meeting their obligations under the scheme.

The bill provides a one-year transition period from commencement before a person must comply with departmental standards for substance management plans and minimum competency requirements. With commencement expected in mid-2020, this means that industry will have until mid-2021 before it is required to comply with these requirements. Queensland Health will also assist the rural and agricultural sectors to prepare by developing templates and sample substance management plans tailored to their specific needs. Queensland Health will maintain ongoing consultation with peak agricultural bodies to ensure that the sector is well prepared for the new framework.

In recommendation 8, the committee recommended implementing real-time prescription monitoring in Queensland's hospitals as a matter of priority. The government accepts this recommendation in principle. The purpose of real-time prescription monitoring is to protect individuals and our community from the harm caused by the misuse of dependence-forming medicines. The government is committed to a comprehensive rollout of the monitored medicines database to minimise overprescription, reduce dependence and allow for early identification of high-risk patients or practices.

We know that the greatest risk comes from prescription opioid medicines and that the vast majority of prescriptions are issued in the community by general practitioners and dispensed by community pharmacies. This is our most pressing priority and that is why the monitored medicines database will be implemented in the community first. However, the database will also be searchable by doctors and pharmacists working in hospitals and emergency departments. They will be able to use this information to identify high-risk individuals and decide how to best support their patient.

Recommendation 9 asked that I provide an update on cross-jurisdictional data-sharing arrangements for the national real-time prescription monitoring database. The government is committed to supporting the rollout of a fully national system. It is vital that there is information sharing across state lines, particularly in major cities near a border, like the Gold Coast. Without a national system, we cannot fully inform health practitioners of a patient's prescription history of monitored medicines. Before a national system is possible, each jurisdiction must pass its own legislation and implement real-time monitoring within its own borders. Once this happens, each state and territory's information will be integrated into the Commonwealth's national data exchange.

Queensland is already doing its part to make a national system a reality by legislating for the monitored medicines database. Once it is operational, Queensland will be well placed to share information with other jurisdictions. A national system for real-time prescription monitoring requires all jurisdictions to work together. Queensland Health is working with the Commonwealth and other jurisdictions to help bring this about.

In recommendation 10, the committee asked about the need to publish information about schedule 7 poisons held on private rural properties on the substance authority register. The public register plays an important role in ensuring public safety. It lets the public check that a person is both qualified and authorised to do a regulated activity with a regulated substance. The government recognises the sensitivity of personal information and respects people's right to privacy and the bill includes certain safeguards. The public register must not include confidential information unless it is reasonably necessary to avoid a health risk and publishing the information will not place a person at risk of harm.

Queensland Health is currently consulting with affected stakeholders. This feedback will be used to inform the amount of information that will be published on the public register or if the information will be published at all. As the bill includes a discretion for the chief executive to publish information about substance authorities, the chief executive can exercise discretion not to publish information in appropriate cases.

I also briefly wish to address the statement of reservation on the bill by the non-government committee members. The statement of reservation states that the non-government committee members do not oppose the intent of the bill. I have already addressed some of the specific issues raised in my response to the recommendations. I particularly want to address the claim that insufficient detail has been provided for the committee to consider the scheme.

The new legislative framework for medicines and poisons is a significant reform. It replaces the existing suite of legislation with a comprehensive framework that consists of the bill and the supporting regulations, which will be supplemented by departmental standards. Indicative draft regulations were tabled on introduction of the bill to allow the committee and stakeholders to consider the scheme holistically. It is not a requirement for draft regulations to be tabled with a bill, but the government has done so to ensure transparency and to enable the committee to more fully understand the extent and scope of the new framework. The regulations and departmental standards are still being finalised. Consultation and policy refinement is ongoing and is being informed by the views of stakeholders, including feedback received on the draft regulations during the committee process for the bill.

The government has already responded to stakeholder feedback where appropriate. For example, it is planned to make separate regulations for poisons and pest management to recognise that they have different stakeholders with different needs and interests. This flexible and responsive approach will ensure the effectiveness of the scheme.

As industry practice evolves and technology changes the way businesses operate, it is critical that Queensland provides a flexible and contemporary framework to regulate medicines and poisons. The Medicines and Poisons Bill and the Therapeutic Goods Bill were developed following an extensive review of the existing legislation and significant consultation with a wide range of stakeholders. These new bills will ensure that our legislative framework is contemporary and fit for purpose. I commend the bills to the House.