Speech By

Hon. Dr Steven Miles

MEMBER FOR MURRUMBA

Record of Proceedings, 14 May 2019

THERAPEUTIC GOODS BILL

Message from Governor

Hon. SJ MILES (Murrumba—ALP) (Minister for Health and Minister for Ambulance Services) (11.53 am): I present a message from His Excellency the Governor.

Mr DEPUTY SPEAKER (Mr Stewart): The message from His Excellency recommends the Therapeutic Goods Bill. The contents of the message will be incorporated in the *Record of Proceedings*. I table the message for the information of members.

MESSAGE

THERAPEUTIC GOODS BILL 2019

Constitution of Queensland 2001, section 68

I, PAUL de JERSEY AC, Governor, recommend to the Legislative Assembly a Bill intituled—

A Bill for an Act to apply the Therapeutic Goods Act 1989 (Cwlth) and related Commonwealth laws in Queensland

GOVERNOR

Date: 14 May 2019

Tabled paper: Message, dated 14 May 2019, from His Excellency the Governor recommending the Therapeutic Goods Bill 2019 742.

Introduction

Hon. SJ MILES (Murrumba—ALP) (Minister for Health and Minister for Ambulance Services) (11.54 am): I present a bill for an act to apply the Therapeutic Goods Act 1989 (Cwlth) and related Commonwealth laws in Queensland. I table the bill and explanatory notes. I nominate the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee to consider the bill.

Tabled paper: Therapeutic Goods Bill 2019 743.

Tabled paper: Therapeutic Goods Bill 2019, explanatory notes 744.

Queensland shares responsibility for the regulation of medicines, poisons and therapeutic goods with the Commonwealth government. The Commonwealth Therapeutic Goods Act 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. The Commonwealth Therapeutic Goods Act applies to all Queensland corporations, and to Queensland entities of any structure, including partnerships, trusts or sole traders, that trade interstate or overseas.

Due to constitutional limitations, the Commonwealth act does not apply to manufacturers that do not trade as corporations and that also are not engaged in trade outside Queensland. It is important that all commercially manufactured therapeutic goods manufactured in Queensland are subject to the

same regulatory requirements. Anything less risks potential safety issues for those purchasing therapeutic goods, such as herbal medicines and vitamin supplements, from sole traders that are not regulated under the Therapeutic Goods Act.

To ensure that all commercially manufactured therapeutic goods are manufactured to the same high standard, the bill adopts the Therapeutic Goods Act as a law of Queensland. This will provide equitable application of therapeutic goods regulation, and better align Queensland with other jurisdictions and international requirements for the manufacture of therapeutic goods. It will provide competitive fairness in the marketplace and ensure the safety of products manufactured and sold within Queensland.

Adopting the Therapeutic Goods Act in Queensland will benefit Queensland based manufacturers already regulated under the Commonwealth act. It will reduce regulatory duplication by removing the need for separate manufacturing, advertising, labelling and packaging requirements in the Queensland regulatory framework for medicines and poisons. The bill 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 bill includes provisions that allow a regulation to modify the application of the Therapeutic Goods Act. I table a draft Therapeutic Goods Regulation 2019 and explanatory notes.

Tabled paper: Draft Therapeutic Goods Regulation 2019 745.

Tabled paper: Draft Therapeutic Goods Regulation 2019, explanatory notes 746.

The draft regulation modifies the application of the Commonwealth act to ensure it does not apply to the Central Pharmacy Manufacturing Unit, a commercialised business unit within Queensland Health.

Should the bill be passed, the bill will commence by proclamation. The regulation will commence at the same time. The Central Pharmacy provides an essential service to Queensland by manufacturing bespoke medicines that are not commercially available, often because the medicines are not commercially viable for private industry to produce. Central Pharmacy primarily manufactures medicines for complex and rare conditions. This includes vision-saving eye drops for severe fungal infections; specialised dosage forms for children; and solutions for bathing burns victims. These medicines are provided for patients in hospital and health services, dental clinics and Queensland Ambulance Service sites.

The Therapeutic Goods Bill binds all persons, including the state. If the requirements of the Commonwealth Therapeutic Goods Act applied to the state, Central Pharmacy may be required to obtain manufacturing licences and would be required to register some therapeutic goods on the Australian Register of Therapeutic Goods. The cost, technical requirements and administrative processes associated with this are significant, and not obtaining relevant approvals may expose Queensland Health staff to the risk of criminal or civil penalties.

If Central Pharmacy is not exempted from the Commonwealth act, it would more than likely have to cease manufacturing certain medicines, with adverse outcomes for patients in health services across Queensland. To ensure that Central Pharmacy can continue its functions, the bill will be modified by regulation so that it does not apply to departmental employees involved in the manufacture, supply or use of unregistered therapeutic goods or to other individuals supplying or using unregistered therapeutic goods manufactured by a departmental employee. This exemption will ensure patients continue to have access to these life-saving and emergency medicines and will not impact on the safety and quality of the products. Central Pharmacy will be required to hold a manufacturing licence under the medicines and poisons framework and to adhere to the relevant code of good manufacturing practice.

The Palaszczuk government is committed to ensuring the safety and effectiveness of therapeutic goods manufactured in Queensland. This bill will enhance national consistency and ensure appropriate safeguards are in place to protect the health and safety of the community. I commend the bill to the House.

First Reading

Hon. SJ MILES (Murrumba—ALP) (Minister for Health and Minister for Ambulance Services) (11.58 am): I move—

That the bill be now read a first time.

Question put—That the bill be now read a first time.

Motion agreed to.

Bill read a first time.

Referral to Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee

Mr DEPUTY SPEAKER (Mr Stewart): In accordance with standing order 131, the bill is now referred to the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee.