Health (Drugs and Poisons) Amendment Regulation (No. 2) 2020

Human Rights Certificate

Prepared in accordance with Part 3 of the *Human Rights Act 2019*

In accordance with section 41 of the *Human Rights Act 2019,* I, the Honourable Steven Miles, Deputy Premier and Minister for Health and Minister for Ambulance Services provide this human rights certificate with respect to the Health (Drugs and Poisons) Amendment Regulation (No. 2) 2020 made under the *Health Act 1937*.

In my opinion, the Health (Drugs and Poisons) Amendment Regulation (No. 2) 2020, as tabled in the Legislative Assembly, is compatible with the human rights protected by the *Human Rights Act 2019*. I base my opinion on the reasons outlined in this statement.

Overview of the Subordinate Legislation

On International Women's Day 2020, the Premier and Minister for Trade announced the Government would make the oral hormonal contraceptive and urinary tract infection (UTI) medications more easily accessible for women over the counter at pharmacies.

The Health (Drugs and Poisons) Amendment Regulation (No. 2) 2020 (Amendment Regulation) will implement the Premier's commitment by amending the *Health (Drugs and Poisons) Regulation 1996* (HDPR) to:

- enable a pharmacist to supply an oral hormonal contraceptive without a prescription; and
- include an authority for pharmacists to sell a restricted drug under the Pharmacist UTI Trial Drug Therapy Protocol.

The Amendment Regulation also makes amendments to the HDPR to reduce the regulatory burden on medical practitioners, pharmacists and community by:

- removing the requirement for non-specialist medical practitioners to obtain a state-based approval to prescribe controlled drug medicinal cannabis products;
- enabling staff of Queensland pathology providers and Australian Red Cross LifeBlood, as categories of persons exempted from requiring endorsements to carry out certain activities with restricted drugs that are immunoglobulin blood products listed on the National Product Price List for blood and blood products; and
- enabling the chief executive to grant an exemption to the labelling requirements in part 2 of the Standard for the Uniform Scheduling of Medicines and Poisons (Poisons Standard).

Human Rights Issues

Human rights relevant to the subordinate legislation (Part 2, Division 2 and 3 *Human Rights Act 2019*)

The Amendment Regulation engages the right to health services (section 37 of the Human Rights Act). Section 37 of the Human Rights Act provides that every person has a right to access health services without discrimination.

Pharmacist supply of oral hormonal contraceptive

In October 2018, the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee recommended 'that the Department of Health develop options to provide low-risk emergency and repeat prescriptions (for example, repeats of the contraceptive pill) through pharmacies subject to a risk-minimisation framework' as part of the report on the *Inquiry into the establishment of a pharmacy council and transfer of pharmacy ownership in Queensland* (Report No. 12, 56th Parliament).

The Amendment Regulation will allow a pharmacist to supply the smallest available manufacturer's pack of a Pharmaceutical Benefits Scheme (PBS) subsidised and non-PBS subsidised oral hormonal contraceptive to a patient who presents to a pharmacy without a prescription.

Pharmacists will be required to take reasonable steps to satisfy themselves that a patient has recently been reviewed by a prescriber. For example, by sighting an expired prescription or phoning the last pharmacy who supplied the medicine on a prescription.

The amendment promotes the right to health services by introducing provisions that are more equitable and practical for women. Women who need an urgent supply of an oral hormonal contraceptive can be given a four-month supply if they are taking a brand that is subsidised under the PBS. However, for the approximately 40 per cent of women who are taking a brand that is not subsidised under the PBS, the legislation limits supply to three tablets only.

The provision of three tablets is impractical because oral hormonal contraceptives are supplied in calendar packs where each foil strip is organised in the sequence necessary to suppress ovulation to promote their safe and proper use. Depending on the brand, there may be up to four different tablets in a 28-day foil strip of the oral hormonal contraceptive, each of which must be taken in the correct order to provide effective contraception.

The pharmacist would need to identify the necessary tablets that correspond to the stage of the woman's menstrual cycle. Also, in some rural areas with limited access to prescribers, three days' supply may not give enough time for the patient to obtain a prescription for the medicine.

Pharmacist urinary tract infection trial

On 8 March 2020, the Premier and Minister for Trade announced that the government had engaged a consortium led by the Queensland University of Technology (QUT) to manage the development and implementation of a state-wide trial of the management of UTIs by pharmacists.

The trial, which will start mid-2020 and run until 2023 involves a pharmacist selling a course of one of three antibacterial drugs to a consumer without a prescription. The pharmacist would select the most appropriate treatment after talking to the consumer about their symptoms and medical history. Participating pharmacists will be required to successfully complete the online training program developed by QUT and be practising at a site that is enrolled in the trial.

UTIs are very common in women, with one in three women experiencing a UTI in their lifetime. UTIs are considered uncomplicated when they occur in non-pregnant, pre-menopausal women with no relevant underlying conditions or urinary tract abnormalities.

The Amendment Regulation will include an authority for pharmacists to sell a restricted drug under a new Drug Therapy Protocol — Pharmacist UTI Trial (DTP). The DTP will allow patients to be provided with timely treatment of uncomplicated UTIs directly from a pharmacist without consulting a medical practitioner. The DTP will give effect to the requirements of the trial and include the requisite training, model of care and antibacterial drugs approved for use during the trial.

The amendment promotes the right to health services as currently the HDPR does not allow for a pharmacist to sell these antibacterial drugs to a person without a prescription. Typically, restricted drugs can only be dispensed by a pharmacist on presentation of a valid prescription. The ability for pharmacists to provide this acute primary care helps to ensure Queenslanders have access to timely treatment of uncomplicated UTIs and continuity of care.

Prescribing medicinal cannabis

The Australian and State Governments regulate access to, and prescribing of, medicinal cannabis to patients. Most medicinal cannabis products are unregistered medicines in Australia and therefore are only available for access using special access schemes administered by the Therapeutic Goods Administration. Controlled drug medicinal cannabis products are listed in Appendix D of the Poisons Standard, meaning that products (including registered products) are available only from or on the prescription or order of an authorised medical practitioner. State and Territory governments may place additional controls in defining who is an authorised medical practitioner and the conditions that may be treated.

The Amendment Regulation will remove the requirement for non-specialist medical practitioners to obtain a state-based approval to prescribe controlled drug medicinal cannabis products.

Medical practitioners will continue to require an approval from the Therapeutic Goods Administration to prescribe unapproved therapeutic goods (including medicinal cannabis) for patients. The amendment promotes the right to health services as it will remove the dual approval process for medicinal cannabis in Queensland, improving access for patients, reducing the regulatory burden on medical practitioners and the administrative burden on Queensland Health.

Streamlined blood supply arrangements

Supplies of restricted drugs that are immunoglobulin blood products are currently being double handled by pathology laboratories and pharmacies in Queensland hospitals. The double handling of these products ties up valuable pharmacy resources, creates longer wait times for

treating clinicians and patients and may impact on a hospital's ability to appropriately manage immunoglobulin inventory.

The Amendment Regulation will streamline the supply of restricted drugs that are immunoglobulin blood products to patients. The amendment will provide that certain staff of Queensland pathology providers and Australian Red Cross LifeBlood, be included as categories of persons exempted from requiring endorsements to carry out certain activities with restricted drugs that are immunoglobulin blood.

The amendment promotes the right to health services as it reduces the double handling of immunoglobulin blood products. Double handling with these blood products not only ties up valuable pharmacy resources, creates longer wait times for treating clinicians and patients, it also increases the risk of pandemic coronavirus transmission to pathology staff and pharmacy staff as well as immunosuppressed patients who receive double handled products. In addition, double handling of these blood products is an inefficient use of staff resources and may cause delays in the supply chain for patients getting treatment.

Labelling exemption

Medicines that do not meet the labelling requirements in part 2 of the Poisons Standard are not permitted to be supplied in Queensland. Examples of when a product may not meet the specific requirements include if a medicine is rescheduled or if stock is obtained from overseas.

The Amendment Regulation provides that the chief executive may grant an exemption to the labelling requirements in part 2 of the Poisons Standard. The chief executive must be reasonably satisfied the alternative label is as safe as the part 2 requirement.

The Amendment Regulation will also ensure that any exemption in force under a law of the Commonwealth, or of another State or a Territory, corresponding to section 11, has the same effect as an exemption under section 11. The chief executive may declare that such an exemption does not apply in Queensland. This alternative declaration is to be published on the Queensland Health website.

The amendment promotes the right to health services as it provides an exemption, as intended by part 2 of the Poisons Standard, to access some medicines in Queensland which can be delayed until new stock with compliant labels are made, despite being available in other States and Territories. For example, a COVID-19 vaccine or medicines used to ventilate patients in intensive care may be imported, but as they do not meet the labelling requirements cannot be supplied to health professionals to be administered, impacting greatly on treatment options available to clinicians to treat the community effectively.

Consideration of reasonable limitations on human rights (section 13 *Human Rights Act 2019*)

As the Amendment Regulation does not limit human rights, it is not necessary to consider section 13 of the Human Rights Act.

Conclusion

I consider that the Health (Drugs and Poisons) Amendment Regulation (No. 2) 2020 is compatible with the *Human Rights Act 2019* because it raises human rights issues but does not limit human rights.

STEVEN MILES
DEPUTY PREMIER and MINISTER FOR HEALTH and
MINISTER FOR AMBULANCE SERVICES