Medicines and Poisons (Medicines) Amendment Regulation (No. 3) 2024 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 Shannon Fentiman MP, Minister for Health, Mental Health and Minster for Ambulance Services and Minister for Women, provide this human rights certificate with respect to the *Medicines and Poisons (Medicines) Amendment Regulation (No. 3) 2024* (Amendment Regulation) made under the *Medicines and Poisons Act 2019* (Act).

In my opinion, the Amendment Regulation, 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

The Act provides the regulatory framework for the use of medicines and poisons in Queensland, and its purpose is to regulate people who deal with medicines and poisons and the dealings they can undertake.

The *Medicines and Poisons (Medicines) Regulation 2021* (Medicines Regulation) supports the Act by setting the scope of lawful practice for dealings with medicines, as well as stipulating how dealings with medicine must occur, including compliance with departmental standards and extended practice authorities.

The Medicines and Poisons (Medicines) Amendment Regulation (No. 3) 2024 (Amendment Regulation) amends the Medicines Regulation to implement recent Commonwealth vaping reforms. The Commonwealth reforms impose a blanket ban on recreational and disposable vaping goods and introduce strict requirements for therapeutic vaping goods, including restrictions on their importation, manufacture, possession and supply. States and territories will be primarily responsible for enforcing these requirements at the wholesale and retail levels. At the retail level, only pharmacists will be lawfully permitted to sell vaping goods to members of the public in Queensland, and only for the purpose of helping people to quit smoking or manage nicotine dependence.

To reflect the new pharmacy-based supply arrangements and ensure that regulated substances in vaping goods are subject to appropriate regulatory controls, the Amendment Regulation amends the Medicines Regulation to:

- classify therapeutic nicotine¹ as a diversion-risk medicine²;
- restrict the sale of therapeutic nicotine to a community pharmacy;

¹ Therapeutic nicotine means nicotine in a therapeutic vaping good, which includes vaping accessories, vaping devices and vaping substances. Therapeutic nicotine does not include nicotine replacement therapy, for example, nicotine patches and gum.

² Diversion-risk medicines are medicines that may have value as an illicit substance, such as anabolic steroids and pseudoephedrine products.

- restrict the sale of schedule 2 (S2), schedule 3 (S3) and schedule 4 (S4) medicines, other than therapeutic nicotine, to a pharmacy³;
- ensure when therapeutic nicotine is stored at a community pharmacy it must be kept in an area that is out of sight from members of the public; and
- ensure a pharmacist must notify the chief executive and the police service if they reasonably suspect therapeutic nicotine has been lost or stolen.

These amendments also address practical and operational issues that have been identified following passage of the Commonwealth vaping reforms, including the down-scheduling of nicotine from an S4 to an S3 medicine from 1 October 2024.

Human Rights Issues

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

In my opinion, the human rights that are relevant to the Amendment Regulation are:

• property rights (section 24).

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

Right to property (section 24 of the Human Rights Act)

(a) the nature of the right

Section 24 of the Human Rights Act protects the right of all persons to own property, alone or with others, and provides that people have a right not to be arbitrarily deprived of their property. This right includes the protection from the deprivation of property. Relevantly, property encompasses chattels and other personal property, and therefore likely extends to the ownership of medicines.⁴ The term 'deprived' is not defined by the Human Rights Act. However, deprivation in this sense is considered to include the substantial restriction on a person's use or enjoyment of their property, to the extent that it substantially deprives a property owner of the ability to use his or her property or part of that property, including enjoying exclusive possession of it, disposing of it, transferring it, or deriving profits from it.⁵

By placing restrictions on dealings with therapeutic nicotine, the Amendment Regulation engages the right to property in these medicines under section 24 of the Human Rights Act. For example, by restricting the sale of therapeutic nicotine to community pharmacies, the Amendment Regulation will prevent a pharmacist from selling therapeutic vaping goods from other settings, such as a vape shop or convenience store. This could be characterised as interfering with their ability to derive profits through particular kinds of employment or economic activity.⁶

While these restrictions engage in the right to property under section 24 of the Human Rights Act, they are unlikely to amount to the kind of arbitrary deprivation of property necessary to

³ A pharmacy is defined as a community pharmacy or a place in a relevant institution, such as a hospital, aged care facility or prison, where medicines are supplied by a pharmacist to the public.

⁴ See Alistair Pound and Kylie Evans, Annotated Victorian Charter of Rights (Lawbook, 2nd ed, 2019) 183.

⁵ Ibid.

⁶ See, e.g., Legal and General Assistance Ltd v Kirk [2002] IRLR 124, [41]; Tre Traktörer Aktiebolag v Sweden (1989) 13 EHRR 309, [53]; Crompton v Department of Transport North Western Traffic Area [2003] RTR 517, [19].

establish a limitation of that right. Section 24(2) of the Human Rights Act provides that even where the right to property is engaged, it is not limited unless a person's property is deprived arbitrarily. In a human rights context, arbitrary refers to actions that are capricious, unpredictable, or unjust, or that unreasonably interfere with rights in the sense of not being proportionate to the aim. Medicines have a varied degree of risk, and the risk to human health depends on how safely they are handled and used. Placing reasonable restrictions on scheduled medicines—such as the controls established by the Amendment Regulation for dealings involving therapeutic nicotine—is necessary to protect the safety of the community, for example by mitigating the potential for misuse, diversion and other harms associated with these regulated substances. At the same time, the Amendment Regulation does not prevent a person from practising their profession, nor from seeking any particular kind of employment. As such, it would be difficult to characterise these restrictions, and by extension, the Amendment Regulation, as an arbitrary deprivation of property rights so as to give rise to a limitation of those rights that must be justified under the Human Rights Act.

Assuming for the sake of argument that the Amendment Regulation does limit property rights, any limitations are reasonably and demonstrably justified for the reasons set forth below.

(b) the nature of the purpose of the limitation, including whether it is consistent with a free and democratic society based on human dignity, equality and freedom

The purpose of the Amendment Regulation is to implement the Commonwealth's vaping reforms, including by providing appropriate regulatory controls and addressing practical and operational issues associated with the supply of therapeutic vaping goods in pharmacy settings.

The Amendment Regulation restricts the sale of therapeutic nicotine to community pharmacies, classifies therapeutic nicotine as a diversion-risk medicine and imposes certain storage, display and notification requirements for therapeutic nicotine. It also clarifies existing requirements for where S2, S3 and S4 medicines may be sold and continues to impose restrictions on who may deal with these substances.

The purpose of imposing restrictions on dealings with therapeutic nicotine is to mitigate the risk of misuse and diversion and to protect public health from the harmful effects of vaping goods. Adding further safeguards on the sale of therapeutic nicotine at community pharmacies will ensure that individuals, including children, are not routinely exposed to display of these products when they visit pharmacies for other health requirements. It will also ensure that diversion risk of these products is mitigated. These additional controls are important to reduce the normalcy of vaping product use and contribute to achieving the aim of the national vaping reforms to prevent uptake and use of vaping products, especially by children and young adults.

Protecting the health of the community, particularly children and the vulnerable, is a purpose that is consistent with a free and democratic society based on human dignity, equality and freedom.

(c) the relationship between the limitation and its purpose, including whether the limitation helps to achieve the purpose

The limitation achieves its purpose by restricting the sale of therapeutic nicotine to a community pharmacy, placing obligations on pharmacists to ensure that these products are appropriately stored and monitored, and clarifying existing regulatory requirements with respect to the sale of S2, S3 and S4 medicines. These measures give effect to the

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⁷ WBM v Chief Commission of Police (2012) 43 VR 446, 472 [114].

Commonwealth's vaping reforms, which address the health risks posed by vaping, while ensuring therapeutic vaping goods remain available, where clinically appropriate, to patients in pharmacy settings.

The effect of the Amendment Regulation is that only pharmacists working in a community pharmacy will be authorised to sell vaping goods to the public (whether or not the vaping goods contain nicotine), and only for the purpose of helping people to quit smoking or manage nicotine dependence. These changes make it illegal for any other retailer—including tobacconists, vape shops and convenience stores—to sell any type of vaping goods.

(d) whether there are any less restrictive and reasonably available ways to achieve the purpose

The amendments are necessary to achieve their purpose. Any alternative which has a lesser impact on the right to property would fail to provide adequate oversight of the retail sale of therapeutic vaping goods and would risk undermining national efforts to address the uptake of vaping and illicit trade in vaping goods.

In particular, the intent of the Commonwealth vaping reforms is that therapeutic vaping goods will only be sold at retail in community pharmacy settings. Restricting their sale to these settings provides assurance that therapeutic vaping goods will not be sold or diverted for recreational use, and that persons using these products will have access to appropriate clinical advice and supervision, including advice about safer alternative therapies for smoking cessation and nicotine dependence. Further, limiting the sale of vaping goods to traditional pharmacy settings is an important strategy for reducing the normalisation of vaping and preventing uptake and use of vaping products, especially by children and young adults.

(e) the balance between the importance of the purpose of the limitation and the importance of preserving the human right, taking into account the nature and extent of the limitation

The impact on human rights by the Amendment Regulation is minor. Placing reasonable controls on the sale of therapeutic nicotine does not prevent a person from practising their profession or seeking any particular kind of employment.

The need to ensure the safe display, storage and sale of therapeutic nicotine is important for the community as a whole, especially children and the vulnerable. The amendments will deliver benefits to the entire community now and into the future, through improved health outcomes and reduced health costs.

In my opinion, the Amendment Regulation strikes an appropriate balance between achieving these objectives and avoiding any unnecessary interference with property and other human rights protected by the Human Rights Act.

Conclusion

I consider that the Medicines and Poisons (Medicines) Amendment Regulation (No. 3) 2024 is compatible with the Human Rights Act 2019 because it does not limit human rights or, in the

alternative, limits human rights only to the extent that is reasonable and demonstrably justified in a free and democratic society based on human dignity, equality and freedom.

SHANNON FENTIMAN MP MINISTER FOR HEATH, MENTAL HEALTH AND AMBULANCE SERVICES AND MINISTER FOR WOMEN

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