Medicines and Poisons (Medicines) Amendment Regulation 2022

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 Yvette D'Ath MP, Minister for Health and Ambulance Services and Leader of the House provide this human rights certificate with respect to the *Medicines and Poisons (Medicines) Amendment Regulation 2022* (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 was enacted in September 2019 and introduces a new regulatory framework for medicines and poisons in Queensland. The Act outlines who can deal with medicines and what 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 be done, including compliance with departmental standards and substance management plans.

The medicines and poisons scheme was a major reform to modernise and streamline the medicines and poisons regulatory framework, ensuring the scheme is easier for industry and the community to understand and apply in practice. The scheme has largely been implemented without significant issues. However, a number of minor and technical issues have been identified during implementation by either stakeholders or Queensland Health.

The Amendment Regulation amends the Medicines Regulation to reflect changes to the Commonwealth *Standard for the Uniform Scheduling of Medicines and Poisons* (Poisons Standard), to update references to external documents that have been revised since commencement on 27 September 2021 and makes the following minor and technical amendments:

- updates the references to a new version of the Aboriginal and Torres Strait Islander health practitioners extended practice authority;
- updates the reference to a new version of the *Guidelines for use of scheduled medicines* made by the Optometry Board of Australia (Optometry Board) on 10 December 2021 (Optometry Guidelines) and updates a reference to the correct appendix;
- authorises specialist medical practitioners in respiratory and sleep medicine to prescribe, give a treatment dose, administer, give a purchase order and possess the restricted

medicines ambrisentan; bosentan; macitentan and riociguat, consistent with the approach that applied under the repealed *Health (Drugs and Poisons) Regulation 1996* (HDPR);

- ensures consistency with Appendix D of the Poisons Standard by specifying whether the restricted medicines in schedule 2, part 1 of the Medicines Regulation are for human use and includes ivermectin (oral preparations) in the list of restricted medicines;
- enables certain classes of approved person, including a new class of person (gastroenterologists and hepatologists), to deal with ivermectin for human oral use, to implement changes made to the Poisons Standard;
- updates the requirements for sending prescriptions electronically to ensure these apply to all prescriptions and not only prescriptions for diversion-risk medicines;
- amends the definition of *shared clinic* to ensure settings that supply or administer medicines to animals are required to prevent unauthorised access and to manage inappropriate use and diversion risks for the medicines;
- streamlines the use of electronic prescription management systems by removing the requirement for both words and numbers to be included in an electronic prescription, while retaining this requirement for written prescriptions to describe the quantity of medicine to be dispensed; and
- replaces the phrase 'minimum standard pack' with 'smallest available size of manufacturer's pack of the medicine'.

Human Rights Issues

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

Regulation of medicines

Section 37 of the Human Rights Act provides that 'every person has the right to access health services without discrimination'. The right of access to health services includes access to medication. By imposing restrictions on dealings with medicines, the Medicines Regulation limits that right.

Generally, chapter 2, part 1 of the Act creates certain offences in relation to 'medicines' as defined in section 11 of the Act. Certain activities and dealings with medicines are prohibited unless done in an authorised way.

Chapter 1, part 5 and schedule 2 of the Medicines Regulation define certain categories of medicines being restricted medicines, high-risk medicines, diversion-risk medicines and monitored medicines.

The Amendment Regulation makes provision for a range of authorisations for the purposes of the Act, such as:

- approved extended practice authorities in Schedule 1;
- classes of approved persons authorised to carry out dealings stated in schedules 3 to 15 of the Medicines Regulation.

The authorisations define the scope of permitted activities under the Act, so that limits, restrictions and conditions in the authorisations effectively limit access to medicines and therefore the right to access health services.

Impacts on work and carrying out an occupation

In regulating medicines, the Amendment Regulation may engage a number of rights associated with work and carrying on a profession or occupation, being the rights to equality and non-discrimination (section 15(3)) and property (section 24) of the Human Rights Act.

The regulation of medicines is achieved in part by regulating certain activities by reference to certain classes of persons, for example by reference to classes of approved persons (schedules 3 to 15) for various occupations and professions. This means that the Medicines Regulation applies to people differently depending on their occupation.

This engages, but does not limit, the human right in section 15(3) of the Human Rights Act. Under section 15(3), every person has a right to equal protection of the law without discrimination. Discrimination is defined to include direct and indirect discrimination on the basis of the attributes protected in section 7 of the *Anti-Discrimination Act 1991*. Employment status or occupation is not one of those attributes.

Persons who are not in the occupations or professions authorised under the Medicines Regulation do not generally suffer from disadvantage or stereotyping, and the distinctions drawn by the Medicines Regulation do not have the effect of devaluing or marginalising them within our society. Although the different classes of approved persons under the Medicines Regulation are given different authorisations to deal with medicines, this reflects 'the permitted regulated activities and scope of practice for the relevant person, the medicines and poisons within that scope and any limits to the permitted regulated activities'. For example, only a specialist medical practitioner may be authorised to prescribe a specific restricted medicine.

Accordingly, the differential treatment of people according to their occupation does not involve discrimination under section 15(3) of the Human Rights Act.

The right to property in section 24 of the Human Rights Act may be engaged by impacts on a person's employment. However, the Medicines Regulation does not prevent a person from practising their profession, nor from seeking any particular kind of employment. It does impose requirements on carrying out certain professions or engaging in employment, for example, by requiring a substance authority for certain dealings in medicines.

The right not to be deprived of property in section 24(2) is a right not to be 'arbitrarily' deprived of property. Because the human rights meaning of arbitrary is, among other things, disproportionate, it is convenient to address whether the deprivation is arbitrary when considering whether it is proportionate under section 13 of the Human Rights Act.

Aboriginal and Torres Strait Islander health professions

The Medicines Regulation provide for a distinct regime of approvals and authorisations for Aboriginal peoples and Torres Strait Islander peoples. In particular, schedule 3 of the Medicines Regulation deals with Aboriginal and Torres Strait Islander health professions,

which allows persons qualified in this health profession to deal with specific medicines under the Aboriginal and Torres Strait Islander health practitioner extended practice authority.

Although a reference to the Aboriginal and Torres Strait Islander health practitioner extended practice authority specifically applies to Aboriginal peoples and Torres Strait Islander peoples and does not include other people, the authority applies to the existence of a distinct health practice profession of 'Aboriginal and Torres Strait Islander health practice' under the Health Practitioner Regulation National Law and approved Aboriginal health services under the *National Health (Remote Area Aboriginal Health Services Program) Special Arrangement 2017* (Cwlth) made under the *National Health Act 1953* (Cwlth).

The authorities in the Medicines Regulation allow Aboriginal and Torres Strait Islander health practitioners to deal with medicines in accordance with an individualised practice plan and under instruction from a medical practitioner, nurse practitioner or dentist, in order to support care delivery by Aboriginal controlled health services and Hospital and Health Services.

Closing the Gap for Aboriginal and Torres Strait Islander people in Queensland is dependent on the delivery of culturally safe health services for this population, particularly in isolated areas where there is limited access to other health services. The delivery of such services can be achieved by supporting Aboriginal and Torres Strait Islander health practitioners to use scheduled medicines where necessary and within the practitioner's scope of practice.

As such, the right to protection against discrimination does not apply (section 15(5) of the Human Rights Act). Accordingly, no limit on human rights arises.

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

Each of the limits on human rights is authorised by law for the purposes of section 13(1) because the Medicines Regulation is made under section 240 of the Medicines and Poisons Act.

Right to access health services

The limit on the right of access to health services is reasonable and demonstrably justified for the following reasons.

(a) the nature of the right

The UN Committee on Economic, Social and Cultural Rights offers some guidance on the right to health in General Comment No 14, relating to the corresponding right to health in Article 12 of the *International Covenant on Economic, Social and Cultural Rights*, upon which section 37 of the Human Rights Act is based. As to the purpose and underlying values of the right to health, the Committee said the right to health is 'indispensable for the exercise of other human rights' and it is 'conducive to living a life in dignity'. Article 12 is not a right to be healthy (which would be impossible for the state to ensure), but rather 'a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realisation of the highest attainable standard of health.' However, section 37 is not intended to encompass rights in relation to the underlying determinants of health, such as food and water, social security, housing and environmental factors.

As noted above, it is likely to include the right to access to medication.

(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

Imposing restrictions on transactions with medicines (such as prescribing and dispensing) is needed to mitigate the risks of misuse or substance abuse by vulnerable persons. These restrictions support the overall purpose of the Medicines Regulation in protecting human life, which is consistent with the values of our society.

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

Regulating transactions with medicines, such as prescribing and dispensing, helps to achieve the purpose of minimising harm to patient health.

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

There are no other ways of achieving the harm-minimisation purpose which would impose a lesser burden on the right to access health services in the form of medication.

(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 limit on the right to access health services is imposed for the purpose of protecting persons vulnerable to substance abuse or misuse of medicines from further harm. The importance of protecting the right to life of those persons outweighs the limit on the right to access health services.

Impacts on work

Provisions of the Amendment Regulation may impose minor impacts on the right to property and the right to privacy by interfering with a person's work and occupation.

(a) the nature of the right

The right to property is valuable in itself as a component of human dignity, but it also has strategic value. Property – including property in the legitimate expectation or goodwill of one's profession or occupation – is 'crucial to the economic development necessary to ensure that human beings can supply themselves with food and otherwise support themselves.'

The purpose of the right to privacy is 'to protect and enhance the liberty of the person – the existence, autonomy, security and well-being or every individual in their own private sphere'.

One of the values underlying the right to privacy is personal development, which includes the development of relationships with the outside world through one's work.

(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 restrictions in the Amendment Regulation in the course of a person's occupation is to ensure the safety of the broader community. That purpose is ultimately to protect the right to life and is clearly consistent with the values of our society.

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

By providing appropriate regulation of medicines, the restrictions in the Amendment Regulation in the course of a person's occupation help to achieve their safety purpose.

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

The restrictions in the Amendment Regulation are necessary to achieve their safety purpose. Any alternative which had a lesser impact on work and the carrying on of an occupation would carry a greater risk to safety.

(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 from the provisions of the Amendment Regulation is minor. While a person's work and occupation can be critical to their sense of self and their ability to live a dignified life, the restrictions imposed by the Amendment Regulation regulate rather than prevent a person from those benefits.

The need to ensure safe use of medicines is important for the community. Considering the State's obligation to protect the right to life, the safety purpose outweighs any impact on the rights to property and privacy as an aspect of the impact on a person's work and occupation.

Conclusion

I consider that the *Medicines and Poisons (Medicines) Amendment Regulation 2022* is compatible with the *Human Rights Act 2019* because it 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.

YVETTE D'ATH MP
MINISTER FOR HEALTH and AMBULANCE SERVICES
and LEADER OF THE HOUSE