Medicines and Poisons (Medicines) Amendment Regulation (No. 2) 2023

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 Ambulance Services and Minister for Women, provide this human rights certificate with respect to the *Medicines and Poisons (Medicines) Amendment Regulation (No. 2) 2023* (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 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 extended practice authorities.

The Amendment Regulation amends the Medicines Regulation to:

- remove barriers and facilitate ease of access to naloxone to support the take home naloxone program by:
    - facilitating easy access to naloxone from any organisation where staff have completed training in recognising signs and symptoms of suspected opioid overdose and how to administer naloxone;
    - allowing pharmacies and wholesalers to supply naloxone to these organisations;
    - removing the requirements for pharmacists to label take home naloxone with a patient's name; and
    - exempting naloxone from offences of supply and administration.
- enable psychiatrists to prescribe, administer, give a purchase order and possess N, α-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) for post-traumatic stress disorder (PTSD) and psilocybine for treatment resistant depression. The proposed amendments align with changes to the Commonwealth Standard for the Uniform Scheduling of Medicines and Poisons (Poisons Standard) in down-scheduling MDMA and psilocybine from a schedule 9 to a schedule 8 medicine;
- restrict follitropin delta, sitaxentan and alefacept to prescribers with the same qualifications as those in Appendix D of the Poisons Standard;

- update a reference to the new version of the Storage Standard for S8 Medicines departmental standard to clarify storage requirements in operational Queensland Ambulance Service vehicles; and
- update a reference to the new version of the Registered Nurses Extended Practice Authority to clarify approved courses in sexual and reproductive healthcare and to facilitate registered nurses administering the Japanese encephalitis virus vaccine.

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:

- rights to equality and non-discrimination (section 15(3));
- right to life (section 16);
- property rights (section 24);
- privacy and reputation (section 25); and
- right to access health services (section 37).

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 and departmental standards in schedule 1 of the Medicines Regulation; and
- 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. These limits, restrictions and conditions in the authorisations effectively limit access to medicines and therefore the right to access health services.

By placing restrictions on dealings with medicines, the Medicines Regulation also engages the right to property in those goods under section 24 of the Human Rights Act. The right to property

in section 24(2) will be limited where property is deprived arbitrarily and extends to chattels such as medicines.[1]

'Deprivation' also likely extends beyond a formal deprivation to de facto expropriation, which is where substantial restrictions are placed on a person's use or enjoyment of their property. However, a reduction in the value of a commodity is not enough.[2] The interference needs to be so great that it effectively amounts to depriving a person of their property.

Placing restrictions on medicines does not interfere with the right to own those things to such an extent that property is deprived. As there is no deprivation of property, the Medicines Regulation engages, but does not limit the right to property in section 24(2) of the Human Rights Act.

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)), property (section 24) and privacy (section 25(a)) 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 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'.

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 with 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,

[1] *Acts Interpretation Act 1954*, sch 1 (definition of 'property').
[2] *Lough v First Secretary of State* [2004] EWCA Civ 905; [2004] 1 WLR 2557, 2575 [51].

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.

Finally, aspects of the right to work may also be comprehended by the right to privacy in section 25(a) of the Human Rights Act.[3] The right to privacy 'protects a right to personal development, and the right to establish and develop relationships with other human beings and the outside world'.[4] In Europe, that has been found to include a right to establish and develop 'relationships of a professional or business nature'.[5] 'It is, after all, in the course of their working lives that the majority of people have a significant opportunity of developing relationships with the outside world'.[6] On this basis, work restrictions have been held to involve an interference with privacy.

Again, even if the Medicines Regulation has the practical effect of interfering with a person's work as an aspect of their privacy (for example, because they do not satisfy the training or competency requirements), any impact on the right to privacy in section 25(a) of the Human Rights Act would be very limited.

The right in section 25(a) is a right to not have one's privacy interfered with 'unlawfully' or 'arbitrarily'. In a human rights context, 'arbitrary' means capricious, unpredictable, unjust or unreasonable in the sense of not being proportionate to a legitimate aim sought.[7] Because questions of lawfulness and proportionality arise when considering justifications of limits on human rights under section 13, it is convenient to consider these questions below.

Right to life

Section 16 of the Human Rights Act states that every person has the right to life and has the right not to be arbitrarily deprived of life. The right imposes substantive and procedural obligations on the State to take appropriate steps and adopt positive measures to protect life.

Queensland has a high prevalence of drug-related deaths. Most overdose deaths can be prevented through a range of options, including by improving access to naloxone. Naloxone is a medicine that works by blocking prescription and non-prescription opioid drugs, such as heroin and oxycodone, from attaching to opioid receptors in the brain. There is no evidence of significant adverse reactions to naloxone. It can be administered by injection or via a nasal spray. The Amendment Regulation increases access to naloxone by exempting Schedule 3 naloxone from the operation of the Act, thereby potentially preventing overdose deaths and promoting the right to life.

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

Right to access health services (section 37 of the Human Rights Act)

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

[3] *ZZ v Secretary, Department of Justice* [2013] VSC 267, [82]-[95].
[4] *Pretty v United Kingdom* (2002) 35 EHRR 1, 36 [61].
[5] *C v Belgium* (2001) 32 EHRR 2, 33-4 [25].
[6] *Volkov v Ukraine* [2013] ECHR 32, [165].
[7] Explanatory note, Human Rights Bill 2018 (Qld) 22; *PJB v Melbourne Health* (2011) 39 VR 373, 395 [85].

(a) the nature of the right

Section 37 of the Human Rights Act provides that 'every person has the right to access health services'.

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.

(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

Though the Amendment Regulation enhances the right to access health services by expanding access to naloxone, it continues to limit the right to access health services by placing restrictions on who may deal with medicines.

The purpose of imposing restrictions on dealings with medicines is to mitigate the risk of misuse or substance abuse by vulnerable persons. This is necessary to ensure that those who possess the appropriate knowledge and training and have a thorough understanding of the risks of medicines, have oversight and control over medicines. 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 achieve the purpose

Regulating dealings 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 while extending access to the supply and administration of naloxone.

(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 Amendment Regulation balances the need to ensure medicines are not misused with the need to improve access to health services for the public.

The Amendment Regulation is unlikely to lead to any increased misuse of medicines in the community, and health practitioners and workers are required to follow relevant professional practice standards. The improved service available for patients at risk of opioid overdose outweighs any potential increased risk of misuse.

Right to property (section 24 of the Human Rights Act) and right to privacy (section 25 of the Human Rights Act)

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

(a) the nature of the right

The right to property is valuable 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'.[8]

The purpose of the right to privacy is 'to protect and enhance the liberty of the person – the existence, autonomy, security and well-being of every individual in their own private sphere.'[9]

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.[10]

(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 limitation on the right to property and privacy in the Amendment Regulation during a person's occupation is to ensure the safety of the broader community. The purpose of the restrictions 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 achieve the purpose

By providing appropriate regulation of medicines, the restrictions in the Amendment Regulation during a person's occupation help to achieve the purpose of patient and community safety. This helps ensure patient safety is maintained while access to health services is improved.

(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 has 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 by 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.

[8] Rhoda E Howard-Hassmann, 'Reconsidering the Right to Own Property' (2013) 12(1) *Journal of Human Rights* 180, 181.
[9] *Director of Housing v Sudi* (2010) 33 VAR 139, 145 [29] (Bell J).
[10] *Pretty v United Kingdom* (2002) 35 EHRR 1, 36 [61]; *C v Belgium* (2001) 32 EHRR 2, 33-4 [25].

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 (No. 2) 2023* 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.

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