Medicines and Poisons (Medicines) Regulation 2021

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) Regulation 2021* (Medicines Regulation) made under the following Acts:

- *Animal Care and Protection Act 2001*
- *Electoral Act 1992*
- *Environmental Protection Act 1994*
- *Medicines and Poisons Act 2019*
- *Planning Act 2016*
- *Police Powers and Responsibilities Act 2000*
- *Prostitution Act 1999*
- *State Penalties Enforcement Act 1999*
- *Veterinary Surgeons Act 1936*
- *Waste Reduction and Recycling Act 2011*.

In my opinion, the Medicines Regulation, as tabled in the Legislative Assembly, is compatible with the human rights protected by the Human Rights Act. I base my opinion on the reasons outlined in this statement.

Overview of the Subordinate Legislation

The *Medicines and Poisons Act 2019* (the Act) was enacted in September 2019 and introduces a new regulatory framework for medicines and poisons in Queensland. The purpose of the Act is to repeal and replace the existing legislation with a new regulatory framework comprising the Act, the Medicines Regulation, the *Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021* and the *Medicines and Poisons (Pest Management Activities) Regulation 2021*.[1]

Broadly, the Act outlines who can deal with medicines and what dealings they can undertake. The 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 Regulation applies in relation to dealings with medicines.[2]

[1] Explanatory Notes to the Medicines and Poisons Bill 2019, page 2. The Explanatory Notes refer to a proposed *Medicines and Poisons (Pest Management, Poisons and Other Regulated Substances) Regulation*. That proposed regulation has been split into two separate regulations.

[2] Section 3 of the Medicines Regulation.

Human Rights Issues

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

The main purpose of the Act is to ensure particular substances are made, sold, used and disposed of in an appropriate, effective and safe way, to ensure health risks arising from the use of the substances are appropriately managed and to ensure persons who are authorised to carry out activities using the substances have the necessary competencies to carry out the activities safely.[3]

These purposes are to be achieved by, among other things, identifying particular activities and substances to be controlled, authorising classes of persons to use the substances in controlled ways for particular purposes, providing a scheme to authorise additional activities using the substances under approvals or licences, requiring persons authorised to use the substances to have competencies and be accountable for the safe and effective use of the substances and requiring particular things to be done to ensure the appropriate use, quality, safety and disposal of the substances at all stages, from manufacture to supply to the consumer and final disposal as waste.[4]

The purpose of the Medicines Regulation is to achieve the purposes of the Act in the manner outlined above, in relation to substances which are medicines as defined in the Act.[5]

In promoting safe and effective use of medicines and ensuring the appropriate use, quality, safety and disposal of medicines, which can be dangerous to health if used incorrectly or not appropriately controlled, the State fulfils its positive obligation under section 16 of the Human Rights Act to take steps to protect human life.[6]

However, in pursuit of its aim to protect human life (and other aims), the Medicines Regulation limits or engages other human rights.

Regulation of medicines

Section 37 of the Human Rights Act provides that '[e]very person has the right to access health services without discrimination'. The right of access to health services likely includes access to medication.[7] 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.

3 Section 3 of the Act.
4 Section 4 of the Act.
5 Section 11 of the Act.
6 *Taşkin v Turkey* [2004] X Eur Court HR 179.
7 *Minister of Health v New Clicks South Africa (Pty) Ltd* [2005] ZACC 25; 2006 (8) BCLR 872, [514], [705].

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

- approved extended practice authorities and approved departmental standards in Schedule 1;[8]
- classes of approved persons authorised to carry out dealings stated in schedules in Schedules 3 to 15 of the Medicines Regulation;[9]
- general approvals for acute health conditions at isolated sites, emergency first aid and emergency management of animals in Schedule 16;[10]
- prescribing standard conditions applying in relation to substance authorities (manufacturing licences, retail licences, prescribing approvals and general approvals);[11]
- prescribing general requirements for approved persons, holders of substance authorities and persons acting under substance authorities dealing with medicines;[12]
- prescribing special requirements for certain dealings by pharmacists and pharmacy employees and particular persons dealing with medicated animal feed;[13]
- prescribing requirements for substance management plans to be made in certain regulated places;[14] and
- setting out other requirements for electronic prescription management systems, secure storage systems for medicines, medicine containers, recording and keeping information, reporting particular matters and advertising and vending machines.[15]

On one view, these authorisations do not limit the right to access health services, as they are permissive authorisations which authorise activities which would otherwise be prohibited by the Act. However, the better view is that 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.

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.[16]

'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.[17] However, a reduction in the value of a commodity is not enough.[18] The interference needs to be so great that it effectively amounts to depriving a person of their property.

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8 Clauses 7 and 8 of the Medicines Regulation.
9 Clause13 of the Medicines Regulation.
10 Clauses 14 to 17 of the Medicines Regulation.
11 Chapter 3 of the Medicines Regulation.
12 Chapter 4 of the Medicines Regulation.
13 Chapter 5 of the Medicines Regulation.
14 Chapter 6 and Schedule 17 of the Medicines Regulation.
15 Chapter 8 of the Medicines Regulation.
16 *Acts Interpretation Act 1954*, sch 1 (definition of 'property').
17 *Sporrong and Lönnroth v Sweden* [1982] ECHR 5; (1982) 5 EHRR 35, [63]; *Zwierzynski v Poland* [2001] ECHR 401; (2004) 38 EHRR 6, [69].
18 *Lough v First Secretary of State* [2004] EWCA Civ 905; [2004] 1 WLR 2557, 2575 [51].

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 s 24(2) of the Human Rights Act.

Medical information and other personal information

Section 25 of the Human Rights Act provides that a person has the right 'not to have the person's privacy, family, home or correspondence unlawfully or arbitrarily interfered with'. Several provisions of the Medicines Regulation engage this right by requiring personal information, including medical information, to be collected, disclosed or used:

- clause 25 requires the supplier of medicated feed to a group of animals to give the farmer of the animals a document containing certain personal information including the name and address of the farmer, and to keep a copy of the document or a record of the details, and to give a copy of the document to the veterinary surgeon who prescribed the feed, if asked to do so;
- clause 31 requires the holder of a prescribing approval for approved opioids to notify the chief executive when the holder starts and stops treating a patient;
- clause 42 requires the holder of a substance authority to give notice to the chief executive about particular changes affecting the authority, including a change to a relevant person stated in the substance authority;
- clause 52 requires that certain personal information such as the name and address of the buyer be contained in a purchase order for stock of a medicine;
- clause 61 requires that certain personal information such as the name of the buyer be contained in an invoice or other notice given by a supplier of stock of medicine;
- clause 69 requires the supplier of stock of an S8 medicine to notify the chief executive if the supplier has not received a notice of receipt from the buyer within 5 business days after the date of delivery;
- clause 86 requires certain personal information to be contained in a prescription for a medicine, including the names of the prescriber and patient and, if the medicine is a monitored medicine, the patient's date of birth;
- clause 95 requires certain personal information to be contained in a prescription for the administration of a medicine by an authorised person, including the names of the prescriber and patient and, if the medicine is a monitored medicine, the patient's date of birth;
- clause 136 requires an authorised person to make and keep a record of certain information after giving a treatment dose of an S3 medicine that contains pseudoephedrine or an S4 or S8 medicine, including the name and address of the patient;
- clause 141 requires an authorised person to make and keep a record of certain information after administering medicine on a standing order, including the name and address of the patient;
- clause 162 requires a pharmacist selling an S3 medicine containing pseudoephedrine to make and keep a record of certain information including the name and address of the person who bought the medicine, the type of document used to identify the person and an identifier for the document (such as a driver licence number or passport number), if applicable;

- clause 168 requires certain information to be stated in a prescription for S4 medicines or medicated feed for a group of animals, including the name and address of the farmer of the animals to which the feed is to be administered;
- clause 177 prescribes additional purposes for keeping the monitored medicines database, being to manage the operation of the database and to exercise a power, or perform another function, under the Act relating to monitored medicines;
- clause 179 prescribes the information to be included in the monitored medicines database kept by the chief executive under section 225 of the Act, including certain information in relation to a patient's treatment, registration details of a health practitioner and personal information to identify a health practitioner for accessing or using the monitored medicines database;
- clause 180 and Schedule 18, Part 2 prescribe certain persons as 'information providers' who are required under section 226 of the Act to give the chief executive the information mentioned in clause 179;
- clause 183(1) prescribes entities listed in column 1 of the table in Schedule 18, Part 3 as 'users' to whom the chief executive may disclose information in the monitored medicines database under section 227 of the Act;
- clause 183(2) and Schedule 18, Part 3 prescribe certain purposes to be purposes for which information in the monitored medicines database can be disclosed to that user;
- clauses 188 to 193 allow a system administrator of an entity's electronic prescription management system to give a person access, cancel access and manage access to that system;
- clauses 211 to 213 require certain information including names and addresses to be recorded in a medicine register for an S8 safe;
- Chapter 8, Part 5 requires persons to report certain matters such as lost or stolen medicines, prescribers failing to give written prescriptions, the use of unlawful documents, supply on false prescriptions and purchase orders for diversion-risk medicines, loss or theft of a diversion-risk medicine and incidents of persons seeking unreasonable amounts of a diversion-risk medicine from a pharmacist.

By requiring contact details and other personal information to be disclosed or recorded as set out above, the Medicines Regulation engages the right to privacy in section 25(a) of the Human Rights Act.

The right to privacy is clearly engaged whenever a person's name and other personal information is required to be disclosed.[19] Disclosing a person's residential address can have a significant impact on privacy (for example, where a person has moved in an attempt to escape domestic violence).[20]

The requirement to provide this information also limits the freedom of expression in section 21 of the Human Rights Act. The 'freedom of expression necessarily entails the right to say nothing or the right not to say certain things'.[21]

[19] *DPP (Vic) v Kaba* (2014) 44 VR 526, 564 [134].
[20] *SF v Department of Education* [2021] QCAT 10, [42]-[53].
[21] *Slaight Communications Inc v Davidson* [1989] 1 SCR 1038, 1080.

Impacts on work and carrying out an occupation

In regulating medicines, the Medicines 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).

First, the regulation of medicines in the Medicines Regulation 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, or the special requirements in Chapter 5 which apply to pharmacists and pharmacy employees. 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.

However, because the definition is inclusive, discrimination under the Human Rights Act may extend to other analogous grounds of discrimination. That is the approach that is taken to the right to equality and non-discrimination in the *Canadian Charter of Rights and Freedoms*, which also has an inclusive meaning of discrimination. The Canadian Supreme Court has held that professional status, occupational status or employment by a particular organisation is not an analogous ground of discrimination.[22] I consider that the same approach applies in Queensland.

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 in relation to 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.[23]

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

Additionally, in several instances the Medicines Regulation applies the law differently based on whether a person is a departmental employee (for example, Schedule 13, Part 7 applies to Health department employees). For the same reasons as set out above, this also engages, but does not limit, the human right in section 15(3) of the Human Rights Act.

[22] *Delisle v Canada (Deputy Attorney General)* [1999] 2 SCR 989; *Baier v Alberta* [2007] 2 SCR 673; *Health Services and Support-Facilities Subsector Collective Bargaining Association v British Columbia* [2007] 2 SCR 391.

[23] Explanatory Notes to the Medicines and Poisons Bill 2019, page 4.

The right to property in section 24 of the Human Rights Act may be engaged by impacts on a person's employment. The equivalent right in the *European Convention on Human Rights* has been held to cover:

- the right to practise a profession;[24]
- a right to seek a particular kind of employment;[25] and
- a licence to carry out an economic activity.[26]

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 the carrying out of certain professions or engaging in employment, for example by requiring a substance authority for certain dealings in medicines. Even if these requirements have the practical effect of depriving some people of a right to their occupation (for example, the requirement in clause 27 that the holder of an S2 retail licence must only sell S2 medicines from business premises that is not within 25km of a pharmacy), that impact on section 24 of the Human Rights Act is very limited.

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 below 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.[27] 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'.[28] In Europe, that has been found to include a right to establish and develop 'relationships of a professional or business nature'.[29] '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'.[30] 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 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.[31] Because

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[24] *Van Marle v The Netherlands* (1986) 8 EHRR 483, [41]-[42]; *Karni v Sweden* (1988) 55 DR 157, 165; *R (Abrahaem) v General Medical Council* [2004] EWHC 279, [5].
[25] *Legal and General Assistance Ltd v Kirk* [2002] IRLR 124, [41].
[26] *Tre Traktörer Aktiebolag v Sweden* (1989) 13 EHRR 309, [53]; *Crompton v Department of Transport North Western Traffic Area* [2003] RTR 517, [19]; *R (Quark Fishing Ltd) v Secretary of State for Foreign Commonwealth Affairs* [2003] EWHC 1743 (Admin), [35]-[37].
[27] *ZZ v Secretary, Department of Justice* [2013] VSC 267, [82]-[95].
[28] *Pretty v United Kingdom* (2002) 35 EHRR 1, 36 [61].
[29] *C v Belgium* (2001) 32 EHRR 2, 33-4 [25].
[30] *Volkov v Ukraine* [2013] ECHR 32, [165].
[31] Explanatory note, Human Rights Bill 2018 (Qld) 22; *PJB v Melbourne Health* (2011) 39 VR 373, 395 [85].

questions of lawfulness and proportionality arise when considering justification of limits on human rights under section 13, it is convenient to consider these questions below.[32]

Restricted access to certain places

The Medicines Regulation requires approved persons to prevent public access to certain places, such as:

- places where waste from medicines is placed;[33] and
- places where medicine stores are kept.[34]

By preventing public access to such places, the Medicines Regulation engages the right to freedom of movement in section 19 of the Human Rights Act. The freedom of movement is a freedom to 'move from one place to another' anywhere within 'the whole territory of a State'.[35] However, the restriction on movement is minor, being confined to small areas where medicines are stored or left or where waste from medicines is placed.

Age requirements

By only allowing people above a certain age to carry out certain activities (in clauses 68, 70, and 78 and Schedule 9, clause 12 and Schedule 13, clause 17), the Medicines Regulation treats people differently on the basis of age. Age is a protected attribute under s 7(f) of the Anti-Discrimination Act. Accordingly, these provisions of the Regulation limit the right to equality and non-discrimination in s 15(3) of the Human Rights Act.

Ability to dispense generic medicines

Clause 128 allows a dispenser to dispense a medicine available under another brand name or without a brand name (generic medicines) if a medicine using an approved name or brand (prescribed medicine) is prescribed for a patient.

Intellectual property in brand medicines is a form of property, so clause 128 engages the right to property. Although generic medicines may only be produced once a patent on brand name medicines has expired, the producer still retains copyright in the brand name which is a form of intellectual property. In some circumstances, permitting a dispenser to dispense a generic medicine instead of a brand medicine may diminish the value of the copyright by reducing sales or the value of the medicine itself by reducing its price.

However, as set out above, interference in property rights by a reduction in the value of a commodity is not enough.[36] The interference needs to be so great that it effectively amounts to depriving a person of their property.

Clause 128 therefore does not limit the right to property in section 24 of the Human Rights Act.

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[32] Following the approach in *Minogue v Thompson* [2021] VSC 56, [86], [140].
[33] Clause 148 of the Medicines Regulation.
[34] Clause 199 of the Medicines Regulation.
[35] Human Rights Committee, *General Comment No 27: Freedom of moment (article 12)*, 67th sess, UN Doc CCPR/C/21/Rev.1/Add.9 (1 November 1999) 2 [5].
[36] *Lough v First Secretary of State* [2004] EWCA Civ 905; [2004] 1 WLR 2557, 2575 [51].

Aboriginal and Torres Strait Islander health professions

Several provisions of the Medicines Regulation provide for a distinct regime of approvals and authorisations for Aboriginal peoples and Torres Strait Islander peoples. In particular, Schedule 3 deals with Aboriginal and Torres Strait Islander health professions which confers authority on:

- an Aboriginal and Torres Strait Islander health practitioner employed by a relevant health service and practising in an isolated practice area (Schedule 3, Part 1);
- an Indigenous health worker practising in an isolated practice area employed by the Cairns and Hinterland Hospital and Health Service, the North West Hospital and Health Service or the Torres and Cape Hospital and Health Service (Schedule 3, Part 2); and
- a health practitioner employed by an approved Aboriginal health service (Schedule 3, Part 3).

Additionally, clause 56(5)(b) makes a purchase order under the *National Health (Remote Area Aboriginal Health Services) Program Special Arrangement 2017* (Cwlth) a 'compliant purchase order'.

Although these provisions are more likely to apply to Aboriginal peoples and Torres Strait Islander peoples and not other people, they reflect 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 granted under schedule 3 described above are granted to appropriately qualified Indigenous health workers employed by three Hospital and Health Services across north Queensland (requiring completion of a particular course relevant to acute primary care in isolated practice areas). They 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.

Closing the Gap for Aboriginal and Torres Strait Islander people in Queensland depends on the delivery of culturally safe health services to 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 Indigenous health workers and 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.

Requirements to write in English

By requiring that paper or electronic documents be written in English (clauses 222 and 223), the Medicines Regulation engages the right to non-discrimination on the basis of language (section 15(3)), right to freedom of expression (section 21), and possibly cultural rights (section 27 of the Human Rights Act).

Requiring documents such as prescriptions or purchase orders to be written in English may indirectly discriminate against people required to read the information, if their first language is not English. Although language is not a protected attribute in section 7 of the Anti-Discrimination Act, language may be an incident of race and national origin under section 7(g).[37] Minorities may also have a right to communicate in their own language, including in official communications, under sections 27 and 28(2)(b) of the Human Rights Act, but most likely only in particular areas where 'their numbers warrant'[38] or 'there is sufficient demand'.[39] In Queensland, there are likely to be very few, if any, areas where official communications in a language other than English is warranted.

The freedom of expression in section 21 of the Human Rights Act is a freedom to communicate 'every form of idea and opinion capable of transmission to others'.[40] Regulating how a person is to communicate ideas represents a minor limitation on this right. The limitation does not go to the content of the ideas or discriminate against particular viewpoints.

Right to freedom of expression

The right to freedom of expression is protected by section 21 of the Human Rights Act and includes 'the freedom to seek, receive and impart information and ideas of all kinds' including in writing or in print. Restrictions in the Medicines Regulation on the advertising of medicines (clause 234) and labelling and packaging of medicines (clause 237) limit this right.

Fees

By prescribing fees for applications and processing fees (Chapter 9, Part 2 and Schedule 19), the Medicines Regulation engages the right to property in section 24 of the Human Rights Act. Money is a form of property for the purposes of section 24 of the Human Rights Act.[41] The levying of money in the form of taxes and other contributions will likely amount to a de facto deprivation of the property.[42] However, a fee that is voluntarily paid in exchange for something of value likely does not involve a deprivation of property. The fees for applying for the grant, amendment or renewal of a substance authority and for processing the application are less like a tax and more like a fee for service which is voluntarily paid. Accordingly, the fees do not deprive people of property and the right in section 24(2) of the Human Rights Act is not limited. Even if the fees are a form of levying a tax or contribution, the deprivation of property would be readily justified by reference to the purpose of revenue raising in the public interest.[43]

Penalty Infringement Notices

To support the effective implementation of the Act, the offences in the Act were reviewed to identify offences deemed suitable to be ticketed or infringement notice offences.

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37 *DPP v Natale* [2018] VSC 339, [71], [89]-[90].
38 Human Rights Committee, *Concluding Observations: Poland*, UN Doc CCPR/CO/82/POL, [20].
39 Human Rights Committee, *Concluding Observations: Austria*, UN Doc CCPR/C/AUT/CO/4, [21].
40 Human Rights Committee, *General Comment No 34: Article 19: Freedoms of opinion and expression*, 102nd sess, UN Doc CCPR/C/GC/34 (12 September 2011) 3 [11].
41 *Acts Interpretation Act 1954*, sch 1 (definition of 'property').
42 *Burden v United Kingdom* (European Court of Human Rights, Grand Chamber, Application no 13378/05, 29 April 2008) [59].
43 *Gasus Dösier-und Fördertechnik GmbH v Netherlands* (1995) 20 EHRR 403, [60].

Clause 264 of the Medicines Regulation amends Schedule 1 of the *State Penalties Enforcement Regulation 2014* (SPE Regulation) to prescribe five offences of the Act as penalty infringement notice (PIN) offences.

The relevant offences of the Act are:

- section 41(2) – Requirement to check database for particular dealings with monitored medicines;
- section 71 – Failure to comply with substance authority conditions;
- section 93(1) – Requirements for substance management plan;
- section 137 – Return of identity card; and
- section 226(1) – Giving information.

Inclusion of these offences in the SPE Regulation will ensure there is an effective and proportionate enforcement response available to contraventions of these provisions.

Prescribing these offences as PINs engages the right to property (section 24), right to liberty and security of the person (section 29), right to a fair hearing (section 31) and rights in criminal proceedings (section 32).

Summary

To summarise:

- the regulation of medicines under the Medicines Regulation effectively limits access to medicines and therefore the right to access health services;
- provisions of the Medicines Regulation requiring personal information, including medical information, to be collected, disclosed or used limit the right to privacy and the freedom of expression;
- provisions of the Medicines Regulation imposing requirements on the carrying out of certain professions or engaging in employment impose minor impacts on the right to property and the right to privacy by impacting on a person's work and occupation;
- clauses 148 and 199 impose very minor limits on the right to freedom of movement by requiring public access to certain places be restricted;
- clauses 68, 70 and 78 and Schedule 9, clause 12 and Schedule 13, clause 17 discriminate on the basis of age and therefore limit the right to equality and non-discrimination;
- clauses 222 and 223 impose very minor limits on the rights to non-discrimination, freedom of expression and cultural rights by requiring certain information to be displayed in a certain way, including in English;
- restrictions in the Medicines Regulation on the advertising of medicines (clause 234) and packaging of medicines (clause 237) impose a minor limit on the right to freedom of expression; and
- prescribing PINs engages the right to property, right to liberty and security of the person, right to a fair hearing and rights in criminal proceedings.

These limits on human rights require justification.

Medicines Regulation: 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 that the right to health is 'indispensable for the exercise of other human rights' and that it is 'conducive to living a life in dignity'.[44] 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 realization of the highest attainable standard of health.'[45] 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.[46]

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.

[44] Committee on Economic, Social and Cultural Rights, *General Comment No 14: The highest attainable standard of health (article 12 of the Covenant)*, 22nd sess, UN Doc E/C.12/2000/4 (11 August 2000) 1 [1].
[45] Committee on Economic, Social and Cultural Rights, *General Comment No 14: The highest attainable standard of health (article 12 of the Covenant)*, 22nd sess, UN Doc E/C.12/2000/4 (11 August 2000) 3 [9].
[46] Explanatory Notes to the Human Rights Bill 2018, 28.

(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 of access health services in the form of medication. In some cases, a necessity requirement is built into the provision. For example, clause 81 provides that a prescriber may prescribe a medicine for a patient only if the prescriber assesses the medicine to be reasonably necessary for the therapeutic treatment of the patient.[47]

(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 those 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.

Right to privacy and freedom of expression

The limit on the right to privacy is reasonable and demonstrably justified for the following reasons.

(a) the nature of the right

The right to privacy is 'the right of the individual to determine for himself [or herself] when, how, and to what extent he [or she] will release personal information about himself [or herself]'.[48] That control over one's personal information is important for autonomy.

Freedom of expression has intrinsic value to individual self-fulfilment as well as instrumental importance for society as a whole. Those values are no different when it comes to the freedom not to impart information. 'Silence is in itself a form of expression which in some circumstances can express something more clearly than words could do.'[49]

(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 personal information required to be recorded or disclosed by the provisions considered above must be recorded or disclosed in order to minimise the risk of harm caused by misuse or diversion of medicines, and ultimately to mitigate the risks of misuse or substance abuse by vulnerable persons.

Ultimately, these restrictions support the overall purpose of the Medicines Regulation in protecting human life, which is consistent with the values of our society.

[47] See to similar effect clause 130 in relation to an authorised person giving a treatment dose of a medicine for a patient without a prescription, and clause 140 in relation to an authorised person administering a medicine to a patient without a prescription.
[48] *R v Duarte* [1990] 1 SCR 30, 46.
[49] *Slaight Communications Inc v Davidson* [1989] 1 SCR 1038, 1080.

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

The recording or disclosing of information pursuant to the above provisions helps to achieve the purpose of the Medicines Regulation in a variety of ways. In some cases that information is necessary for the proper operation of the regulatory system under the Medicines Regulation (such as including personal information on a purchase order or invoice for stock of a medicine). In other cases, the requirement is directed to detecting potential misuse of medicines (such as the requirement for a pharmacist to record information about purchases of an S3 medicine containing pseudoephedrine).

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

The only alternative which would impose a lesser burden on privacy and expression is anonymity, which would undermine the regime for medicines. Accordingly, there are no other ways of achieving the harm-minimisation purpose which would impose a lesser burden on the right to privacy.

There are also safeguards to protect privacy. Clause 224 of the Medicines Regulation also sets out requirements for keeping information in compliance with a requirement under the Act. Existing privacy safeguards under relevant privacy laws will also apply to personal information held by agencies.

(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 limits on the right to privacy and the freedom of expression are minor. On the other hand, protecting human life by minimising the risk of harm from improperly prescribed medicines or misuse or diversion of medicines is clearly important. The importance of that safety purpose outweighs the minor impact on privacy and expression.

Impacts on work

Provisions of the Medicines 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.'[50]

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.'[51]

[50] Rhoda E Howard-Hassmann, 'Reconsidering the Right to Own Property' (2013) 12(1) *Journal of Human Rights* 180, 181.
[51] *Director of Housing v Sudi* (2010) 33 VAR 139, 145 [29] (Bell J).

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.[52]

(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 Medicines 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 Medicines 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 Medicines 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 Medicines 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 Medicines Regulation regulate rather than prevent a person from those benefits.

The need to ensure safe use of medicines is important for the community as a whole. Taking into account 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.

Restrictions on freedom of movement

(a) the nature of the right

The freedom of movement is a freedom to 'move from one place to another' anywhere within 'the whole territory of a State'.[53]

[52] *Pretty v United Kingdom* (2002) 35 EHRR 1, 36 [61]; *C v Belgium* (2001) 32 EHRR 2, 33-4 [25].
[53] Human Rights Committee, *General Comment No 27: Freedom of moment (article 12)*, 67th sess, UN Doc CCPR/C/21/Rev.1/Add.9 (1 November 1999) 2 [5].

(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 restricting public access to places where medicines are stored or waste from medicines is placed is to reduce the risk of unauthorised access to medicines.

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

By imposing requirements to store medicines or place waste from medicines in places where the public does not have access, clauses 148 and 199 of the Medicines Regulation help to achieve that purpose.

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

There are no less restrictive and reasonably available ways to achieve the purpose.

(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 restriction on freedom of movement is minor and demonstrably justified in light of the public safety concerns of allowing public access to areas where medicines are stored or waste from medicines is placed.

Discrimination on basis of age

(a) the nature of the right

The value underlying equality is the dignity that all human beings have by virtue of being human. When we discriminate for no rational reason we fail to see people as fellow human beings.[54]

(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

Provisions in the Medicines Regulation which set age limits are about ensuring that a capable and competent person handles stock of a medicine (clauses 68, 70 and 78) or assists in compounding at a pharmacy (Schedule 9, clause 12) or possesses medical gas (Schedule 13, clause 17), which is ultimately about ensuring safety. The purpose of requiring that person to be an adult (or, in the case of Schedule 9, clause 12, at least 16 years of age) is to ensure that the person being relied upon is sufficiently mature to understand the health risks at stake.

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

The age limits will help to ensure that the relevant person has sufficient maturity to understand the health risks.

[54] *Re Lifestyle Communities Ltd [No 3]* [2009] VCAT 1869; (2009) 31 VAR 286, 311 [109].

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

Consideration was given to a different age limit. However, the age limits specified were considered to strike the appropriate balance between safety considerations and the right to be free from discrimination on the basis of age.

(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

While the Medicines Regulation treats people differently on the basis of their age, it has important reasons for doing so. The safety objective is best achieved by ensuring that the relevant person is sufficiently mature to grasp the health risks. That safety objective outweighs the impact on the right to equality and non-discrimination of people younger than the age requirements.

The limits imposed on the right to equality and non-discrimination by the age requirements in the Medicines Regulation are reasonable and demonstrably justified.

Requirements to display information

(a) the nature of the right

The nature of the right to equality and non-discrimination is set out above.

Freedom of expression has intrinsic importance for individual fulfillment and is indispensable for society as a whole as the foundation of democracy and the rule of law.[55]

The right of minorities to 'use their language' in section 27 and of Indigenous peoples to 'enjoy, maintain, control, protect, develop and use their language' in section 28(2)(b) of the Human Rights Act recognises the intrinsic link between language and identity. When a person's identity is affirmed they are 'recognised for who they are'.[56]

(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 requiring information on prescriptions and purchase orders to be displayed in a certain way is to ensure that those documents are expressed in the way that is most likely to ensure it is understood and to avoid any risk of error in filling the prescription or purchase order. That ultimately serves to protect safety which is a purpose 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

Stipulating how information is to be displayed or provided helps to achieve that purpose.

[55] *McDonald v Legal Services Commissioner [No 2]* [2017] VSC 89, [22].
[56] *PBU v Mental Health Tribunal* (2018) 56 VR 141, 203 [199].

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

Allowing people greater freedom to express the information in another way would put people at risk because they may not receive the information in a way that is understood.

Accordingly, the limits on freedom of expression and the language in which it is expressed is no greater than necessary to achieve the safety purpose.

(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

Freedom of expression and language rights are important, but the Medicines Regulation merely regulates expression. It does not prevent ideas from being expressed, including the language in which the ideas are expressed (provided it is also expressed in English). Ensuring prescriptions and purchase orders are expressed in a way that people can understand is also important. Because lives may be put at risk without regulating how the information is provided, the importance of ensuring safety outweighs the minor impact on freedom of expression and language rights.

The limits imposed on the right to non-discrimination, freedom of expression and cultural rights are reasonable and demonstrably justified.

Restrictions on advertising and packaging

(a) the nature of the right

The nature of the rights to freedom of expression is set out above.

(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 imposing restrictions on advertising of medicines is to protect consumers, who may be susceptible to advertising claims due to health concerns and not able to critically evaluate whether a particular medicine is appropriate for them.

Likewise, the purpose of restricting the labelling or packaging of a medicine is intended to protect consumers by preventing labelling or packaging which may adversely affect public safety.

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

Clauses 234 and 237 of the Medicines Regulation help to achieve that purpose.

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

Allowing people greater freedom to express the information in another way would put people at risk because they may not receive the information in a way that is understood.

Accordingly, the limits on freedom of expression are no greater than necessary to achieve the safety purpose.

(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

Freedom of expression is important, but the Medicines Regulation merely regulates expression. Ensuring warnings and safety messages are received in a way that people can understand is also important. Because lives may be put at risk without regulating how the information is provided, the importance of ensuring safety outweighs the minor impact on freedom of expression.

The limits imposed on the right to freedom of expression is demonstrably justified.

1. Offence provisions listed in the SPE Regulation as a PIN offence as amended by the Medicines Regulation: Consideration of reasonable limitations on human rights (section 13 of the Human Rights Act)

Penalty infringement notices

(a) the nature of the right

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

The right to property protects the right of all persons to own property, alone or with others, and provides that people have a right not be arbitrarily deprived of their property. The right includes the protection from the deprivation of property. 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).

Prescribing infringement notice offences limits property rights. A person issued with an infringement notice must pay a monetary fine to the State, unless they choose to have the matter dealt by a court. Having the matter dealt with by a court also affects the person's property rights, as there are material expenses in preparing for and appearing before a court.

A person who fails to pay an infringement notice fine may have enforcement action taken against them by the registrar of the State Penalty Enforcement Registry (SPER). Enforcement actions are provided for in the *State Penalties Enforcement Act 1999* (SPE Act) and may include seizure and sale of property, imposing a charge over property, taking the fine amount directly from the person's earnings or savings, cancelling the person's drivers licence or immobilising the person's vehicle.

Right to liberty and security of person (section 29 of the Human Rights Act)

Section 29 of the Human Rights Act provides that every person has the right to liberty and security, including not being arbitrarily arrested or detained. The right also protects against arbitrary arrest and detention. The concept of arbitrariness carries a human rights meaning of

'capriciousness, unpredictability, injustice and unreasonableness – in the sense of not being proportionate to the legitimate aim sought'[57].

The Medicines Regulation may limit the right to liberty and security of a person to the extent that a failure to pay an infringement notice fine may result in enforcement action under the SPE Act, including that the registrar may issue a warrant for the arrest and imprisonment warrant by the registrar of SPER against a person for unpaid fines.

Right to a fair hearing and rights in criminal proceedings (sections 31 and 32 of the Human Rights)

Section 31 of the Human Rights Act provides that a person has the right to have criminal charges or civil proceedings decided by a competent, independent and impartial court or tribunal after a fair and public hearing. Section 32 of the Human Rights Act protects the right to be presumed innocent until proven guilty and identifies minimum guarantees for which the person charged is entitled to be informed of the nature and reason for a charge and to defend themselves personally or through legal assistance.

A person issued with an infringement notice is subject to a punishment through payment of a fine without the benefit of a finding of guilt by a court after a fair and public hearing. However, nothing in the SPE Act or SPE Regulation prevents a person who is issued with an infringement notice from electing to have the alleged offence dealt with by a court. In this case, the person is afforded all the rights in criminal proceedings guaranteed under the Human Rights Act.

(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

Unlawful or unsafe dealings with medicines and poisons pose risks to public health and safety. The purpose of prescribing infringement notice offences is to minimise these risks and support the monitoring and compliance framework in the Medicines and Poisons Act by giving inspectors the option to issue infringement notices for suitable offences, in addition to other administrative and legislative enforcement mechanisms. This allows inspectors to issue a fine in response to offending behaviour. When used appropriately and in conjunction with other enforcement mechanisms, infringement notices are an effective enforcement response that is proportionate to the risk to public health and safety created by the offending behaviour and helps manage demand on the courts in Queensland while maintaining a person's right to access the judicial system. Prescribing infringement notice offences also benefits the monitoring and compliance framework by creating a cost-effective method of enforcement and increasing administrative efficiency.

A secondary purpose of prescribing infringement notice offences is to benefit alleged offenders by giving them an alternative to prosecution. Choosing to accept the infringement notice and pay the fine means the person does not need to attend court, prepare a defence, will not have a finding of guilt for the alleged offence, and has certainty about their legal liability.

These objectives are consistent with a free and democratic society based on human dignity, equality and freedom.

[57] *WBM v Chief Commissioner of Police* (2012) 43 VR 466, 472 (Warren CJ, Hansen JA agreeing).

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

The relationship between the prescribed offences and the potential limitation is to provide an efficient system for issuing and enforcing proportionate penalties outside the court process as well as maintaining public health and safety. The limitation through enforcement acts as a deterrent to both the offending party and other people considering offending in the same way. This will encourage individuals to comply with the law by dealing with substances lawfully and in accordance with the objectives of the Act.

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

It is considered that there is no less restrictive and reasonably available way to achieve the purpose of safeguarding the dealing with substances and ensuring there is an efficient system for issuing and enforcing fines relating to the offences, other than by prescribing the offences to be infringement notice offences under the SPE Regulation.

The offences to be prescribed in the SPE Regulation are specific, discrete and relate to administrative matters only. These offences establish legislative obligations that are clear and unambiguous so both alleged offenders and inspectors can clearly identify and rectify breaches.

The SPE Act contains a number of protections against excessive or arbitrary interferences with human rights. These protections include:

- SPER enforcement activities are performed in accordance with the SPER Charter in section 9 of the SPE Act. The Charter ensures the power to issue arrest and imprisonment warrants are rarely used in practice by encouraging alternative enforcement mechanisms.
- A person who considers a fine should not have been issued may elect to have the matter heard by a court instead of paying the fine.
- If a fine is not paid within the specified timeframe and the infringement notice is registered with SPER for enforcement action, the person may apply to pay their debt by instalments.
- Individuals who are experiencing hardship can apply to resolve their debt under a work and development order (which can include undertaking relevant courses, attending counselling and treatment programs or completing work with an approved hardship partner). Certain decisions, such as refusing to grant, vary or revoke a work and development order are reviewable by the Queensland Civil and Administrative Tribunal (QCAT).
- A warrant to seize and sell property, impose a charge over property, or take money directly from a person's wages or bank account, can only be issued after the alleged offender has been given two opportunities to deal with the infringement notice, including by paying the fine, electing to have the matter dealt with by the court, or applying to pay the fine by instalments.
- The registrar may only suspend a person's drivers licence if satisfied that the person is not taking steps to discharge their debt, and only after issuing the person a notice giving them 14 days to pay their debt before the licence is cancelled.
- The registrar may only order a vehicle to be immobilised after giving the person 14 days to pay the fine and in limited circumstances, including that the person is not taking steps to

discharge their debt and either another form of enforcement action has been unsuccessfully attempted or is not possible or appropriate in the circumstances.

- A warrant for a person's arrest and imprisonment may only be issued after another enforcement action has been unsuccessfully attempted and the registrar is satisfied there is no other way to enforce payment of the debt.

Queensland Health undertakes all enforcement action consistent with the *Public Health Enforcement Decision Guideline* (Guideline). The Guideline requires inspectors to use the enforcement mechanism that is most appropriate in the circumstances and to prioritise the least coercive enforcement mechanism wherever possible.

Inspectors receive significant training to ensure that infringement notices will only be issued where other options such as education about the requirements of the Act, or working with the person to rectify any non-compliance, are ineffective. Inspectors are also trained to ensure they make clear to the person receiving the infringement notice that they can challenge the fine in court. The fine amount has been set at up to 10 per cent of the maximum penalty, which is likely less than a court would impose but still at an amount to act as a disincentive for offending behaviour.

In addition, several of the prescribed offences do not apply if the person has a reasonable excuse. Guidance will be provided to inspectors on what may be considered a 'reasonable excuse' for the offences.

It is considered that there is no less restrictive and reasonably available way to achieve the purpose of an effective enforcement mechanism that acts as an alternative to prosecution through the court system, other than by prescribing the offences to be infringement notice offences under the SPE Regulation.

(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

It is necessary for Queensland Health to be able to monitor and respond to health risks associated with the inappropriate access to, and management and use of, medicines more efficiently, as unlawful dealings with substances can create significant risks to public health and safety. The framework for the Act minimises the risk that medicines could be diverted for unlawful purposes or used in an unsafe way by limiting who may supply medicines and introduces real-time prescription monitoring for particular medicines.

Not prescribing the offences as infringement notice offences is likely to reduce the threat of enforcement action against an offender due to the significant cost to the State of court proceedings. A decision to prosecute is made on public interest grounds (including consideration of the costs of prosecution) so it would be reasonable for some offenders to consider that the State is unlikely to issue a complaint and summons to anyone other than the most recidivist offenders therefore significantly reducing the deterrent effect of the offences.

It is considered that the importance of implementing effective enforcement responses that are proportionate to the risk created by the offending behaviour outweighs any potential limits on human rights.

Conclusion

I consider that the *Medicines and Poisons (Medicines) Regulation* 2021 is compatible with the *Human Rights Act 2019* because it does limit, restrict or interfere with human rights, but those limitations are reasonable and demonstrably justified in a free and democratic society based on human dignity, equality and freedom.

YVETTE D'ATH MP
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