Therapeutic Goods 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 *Therapeutic Goods Regulation 2021* made under the *Therapeutic Goods Act 2019*.

In my opinion, the *Therapeutic Goods Regulation 2021*, 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 *Therapeutic Goods Act 2019* applies Commonwealth regulatory controls on therapeutic goods in Queensland, to the extent those controls do not otherwise apply. This allows for the uniform administration of the applied laws by Commonwealth entities and ultimately serves the purpose of managing health and safety risks posed by therapeutic goods in Queensland. The relevant Commonwealth regulatory controls are set out in section 7 of the *Therapeutic Goods Act 1989* (Cwlth) (Commonwealth Act) and are defined as 'Commonwealth Therapeutic Goods Laws'.

However, section 7(2) of the Commonwealth Act allows for regulations to be made modifying the application of the Commonwealth Therapeutic Goods Laws. Pursuant to that power, the Therapeutic Goods Regulation 2021 provides that those Commonwealth Therapeutic Goods Laws do not apply to a thing done in Queensland by a departmental employee for the manufacture, supply or use of unregistered therapeutic goods; or to a thing done in Queensland by another individual supplying or using unregistered therapeutic goods manufactured by a departmental employee.

The modification is required to ensure the continuity of services provided by the Central Pharmacy Manufacturing Unit (a commercialised business unit within Queensland Health). The Central Pharmacy Manufacturing Unit conducts bespoke manufacturing of individual medicines for individual patients, small-scale batch manufacturing of products that are not commercially available and the repackaging of some medicines. These medicines are provided for patients in Hospital and Health Services, dental clinics and Queensland Ambulance Service sites. Applying Commonwealth regulatory controls to the Central Pharmacy Manufacturing Unit would potentially lead to adverse outcomes for patients, as Central Pharmacy would be likely to cease manufacturing of some medicines. To ensure the Central Pharmacy Manufacturing Unit continues to meet high manufacturing standards it will be required to hold a manufacturing licence under the *Medicines and Poisons Act 2019* and meet industry recognised standards for Good Manufacturing Practice.

Human Rights Issues

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

Section 37(1) of the Human Rights Act affirms a right of access to health services, which likely includes access to medicines.[1] By ensuring the continuity of services provided by the Central Pharmacy Manufacturing Unit, without sacrificing high standards of manufacturing, the Therapeutic Goods Regulation promotes this human right.

The Therapeutic Goods Regulation applies the law differently based on whether a person is a departmental employee. This engages, but does not limit, the human right in section 15(3) of the Human Rights Act.

Under section 15(3) of the Human Rights Act, 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 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.[2]

I consider that the same approach applies in Queensland. A person who is not a departmental employee does not generally suffer from disadvantage or stereotyping, and the distinction drawn by the Therapeutic Goods Regulation does not have the effect of devaluing or marginalising them within our society. Accordingly, there is no discrimination and section 15(3) of the Human Rights Act is not limited.

No other human rights are engaged or limited by the Therapeutic Goods Regulation.

Conclusion

I consider that the Therapeutic Goods Regulation 2021 is compatible with the *Human Rights Act 2019* because, although it raises human rights issues, it does not limit human rights.

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

[1] *Minister of Health v New Clicks South Africa (Pty) Ltd* [2005] ZACC 25; [2006] 8 BCLR 872, [514], [705].
[2] *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.