

Health (Drugs and Poisons) (COVID-19 Vaccination Services) Amendment 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 provide this human rights certificate with respect to the Health (Drugs and Poisons) (COVID-19 Vaccination Services) Amendment Regulation 2021 made under the *Health Act 1937*.

In my opinion, the Health (Drugs and Poisons) (COVID-19 Vaccination Services) Amendment 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 Health (Drugs and Poisons) (COVID-19 Vaccination Services) Amendment Regulation 2021 (Amendment Regulation) will facilitate the rollout of the COVID-19 vaccine in Queensland.

The rollout of Queensland's COVID-19 vaccination program in 2021 will be a significant undertaking, far exceeding any previous vaccination program. The program is being delivered in a collaborative approach between the Australian Government and Queensland Government, to rapidly respond to COVID-19 on a large scale and provide vaccine availability to the entire population through a mix of service delivery arrangements. The program is being delivered outside the usual National Immunisation Program. It will require a co-ordinated whole-of system approach to ensure successful implementation. Due to the nature and scale of the undertaking, the existing provisions of the *Health (Drugs and Poisons) Regulation 1996* are not fit for purpose to facilitate all aspects of the rollout.

The Amendment Regulation will not prevent existing provisions of the Health (Drugs and Poisons) Regulation being used for the vaccine rollout where those provisions are able to be used (for example, existing provisions may be sufficient for some arrangements with general practitioners, community pharmacists and nurse practitioners). Existing requirements in the Health (Drugs and Poisons) Regulation in relation to the business-as-usual model for immunisation, including wholesaling, supply, sale, administration, prescribing, obtaining and issuing will not change. The changes only apply to the rollout of the COVID-19 vaccine where existing arrangements are not appropriate to be used.

The Amendment Regulation provides for the development of a COVID-19 vaccination code, to be made by the chief executive of Queensland Health or their delegate, which meets Queensland's responsibilities under the *Australian COVID-19 Vaccination Policy* (Vaccination Policy).

To enable the vaccine roll-out, the vaccination code must include requirements in relation to:

- the qualifications, training or supervision necessary for workers for declared providers of COVID-19 vaccination services, who will administer the vaccine (section 213E(2)(a));
- the recording of information related to the provision of the services (section 213E(2)(b)); and
- the reporting of information, including personal information, about vaccination services (section 213E(2)(c)).

The COVID-19 vaccination code will also set out the operational requirements for providing COVID-19 vaccination services, including matters such as:

- specifications for providing the services or setting up COVID-19 vaccination centres (section 213E(3)(a));
- providing for eligibility for the staged rollout of the vaccine, such as determining priority populations (section 213E(3)(b));
- procedures for assessing the health and suitability of persons to be vaccinated (section 213E(3)(c));
- procedures for safely preparing the vaccine, such as the processes for labelling syringes when they are drawn up from multi-dose vials, for example this may include the date and time of preparation (section 213E(3)(d));
- procedures for the vaccine and related drugs to be safely obtained, sold, supplied, issued or disposed of (section 213E(3)(e)); and
- safe and secure storage of the vaccine and related drugs (section 213E(3)(f)).

The chief executive will be responsible for declaring persons as ‘declared providers’ of COVID-19 vaccines and must publish the name of the person and the contact details of the individual who is responsible for overseeing the provision of COVID-19 vaccination services on the Queensland Health website. This will be a ‘source of truth’ for members of the general public to be satisfied that they are receiving a legitimate COVID-19 vaccine from a government-authorised provider.

The Amendment Regulation authorises providers and workers to carry out activities for providing COVID-19 vaccination services, if they comply with the COVID-19 vaccination code (sections 213G to 213L).

The Amendment Regulation also includes an information sharing provision to facilitate data sharing with the Australian Government and other agencies to facilitate a safe and effective vaccination program (section 213M).

Medical practitioners, pharmacists in community pharmacies and nurse practitioners are already authorised to administer Schedule 4 (S4) vaccines under the Health (Drugs and Poisons) Regulation. This means that for vaccinations given by these health practitioners, it will not be necessary for them to be a ‘declared provider’. However, section 200 of the Health (Drugs and Poisons) Regulation requires vaccines to be obtained through a formal purchase order procedure.

The Amendment Regulation amends section 200 of the Health (Drugs and Poisons) Regulation to provide that if an authorised person, such as a medical practitioner, pharmacist or nurse practitioner obtains a COVID-19 vaccine under the Australian COVID-19 vaccination arrangements, they are not committing an offence by not obtaining a restricted drug on a purchase order. The ‘Australian COVID-19 vaccination arrangements’ is defined to mean the arrangements made under the Australian COVID-19 Vaccination Policy to provide COVID-19 vaccines for vaccinating members of the public.

Human Rights Issues

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

The Amendment Regulation engages the following human rights protected by the Human Rights Act:

- right to protection from torture cruel, inhuman or degrading treatment (section 17);
- right to privacy and reputation (section 25); and
- right to health services (section 37).

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

(a) the nature of the right

Right to protection from torture, cruel, inhuman or degrading treatment (section 17 of the Human Rights Act)

The right to protection from torture and cruel, inhuman or degrading treatment prohibits three distinct types of conduct: torture; cruel, inhuman or degrading treatment or punishment; and medical or scientific experimentation or treatment without consent. Treatment has a wide meaning, including giving medical care or attention or applying a process or substance to someone.

For the Amendment Regulation, the relevant aspect to consider is whether it involves medical or scientific experimentation or treatment without consent.

The rollout of safe and effective vaccines for COVID-19 in Australia will be guided by the Vaccination Policy. The Vaccination Policy states that the approach to the COVID-19 vaccination during this pandemic is, “while the Australian Government strongly supports immunisation and will run a strong campaign to encourage vaccination, vaccination is not mandatory and individuals may choose not to be vaccinated”.

Further, the vaccine will only be administered if the person provides their consent. This approach ensures that the rollout of COVID-19 vaccines is consistent with, and does not place limitations on, this human right.

In addition, the rollout of COVID-19 vaccines is not considered to amount to medical or scientific experimentation. All vaccines used in Australia must be approved for use by the Therapeutic Goods Administration (TGA), which has a long-standing and robust process to monitor the implementation and safety of medicines in Australia, including assessing the safety, quality and effectiveness of vaccines. The TGA engaged early with vaccine developers and is undertaking a thorough and efficient review of vaccine candidates. The TGA's approval of vaccines will provide the public with confidence about the vaccines' safety, quality and efficacy.

Serious reactions to current vaccines approved by the TGA are rare. It is also relevant to note that the risk of side effects from a vaccine is far less than the risk of severe complications associated with a disease for which a vaccine is available. Australia also has the advantage that we have been able to monitor the rollout of vaccines in other countries such as the United States of America and the United Kingdom.

As an additional safeguard, clinicians and vaccine service providers are required under the *Public Health Act 2015* to report any adverse event following immunisation to Queensland Health. This information is passed on to the TGA which strictly monitors and manages vaccine safety in Australia.

For these reasons, it is not considered that the Amendment Regulation places limitations on, or interferes with, this human right.

Right to privacy and reputation (section 25 of the Human Rights Act)

Section 25 of the Human Rights Act protects a person's right not to have the person's privacy, family, home or correspondence unlawfully or arbitrarily interfered with and not to have the person's reputation unlawfully attacked. It protects privacy in the sense of personal information, data collection and correspondence. In the human rights context, 'arbitrary' refers to conduct that is capricious, unpredictable or unjust, and also refers to interferences which are unreasonable in the sense of not being proportionate to a legitimate aim that is sought.

This Right is addressed further in section (b).

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

Section 37 of the Human Rights Act provides that every person has the right to access health services without discrimination and a person must not be refused emergency medical treatment that is immediately necessary to save the person's life or to prevent serious impairment to the person.

The COVID-19 vaccination program will be jointly rolled out by the Australian and Queensland Governments and will be done in accordance with the roles and responsibilities outlined in the Vaccination Policy. The rollout in Queensland in 2021 will be a significant undertaking, far exceeding any previous vaccination program. The program is being delivered rapidly to respond to COVID-19 on a large scale to provide availability to the entire population, with multiple vaccines and with a mix of service delivery arrangements. It will require a co-ordinated whole-of system approach to ensure successful implementation.

The COVID-19 vaccination will be free for all Medicare-eligible Australians and visa-holders as described in the Vaccination Policy.

An important aspect of the COVID-19 vaccination rollout is that immunisation not only protects each individual who receives the vaccine, but it helps others by assisting to control the disease in the community. Immunisation triggers the immune system to fight the disease the person is vaccinated for. If a vaccinated person comes in contact with the disease, their immune system is able to respond more effectively. This either prevents the disease from developing or reduces its severity. Herd immunity makes the spread of disease from person to person less likely, reducing transmission rates and protecting those who may not be able to be vaccinated themselves. A high take-up rate for the COVID-19 vaccine will increase the likelihood of achieving a sufficient level of herd immunity, to assist in keeping the most vulnerable members of our community safe.

For these reasons, the proposed universal and free availability of the vaccine to all Queenslanders will be integral to promoting and facilitating this important human right for everyone in the community.

(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

Right to privacy and reputation (section 25 of the Human Rights Act)

Under the Vaccination Policy, responsibilities are allocated for different aspects of the rollout of the COVID-19 vaccination program. The Australian Government is responsible for ensuring that appropriate data collection and monitoring systems are in place. The Queensland Government will be required to report to the Australian Government on the rollout and it will be necessary to share information with the Australian Government for reporting and monitoring purposes.

Personal information will be required to be disclosed and recorded when a person obtains a COVID-19 vaccination, including their identifying details. For most COVID-19 vaccines, two doses will be required for immunisation. To ensure the vaccine is administered appropriately and is effective for the individual, it will be important to ensure that each person has two doses of the same vaccine, for example, either two doses of the Pfizer vaccine or two doses of the AstraZeneca vaccine. This means recording and reporting information on vaccines given will be a critical aspect in ensuring the vaccine works and that the roll-out of the vaccine program is successful.

The Australian Immunisation Register Amendment (Reporting) Bill 2020 is currently before the Australian Parliament. If passed, the Bill will require the giving of COVID-19 and influenza vaccines to be recorded in the Australian Immunisation Register (AIR) by vaccine service providers from 1 March 2021. The AIR is expected to be the unifying national system to monitor both overall immunisation levels and individual immunisation status. Queensland Health will also implement its own systems to record and report information on the vaccine rollout and to facilitate reporting to the AIR.

Under new section 213E(1) of the Amendment Regulation, the chief executive of Queensland Health may publish a document on the department's website stating the requirements for providing COVID-19 vaccination services in Queensland, to be known as the COVID-19 Vaccination Code. Section 213E(2) provides that the Vaccination Code must include requirements in relation to the recording and reporting of information, including personal information, related to the provision of COVID-19 vaccination services. Therefore, the Vaccination Code will set out mandatory requirements for service providers in terms of recording and reporting on the giving of vaccines.

New section 213M of the Amendment Regulation applies to personal information reported to Queensland Health under the Vaccination Code and allows Queensland Health to share that information to:

- facilitate the safe and effective therapeutic treatment of persons vaccinated at COVID-19 vaccination centres; and
- report, or facilitate reporting, about the use of COVID-19 vaccines under the Australian COVID-19 vaccination arrangements.

The term 'Australian COVID-19 vaccination arrangements' is defined to mean the arrangements made under the Australian COVID-19 Vaccination Policy to provide COVID-19 vaccines for vaccinating members of the public.

New section 213M(3) provides that, when giving personal information, Queensland Health must ensure the privacy of any persons to whom the information relates is protected from unjustified intrusion, to the extent possible.

This provision will authorise sharing of personal information between the Australian Government, Queensland Health and vaccine service providers, which will involve an individual's personal information. The Vaccination Code will set out requirements and safeguards for reporting of information to Queensland Health. Health practitioners and health services are accustomed to handling personal information sensitively and securely, and in line with legislative requirements and details about the appropriate systems and processes for COVID-19 vaccinations will be clearly set out in the Vaccination Code.

It is expected the vaccine rollout in Queensland will involve a range of different service delivery arrangements, to cater for priority populations and Queensland's geographic diversity. For example, it is expected the rollout will involve a mix of public and private delivery models to reach the entire Queensland population and will need to be flexible to respond to the approval of new vaccines and their differing transport, storage and handling requirements.

Given the large-scale nature of the rollout, it is expected that members of the community may present to a different service or provider to receive their second or subsequent dose in some cases. To ensure the vaccine can be delivered safely and effectively, it is necessary for Queensland Health to be able to share information about previous vaccinations with providers, such as the type of vaccine received, the date of the first vaccination, the dosage and the individual's personal information so they can be identified.

Consideration is also being given to Queensland Health engaging a third-party provider to SMS a person on certain days after receiving their vaccination to determine their health and whether they have encountered any side-effects. The third party may also send reminder messages to ensure the person books in for their second vaccination.

These proposed uses of personal information illustrate that the purpose of the limitations on a person's privacy is to enable health services to be provided in a safe, accessible and effective way, which also promotes another human right, which is the right to access health services.

Queensland Health will also be able to disclose information to report, or to facilitate reporting, about the use of COVID-19 vaccines under the Australian COVID-19 vaccination arrangements. This is critical to ensure that there is appropriate data and information available across the country to ensure the rollout is being managed appropriately and to facilitate the joint rollout of the vaccination program by the Australian and Queensland Governments. Reporting on the program at the State and national levels helps to ensure a free and democratic society based on human dignity, equality and freedom.

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

Due to the unprecedented nature and scale of the rollout, it is necessary to prioritise the deployment of vaccines, as supplies of approved vaccines will initially be limited. The Australian Government has sought advice from the Australian Technical Advisory Group on Immunisation (ATAGI) about priority population groups for the rollout. ATAGI is a ministerially appointed committee established to advise the Australian Minister for Health and the Commonwealth Department of Health. It comprises medical and scientific experts on immunisation from around the country and consumer representatives. It provides advice on the medical administration of vaccines for the National Immunisation Program as well as vaccine policy generally, including through the development of the Australian Immunisation Handbook. Advice was sought from ATAGI on the basis of ensuring equitable protection from COVID-19 for all people living in Australia.

Based on ATAGI's advice, the first to be vaccinated will be those at greatest risk of exposure and the greatest risk of severe disease, including quarantine and border security staff, selected health care workers, aged care residents and staff, and people living in disability services settings and workers in these settings. More details about the proposed rollout schedule are available in *Australia's COVID-19 vaccine national roll-out strategy*, which is available at: <https://www.health.gov.au/resources/publications/australias-covid-19-vaccine-national-roll-out-strategy> and updated advice will be provided on the Australian Government Department of Health's website.

The COVID-19 vaccination program aims to vaccinate all those who wish to be vaccinated during 2021. Given the size of the program, it is not logistically possible for all Australians to be offered a vaccine at the same time. There are a number of reasons for this, including the initial limited stock of vaccines, the constraints of the available workforce and the sheer number of vaccinations that will be required. Prioritising those at greatest risk of being exposed to COVID-19 or at greatest risk of severe disease will minimise any potential impact on the overall health system. It also provides a manageable, staged approach to the rollout of the vaccine that provides the greatest equity and the most benefit. Prioritising the groups that are most vulnerable helps to ensure the best health outcomes for the greatest number of people.

If a person contracts COVID-19, they will continue to receive immediate medical treatment. This is consistent with section 37 of the Human Rights Act which provides that emergency medical treatment should not be refused.

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

Right to privacy and reputation (section 25 of the Human Rights Act)

The limitations on a person's right to privacy will enable health services to be provided in a safe, accessible and effective way. The sharing of information between the Australian Government, Queensland Government and service providers will assist in ensuring that every individual receives the appropriate doses of approved COVID-19 vaccines. It is reasonable, necessary and proportionate to limit the right to privacy in order to protect individual and public health, which is a fundamental human right.

Members of the community would expect that a government vaccine program would enable them to receive their vaccination at different sites, as they move around Queensland or Australia. The ability for people to receive vaccinations in different places will contribute to an accessible and successful rollout and enable members of the community to continue their normal activities. Therefore, it is considered necessary to have arrangements in place to facilitate information sharing between governments and service providers.

Reporting on the rollout of the vaccine is also important in the context of achieving herd immunity. When a significant level of herd immunity is reached, it is expected this will assist in reducing the need for some of the restrictions that have been used to protect public health during the COVID-19 pandemic. Protecting the health and safety of the public at both the individual and community level is a fundamental responsibility of government and is consistent with the human right to health services.

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

The staged rollout of COVID-19 vaccines is based on expert scientific and health advice from ATAGI. It will help to ensure a manageable, staged and progressive rollout of vaccines. In developing the rollout, various factors have been taken into account, including:

- disease epidemiology and clinical impact;
- safety characteristics of available vaccines;
- efficacy and mechanism of action of available vaccines (that is, the ability to prevent acquisition, reduce viral shedding and transmission, and/or reduce severe clinical outcomes of infection);
- regulatory, programmatic and operational considerations (for example, vaccine supply, storage and delivery);
- public confidence and acceptability;
- social and economic impact; and
- relevant ethical considerations.

Prioritising those who are at most risk of being exposed to COVID-19 (such as quarantine and border security staff and certain health care workers) will help to minimise the spread of COVID-19 within Australia. Giving priority to those most vulnerable to severe disease will help to provide the greatest overall benefit to the health system by minimising the need for hospitalisations.

All Australians will have access to the vaccine in 2021 and making the vaccine available for free to the public will encourage the take up of the vaccine and is expected to contribute to achieving a high level of herd immunity.

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

Right to privacy and reputation (section 25 of the Human Rights Act)

An alternative approach may be to require all individuals to receive their two doses of the vaccine at the same location, from the same service provider. This may lead to some reduction in the need to share information between providers. However, it is considered impractical to require every individual to do this, as it has the potential to restrict a person's usual activities, such as moving around Queensland or Australia for work, family or leisure purposes. It also carries a risk of less people being vaccinated or less people being effectively vaccinated, through receiving their two doses, as vaccinations would be less accessible to members of the community.

In balancing the right to privacy against a successful rollout of the COVID-19 vaccine, it is considered appropriate to allow some limitations on the right to privacy. In addition, an individual's personal information will only be used for limited purposes and a number of safeguards will be in place to minimise any misuse of information.

On balance, it is considered there are no less restrictive and reasonably available ways to achieve the purpose of providing safe, accessible and effective health services for the COVID-19 vaccine rollout, given the large-scale and complex nature of the rollout, as well as the established and nationally agreed approach to the vaccine roll-out, as described in the Vaccination Policy.

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

A staged rollout of COVID-19 vaccines is the only viable option for implementing the unprecedented scale of the vaccination program. The implementation of the program will require coordination across the health system to ensure a successful outcome, as well as between the Australian and Queensland Governments. The Queensland rollout is expected to draw on a range of service delivery mechanisms, including a mix of public and private delivery models. This flexibility is required to provide a universal vaccination approach for the entire population, especially with Queensland's population being geographically dispersed.

Basing the rollout on expert health advice is considered the most equitable and fair way to promote the right of access to health services under the Human Rights Act.

(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

Right to privacy and reputation (section 25 of the Human Rights Act)

The benefits of a successful rollout of the COVID-19 vaccine will include reduced exposure to the risk of COVID-19 for individuals, as well as the potential to reach herd immunity and the likelihood of fewer public health restrictions in the future. The rollout will only be successful if vaccines are given at the right times in an easily accessible way for members of the community. This can only be achieved if information is shared between the Australian Government, Queensland Government and service providers.

It is considered that these purposes outweigh the human right to privacy for individuals in the community. Health services and service providers are experienced in handling sensitive health information and keeping it confidential. The Amendment Regulation also only allows information to be shared for limited purposes, which must be complied with. In addition, safeguards will be provided for in the *Australian Immunisation Register Act 2015* (Cwlth), the national COVID-19 vaccination arrangements between the Commonwealth and all States and Territories and the requirements of Queensland's Vaccination Code. Personal information will also need to be managed in accordance with legislative requirements, including the *Information Privacy Act 2009* (Qld).

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

All Queenslanders will have access to COVID-19 vaccines in 2021 as part of the phased rollout. The staged nature of the rollout will prioritise those who have the greatest need and those whose roles in our community expose them to the greatest risk. In turn, this will have the effect of providing the greatest benefit to the community by minimising the potential spread of COVID-19, particularly at our borders and in health care settings. The staged rollout is based on expert health advice and takes into account logistical and operational considerations. On balance, it will promote and facilitate access to health services for the community in a way that is consistent with a democratic society.

(f) any other relevant factors

Nil.

Conclusion

I consider that the Health (Drugs and Poisons) (COVID-19 Vaccination Services) Amendment Regulation 2021 is compatible with the *Human Rights Act 2019* because it does not limit, restrict or interfere with human rights, but the limitations are reasonable and demonstrably justified in a free and democratic society based on human dignity, equality and freedom.

THE HONOURABLE YVETTE D'ATH MP
MINISTER FOR HEALTH AND
AMBULANCE SERVICES