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Queensland Health

Mr Aaron Harper MP
Chair
Health and Environment Committee
Parliament House
BRISBANE QLD 4000

Email: hec@parliament.qld.gov.au

Dear Mr Harper

Thank you for your letter dated 23 March 2021, on behalf of the Health and Environment Committee, in relation to the Committee's examination of subordinate legislation No. 5 of 2021 – Health (Drugs and Poisons) (COVID-19 Vaccination Services) Amendment Regulation 2021 (Amendment Regulation).

To assist the Committee's examination of the Amendment Regulation, the Committee requested Queensland Health provide additional information about the safeguards in place to protect the confidential nature of personal health information.

The information requested by the Committee is outlined in the attachment.

Should you require further information, Queensland Health's contact is Ms Tricia Matthias, Acting Director, Legislative Policy Unit, on telephone [REDACTED]

Yours sincerely



Dr John Wakefield PSM
Director-General

29.3.2021

**Health (Drugs and Poisons) (COVID-19 Vaccination Services)
Amendment Regulation 2021
Response to Health and Environment Committee**

Committee comment

The committee notes that the amendment regulation includes an information sharing provision to facilitate data sharing with the Australian Government and other agencies to facilitate a safe and effective vaccination program (s 213M).

The requirement set out in new s 213M(3) states 'the chief executive must ensure the privacy of any persons to whom the information relates is protected from unjust intrusion, to the extent possible'.

The committee is seeking additional information on what are the appropriate safeguards in place to protect the confidential nature of personal health information.

Departmental response

Under the *Australian COVID-19 Vaccination Policy*, responsibility for the rollout of COVID-19 vaccines is shared between the Australian Government and state and territory governments. For vaccines administered under arrangements with the Australian Government, such as vaccinations by general practitioners and those occurring in residential aged care facilities, Queensland Health does not receive any personal information about the persons being vaccinated and therefore, section 213M of the *Health (Drugs and Poisons) Regulation 1996* does not apply. In these cases, privacy of personal information is managed by the Australian Government. Section 213M only applies if vaccinations are administered by or on behalf of the Queensland Government, with these services referred to as 'Queensland Government-controlled COVID-19 vaccination services'.

The COVID-19 Vaccination Code (Vaccination Code) has been published on the Queensland Health website, in accordance with section 213E of the *Health (Drugs and Poisons) Regulation*. Under the Vaccination Code, declared providers of Queensland Government-controlled COVID-19 vaccination services must use the Queensland COVID-19 Vaccine Management System (QCVMS) to record and report information relating to the Queensland COVID-19 vaccination program, including vaccination data, adverse events and COVID-19 vaccine stock data. If QCVMS is unavailable or unable to be accessed, declared providers must use another system approved by Queensland Health to support the downtime capture and subsequent reporting of information.

The QCVMS has been developed by Queensland Health to provide a single, secure ICT solution for the recording and reporting of all data related to the Queensland Health COVID-19 vaccination program. Access to QCVMS is restricted to those who are performing functions under the Queensland Health COVID-19 Vaccination Program and it uses a role-based access control model to ensure that access to the system is commensurate with the user's role in the vaccination process. All data stored in QCVMS is encrypted. QCVMS also includes an auditing capability that captures audit trail entries for all interactions, including those of administrators. The audit trail records information about the user, date and time, as well as what data was created, read, updated and deleted. The use of QCVMS by providers ensures that all data related to the vaccination program are stored on one secure ICT system managed by Queensland Health.

It is a requirement under the Vaccination Code for declared providers of Queensland Government-controlled COVID-19 vaccination services to also comply with the National Privacy Principles or the Information Privacy Principles under the *Information Privacy Act 2009* when collecting, storing, using and disposing of personal information.

The Vaccination Code also sets out the circumstances in which information collected for providing health services at a Queensland Government-controlled vaccination service may be shared by Queensland Health. It states that information may be shared with entities such as the Australian Government, Therapeutic Goods Administration and other relevant entities to:

- facilitate the safe and effective therapeutic treatment of persons vaccinated at COVID-19 vaccination centres (section 213M(2)(a)), which may include:
 - health service quality and planning;
 - co-ordination of safety monitoring and surveillance of adverse events;
- report to the entity, or facilitate reporting to the entity, in relation to the use of COVID-19 vaccines under the Australian COVID-19 vaccination arrangements (section 213M(2)(b)), which may include:
 - meeting requirements for mandatory reporting to the Australian Immunisation Register;
 - ensuring the effective rollout of the COVID-19 vaccination program is in accordance with the Australian COVID-19 vaccination arrangements and Australian COVID-19 vaccination policy;
- manage COVID-19 vaccine logistics; or
- as otherwise permitted by law.

Before receiving a COVID-19 vaccine, each person must provide informed consent. The COVID-19 Vaccination Consent Form (Annexure 1) and Queensland COVID-19 Vaccination Information (Patient Information sheet) (Annexure 2) are used to obtain consent. These documents are published on the Queensland Health website at:

<https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/novel-coronavirus-qld-clinicians/covid-19-vaccination-information-for-healthcare-workers>

The consent form requires a person to acknowledge that they have read and understood the Queensland COVID-19 Vaccination Information (Annexure 2), prior to providing consent. This patient information sheet contains a privacy notice outlining that personal information collected by Queensland Health and Hospital and Health Services is handled in accordance with the *Information Privacy Act 2009*. Key information for patients included in the privacy notice includes:

- Name, address, phone number, email address, age, gender, Indigenous status, vaccine details and medical numbers are collected in accordance with the *Australian Immunisation Register Act 2015* to manage recall, reminders, clinical follow up and control and enhanced safety monitoring of vaccines. This information is given to the Australian Immunisation Register to maintain information about vaccinations of individuals;
- Personal information is used to administer the Queensland Health COVID-19 immunisation program. Relevant medical information including the existence of any medical conditions, allergies, or severe reactions following any vaccine is collected for the assessment of whether and which vaccine should be administered. If a patient chooses not to provide the information, it may affect Queensland Health's ability to respond and deliver services, including administering the COVID-19 vaccine;
- All personal information will be securely stored and is only accessible by appropriately authorised officers within Queensland Health;

- De-identified data (information that does not identify a person) will be shared with the Australian Government and national immunisation safety, monitoring and surveillance organisations for monitoring adverse events after immunisation and evaluating disease prevention and control efforts; and
- Personal information will not be disclosed to other third parties without consent, unless the disclosure is authorised or required by or under law.

Registered health practitioners are bound by their professional obligations for maintaining confidentiality of patient information and all health providers, including Queensland Health and Hospital and Health Services, are experienced in maintaining patient confidentiality. Inappropriate use of computer systems, such as QCVMS, is an offence under the *Criminal Code Act 1899*. The offence in section 408E (Computer hacking and misuse) carries a maximum penalty of 2 years imprisonment.



**Queensland
Government**

COVID-19 Vaccination Consent

Adult (18 years and over)

Facility:

Medicare number:

Family name:

Given name(s):

Address:

Date of birth:

Age:

Sex: ☐ M ☐ F ☐ I

A. Vaccine details

☐ Pfizer Comirnaty ☐ AstraZeneca

B. Are you or the person to be vaccinated able to make decisions about your healthcare?

☐ Yes → **GO TO** section C

☐ No → **COMPLETE** section B

You must adhere to the Advance Health Directive (AHD), or if there is no AHD, the consent obtained from a substitute decision-maker in the following order: Category 1. Tribunal-appointed guardian; 2. Enduring Power of Attorney; or 3. Statutory Health Attorney.

Name of substitute decision-maker:

Category of substitute decision-maker:

C. Is an interpreter required?

☐ Yes → **COMPLETE** section B

☐ No → **GO TO** section D

If yes, the interpreter has:

☐ provided a sight translation of the informed consent form in person

☐ translated the informed consent form over the telephone

Name of interpreter:

Interpreter code:

Language:

D. Person/substitute decision-maker consent

I acknowledge that:

- I have read and understood the information provided in the “*Queensland COVID-19 Vaccination Information*” resource which includes details regarding all real and potential side effects associated with having the COVID-19 vaccination.
- I am aware I can discuss the benefits and risks of having the COVID-19 vaccination by telephoning 134 COVID (13 42 68) or discuss with my doctor or vaccination centre health professional.
- I understand that consent can be withdrawn at any time before vaccination.

On the basis of the above statements, I hereby give consent to receive/or the person to receive, the recommended doses of the COVID-19 vaccine.

Name of person/substitute decision-maker:

Signature:

Date:

E. Additional health worker comments

COVID-19 vaccination information

Patient information



COVID-19

Coronavirus (COVID-19) can cause serious ongoing health issues, and sometimes death. It is still a new virus and as such we are still learning more about it.

COVID-19 vaccination

Having a COVID-19 vaccine is an important step to take to reduce the serious effects of COVID-19 in people who become infected with the virus. Current evidence shows that people who have received a COVID-19 vaccine have a much lower chance of developing more serious disease from COVID-19 compared to those who did not get the vaccine. Even though the COVID-19 vaccine has been shown to be very effective there is still a chance you may get COVID-19.

Queensland has two COVID-19 vaccines available – the Pfizer vaccine (also known as Comirnaty) and the AstraZeneca vaccine.

Both vaccines are designed to promote our immune system to make antibodies to the spike protein of the virus. This means if you were to ever get the COVID-19 virus, your body is better prepared to fight the illness and reduce its severity.

Importantly, even after vaccination, Queenslanders will still be encouraged to wash their hands regularly and maintain physical distance to help protect yourself and others.

How is the COVID-19 vaccine given?

The vaccine is given via an injection into your upper arm by a health professional who has been trained in giving the COVID-19 vaccine. You must remain in the vaccination clinic for observation for at least 15 minutes after vaccination. Depending on your medical history, you may be asked to wait in the clinic for 30 minutes. To get the full benefit of the vaccine you will need two injections, several weeks apart.

Who can get the COVID-19 vaccine?

The Pfizer vaccine is suitable for people aged 16 years and older.

The AstraZeneca vaccine is suitable for people aged 18 years and older.

Who should not get the COVID-19 vaccine?

You must not get a COVID-19 vaccine if you have had any of the following:

- anaphylaxis (a severe allergic reaction) to a previous dose of the same COVID-19 vaccine
- anaphylaxis after exposure to any ingredient of the COVID-19 vaccine*.

If you have ever had an allergic reaction or anaphylaxis to anything else, including after receiving a vaccine, you can still get the vaccine, but you must tell the immunisation provider beforehand.

If you have recently had any other vaccine (e.g. flu vaccine) you should wait at least 14 days to have the COVID-19 vaccine.

Is the COVID-19 vaccine safe for pregnant and breastfeeding women?

At this stage, COVID-19 vaccines are not routinely recommended to be given during pregnancy as there is limited experience with the use of COVID-19 vaccines in pregnant women. As we learn more about the vaccines, this advice may change. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you consider receiving this vaccine.

***Pfizer-Comirnaty BNT162b2 [mRNA] COVID-19 Vaccine includes the following ingredients:** mRNA, ((4-hydroxybutyl)azanediyl) bis(hexane-6,1-diyl)bis (2-hexyldecanoate) (ALC-0315), 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159), distearoylphosphatidylcholine (DSPC), cholesterol, potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate and sucrose.

***AstraZeneca (ChAdOx1-S) COVID-19 Vaccine includes the following ingredients:** chAdOx1-S, disodium edetate, ethanol absolute, histidine hydrochloride monohydrate, histidine, magnesium chloride hexahydrate, polysorbate 80, sodium chloride and sucrose.

If you are breastfeeding you can receive a COVID-19 vaccine at any time. You do not need to stop breastfeeding before or after vaccination.

What to expect after your vaccination

All medicines and vaccines can cause side effects and most of these are minor effects. However, if you do experience any side effects following vaccination and are worried, contact your GP.

Common side effects

Pfizer	Injection site pain/swelling, tiredness, headache, muscle pain, chills, fever, joint pain.
AstraZeneca	Injection site tenderness/pain/warmth/itching, generally feeling unwell, tiredness, headache, chills or feeling feverish, joint pain or muscle pain, feeling sick (nausea).

Less common side effects

Pfizer	Injection site redness/itching, nausea, enlarged lymph nodes, feeling unwell, pain in the limb, insomnia.
AstraZeneca	Fever, swelling or redness at the injection site.

These side effects are usually mild and usually go away within one or two days. If you experience pain at the injection site or fever, headaches or body aches after vaccination, you can take paracetamol or ibuprofen. These help reduce the above symptoms (you do not need to take paracetamol or ibuprofen before vaccination). If there is swelling at the injection site, you can use a cold compress.

Rare side effects

Pfizer	Severe allergic reaction (anaphylaxis), temporary one-sided facial drooping (also called Bell's palsy).
AstraZeneca	Severe allergic reaction (anaphylaxis).

After you have left the vaccination location, seek medical attention if:

- You think you are having an allergic reaction. Call 000 if you experience severe symptoms, such as difficulty breathing, wheezing, a fast heartbeat or collapsing.
- You are worried about a potential side effect or have new or unexpected symptoms.
- You have an expected side effect of the vaccine which has not gone away after a few days.

COVID-19 testing after vaccination

Some side effects from COVID-19 vaccination might be similar to symptoms of COVID-19 (e.g. fever). Both COVID-19 vaccines do not contain any live virus and cannot cause COVID-19. You do not need to get a COVID-19 test or isolate if you develop general symptoms like fever, headache or tiredness in the first two days after vaccination or if you are sure that you don't have any respiratory symptoms (e.g. runny nose, cough, sore throat, loss of smell or loss of taste).

Where can I get more information or ask questions?

Call 134 COVID (13 42 68) 24 hours, 7 days a week for information on the vaccine or assistance with vaccination bookings or appointment enquiries. You can also ask for an interpreter – it is free.

Stay informed at www.health.gov.au and www.qld.gov.au/covid19vaccine.

Privacy notice: Personal information collected by Queensland Health and the Hospital and Health Services (collectively Queensland Health) is handled in accordance with the *Information Privacy Act 2009*. Queensland Health is collecting your personal information including your name, address, phone number, email address, age, gender, Indigenous status, vaccine details and Medicare number in accordance with *Australian Immunisation Register Act 2015* in order to manage recall, reminders, clinical follow up; or control and enhanced safety monitoring of vaccines. This information will be given to the Australian Immunisation Register for the purpose of maintaining information about vaccinations of individuals. Your personal information will also be used to administer the Queensland Health COVID-19 immunisation program ('Program'). Your relevant medical information including existence of any medical conditions, allergies, or severe reactions following any vaccine will be collected for the assessment of whether and which vaccine you should be administered. If you choose not to provide the information it may affect Queensland Health's ability to respond and deliver services to you, including administering the COVID-19 vaccine to you. All personal information will be securely stored and only accessible by appropriately authorised officers within the Queensland Health. Your de-identified data (information that will not identify you) will be shared with Commonwealth Government and national immunisation safety, monitoring and surveillance organisations for the purpose of monitoring adverse events following immunisation and evaluating disease prevention and control (immunisation) efforts. Your personal information will not be disclosed to other third parties without consent, unless the disclosure is authorised or required by or under law. For information about how Queensland Health protects your personal information, or to learn about your right to access your own personal information, please see our website at www.health.qld.gov.au/global/privacy and www.health.qld.gov.au/system-governance/contact-us/access-info/privacy-contacts.