

21 March 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H202117364

Tēnā koe s 9(2)(a)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 9 December 2021 for information regarding the COVID-19 vaccine. Each part of your request is responded to below.

1. *Can you please advise what information is provided to registered (& Regulated) health professionals to give to persons prior to vaccination and whether, under the "HDC Code of Rights Act, 1994" that constitutes the definition of "fully informed consent"*

As part of the informed consent process, the consumer is advised on side effects that are both common and rare, and the importance of seeking medical attention in the case of serious side effects.

Below are several resources which are available at the Vaccination Sites that consumers can take home with them. They all include information on common side effects, and what to do in the case of severe side effects:

- *Getting your COVID-19 vaccine: What to expect*
www.health.govt.nz/system/files/documents/pages/covid-19-vaccine-what-to-expect-20oct2021.pdf
- *COVID-19 Vaccine: After your immunisation*
www.health.govt.nz/system/files/documents/pages/covid-19-vaccine-after-your-vaccination-jan2022.pdf
- *COVID-19: Need to know brochure*
www.health.govt.nz/system/files/documents/pages/about-the-pfizer-booster-210122.pdf
- *Protecting your tamariki*
www.health.govt.nz/system/files/documents/pages/protecting-your-tamariki-covid-19-23dec2021.pdf
- *Getting the COVID-19 vaccine: Information for 12-to-15-year-olds*
www.health.govt.nz/system/files/documents/pages/covid-19-vaccine-information-12-15-year-olds-20oct2021.pdf
- *COVID-19 Vaccine: After your child's Pfizer vaccination*
www.health.govt.nz/system/files/documents/pages/after-your-childs-pfizer-vaccination-210222.pdf

2. Can you advise what qualifications a vaccinator for the purposes of Covid 19 requires to vaccinate individuals with the mRNA vaccines?

Vaccinators hold a range of qualifications as there are several vaccinator roles with different scopes. More information about the vaccinator training and pathways available can be found at: covid.immune.org.nz/education/joining-covid-19-workforce/joining-covid-19-workforce-education-profession

3. And how this might differ to historical "attenuated virus" type vaccines?

The only difference in qualifications for the non-COVID vaccines are that the staff will not necessarily have completed the extra COVID vaccine training, The COVID vaccine training is 'top up' to the core training that covers all areas of vaccination.

4. What information is given to vaccinators regarding cold chain custody of vaccines and documentation of these requirements set out by the manufacturer?

Information about cold chain requirements is given to vaccinators through a variety of channels including:

- training
- the Immunisation Advisory Centre (IMAC) resources, which are publicly available at: <https://covid.immune.org.nz/workforce-resources-and-faq/written-resources?tags=183>
- the Ministry COVID-19 Vaccine operating and planning guidelines, which are publicly available at: health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals/covid-19-vaccine-operating-and-planning-guidelines#operate

5. And the end points of when the Vaccines shouldn't be used?

Expiry information is included on the labels of the vaccines.

6. How unused vaccine product is disposed of?

Destruction of the vials that have been opened or are unused must take place at a facility appropriately licensed to handle and destroy pharmaceutical waste, medical waste, and/or hazardous waste, and destruction must be by means of grinding or incineration.

7. Can you confirm if "aspiration" of the syringe is (or is NOT) required for IM (intramuscular) injection of Covid 19 mRNA vaccines?

Information regarding the aspiration/pull back of syringes during COVID-19 vaccination is available on the IMAC website: covid.immune.org.nz/faq/there-need-aspirate-giving-covid-vaccine

8. Can you confirm if vaccinators are not required to be regulated health professionals? I.e working as a lay person having completed a "vaccinator course" online or in person. (I understand a MP of parliament has done training to become a vaccinator)?

A new class of vaccinators was introduced in 2021 to support the COVID-19 vaccine programme rollout. COVID-19 vaccinators in this class are not required to be regulated health professionals however they work under the direct clinical supervision and guidance of

qualified health practitioners to administer the COVID-19 vaccine, after undertaking training and assessment.

Further information about the audience and eligibility for this course can be found on IMAC's website at: covid.immune.org.nz/education/other-covid-19-vaccination-workforce-education/covid-19-vaccinator-working-under, and on the Ministry website at: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-strategy-planning-insights/covid-19-expanding-vaccinator-workforce

All COVID-19 vaccinators are authorised under section 44AB of the Medicines Regulation 1984, which is available at: <https://www.legislation.govt.nz/regulation/public/1984/0143/latest/LMS500584.html>

9. For the general population that do not understand Te Reo Maori can you translate , kaiāwhina, kaiarahi, kaimanaaki listed in the MOH Covid19 vaccinators brochure?

Kaiāwhina, kaiarahi and kaimanaaki are terms used for a range of community health worker roles in New Zealand. They typically work in Māori or Pacific health settings, supporting the wider health team and providing advocacy and practical support to health consumers and whānau to promote health and wellbeing, and to help navigate the health system.

10. Can you please disclose what information is given to "lay" vaccinators in regards to possible adverse effects and end points to which a Registered Health professional would be called over for assistance / triage?

COVID-19 vaccinators working under supervision receive training on warning signs for possible adverse effects, including fainting, anxiety attacks, and any concerns regarding possible anaphylaxis. They always work within the direct clinical supervision and guidance of a qualified health practitioner, who must be on site and in easy calling range to provide immediate support as needed.

11. For drive through vaccination centers, are there wait times, similar to other traditional vaccines, where the vaccinated person must remain for a period of time prior to continuing their day?

Similar to traditional vaccination centres, there are wait times for drive-through vaccinations centres. These centres have capacity for vehicles to park for at least 15 minutes during the observation period.

12. Can you advise what the person being vaccinated is told about possible support options, if on the "very rare" case they suffer harm, disability, or death following a mRNA Vaccine?

The resource provided during vaccination, *Getting your COVID-19 vaccine: What to expect*, includes this information for consumers who are concerned about their symptoms post-vaccination: 'call Healthline on 0800 358 5453. If you have an immediate concern about your safety, call 111, and make sure you tell them you've had a COVID-19 vaccination so that they can assess you properly'.

13. Can you advise what information is given to persons being vaccinated about the process of reporting adverse side effects, side effects of special interest, and other mandatory reporting requirements of the sponsor of the medicine or "therapy" as required by CDC (worldwide) and by our governments medicines relating body MedSafe (CARM)?

The resource handed out at vaccination includes this link for the Post-Vaccine Symptom Check: <https://report.vaccine.covid19.govt.nz/s/>

The Ministry website provides information on vaccine side effects and how to report adverse events and allergic reactions: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-side-effects-and-reactions#how-to-report

You can read more about the vaccine safety monitoring process here: www.medsafe.govt.nz/COVID-19/monitoring-process.asp

14. Can you confirm or deny the presence of "placebos" amongst the vaccination batches and what percentage these might be?

There are no placebos amongst vaccination batches.

15. Can you please provide information on the remuneration provided to vaccinators?

Many health workers administer vaccinations as part of their substantive roles, for which remuneration varies significantly based on the nature of their role, experience and employment agreement. As such we are unable to provide a definitive response to this question.

16. Can you please provide information on the remuneration of a Company or Organisation contracted to become a vaccination center?"

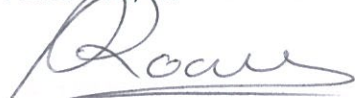
COVID-19 GP and Pharmacy Vaccination per dose	\$36.05 ex GST
COVID-19 GP and Pharmacy Vaccination-Out of Hours per dose	\$48.72 ex GST

Please note, vaccination providers may be eligible for additional payments in some circumstances. For example, in-home providers or mobile clinics.

I trust this information fulfils your request. Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests

Nāku noa, nā



Astrid Koornneef

Director

National Immunisation Programme