MINISTRY OF HEALTH
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11 February 2022

Ross Francis

By email: fyi-request-15415-2c249621@requests.fyi.org.nz
Ref: H202105506

Tēnā koe Ross

Re. 554392 Official Information Act investigation – Refusal complaint

I refer to your request under the Official Information Act 1982 (the Act) on 10 May 2021 to the Ministry of Health (the Ministry). Following your complaint to the Ombudsman, the Ministry has reconsidered the responses to questions 2, 6, 7, 8, 9, 13 and 14 of your 10 May 2021 request. These have been set out for you below.

> *2. What new information, if any, has been added to the online education course for May 2021? (Online course for vaccinators administering the COVID-19 vaccine).*

The Immunisation Advisory Centre (IMAC) has been contracted by the Ministry to provide education, training and support to all health professionals and allied workforces during the COVID-19 vaccine rollout. This part of your request would be best directed to IMAC to confirm whether any information has been added to the *COVID-19 Authorised Vaccinator Education Course and COVID-19 Vaccinator – Working Under Supervision Course*. IMAC are not subject to the Act, however, can be contacted with questions here: https://covid.immune.org.nz/about/contact-us

> *6. The online course states: "A few groups of people should not get the vaccine, and some others should consult with their doctor or follow special procedures". Which groups should not get the vaccine, and who should consult with their doctor or follow special procedures? What special procedures should be followed?*

The Ministry has interpreted 'special procedures' to mean waiting for a period of time before getting the vaccination. Vaccine advice for other groups, including whether they should discuss the timing of their vaccination with their doctor or specialist, or whether they should wait for a period of time before they get their vaccination is available on the Ministry website here: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-health-advice

The Pfizer/BioNTech COVID-19 vaccine (the Pfizer vaccine) has an excellent safety profile and there are estimated to be less than a hundred people in Aotearoa who cannot receive it at all. The list of reasons why the Pfizer vaccine may not be suitable is short:

Before the first dose:

- A history of severe allergic reaction (anaphylaxis) to an ingredient of the vaccine. This is very rare, and only applies to previous anaphylaxis to a stabiliser in the vaccine called polyethylene glycol (PEG). However, problems with PEG most commonly occur after having it by mouth, and so there may not be any problem with having it in a vaccine. Cases like this require expert assessment by an immunology specialist.

After problems with the first dose:

- Those who had a severe allergic reaction (anaphylaxis) after the first dose. This typically occurs within 15 minutes of receiving it and is the main reason for the post-vaccination observation period. Even when suspected anaphylaxis has occurred after the first dose, increasing experience now shows that many people can be revaccinated safely in a specialist immunology clinic setting.
- Those who had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining around the heart) after their first dose of this vaccine. Myocarditis or pericarditis after the vaccine is rare. Diagnosis requires special tests and often assessment by a heart specialist.

The IMAC fact sheet for health professionals regarding the management of those with allergic reaction to their first dose of Comirnaty or history of PEG allergy is available here: https://covid.immune.org.nz/sites/default/files/2021-09/Update%20around%20management%20of%20those%20with%20allergic%20reaction%20to%20their%20first%20dose%20of%20Comirnaty%20or%20history%20of%20PEG%20allergy.pdf

7. The online course states: "The safety and efficacy of the mRNA-CV in children and young adults aged less than 16 years of age have not yet been established". Has anyone under 16 received one or two doses of the Pfizer vaccine in New Zealand?

From 19 August 2021, 12- to 15-year-olds became eligible for the Pfizer vaccine. Prior to this date, 20 verified vaccinations were administered to children under the age of 16 years.

8. To date, what have been the most serious adverse reactions to the Pfizer vaccine, in New Zealand and overseas?

Adverse reactions to COVID-19 vaccines are continuously being carefully monitored by Medsafe to continue to ensure their safety. Suspected adverse events following immunisation (AEFIs) to COVID-19 vaccines are reported to the Centre for Adverse Reactions Monitoring (CARM). Regularly updated summaries of any adverse effects from the vaccine can be found at www.medsafe.govt.nz/COVID-19/vaccine-report-overview.asp

An AEFI is considered serious if it:

- is a medically important event or reaction
- requires hospitalisation or prolongs an existing hospitalisation
- causes persistent or significant disability or incapacity
- is life threatening
- causes a congenital anomaly/birth defect
- results in death.

Determining which AEFI is the most serious is considered an opinion. As such, this part of your request for the most serious adverse reaction to the Pfizer vaccine in New Zealand is refused under section 18(g)(i) of the Act, as the information requested is not held by the Ministry.

Please note however, that as of 31 December 2021 there have been two deaths that the COVID-19 Vaccine Independent Safety Monitoring Board considers likely to be related to COVID-19 vaccination.

The Ministry does not hold information on serious adverse reactions to the Pfizer vaccine overseas, therefore this part of your request is also refused under section 18(g)(i) of the Act.

9. How many people have declined to be vaccinated because the vaccinator was unable to answer their question(s) about the vaccine?

The Ministry has received reporting that shows, as of 28 January 2022, a total of 1,488 people have attended a clinic for vaccination and then declined the vaccination. However, the Ministry does not have information on the reason why these people declined. As such, this part of your request is refused under section 18(g)(i) of the Act, as the information is not held by the Ministry or any other agency subject to the Act.

13. The online course states: "We would expect COVID-19 vaccines to provide protection for longer than 2 months, although exactly how long for, remains unknown at this stage". What action, if any, does the Health Ministry intend to take in the event that the vaccine offers little or no long-term protection?

Current evidence shows that immunity produced by the Pfizer vaccine wanes over time, particularly from six months after a primary vaccination course.

On 21 October 2021, Pfizer released preliminary trial data indicating that boosters of the Pfizer vaccine achieved 95.6 percent relative efficacy against symptomatic disease (compared to two primary doses and no booster dose) during a period in which Delta was the prevalent strain of transmission. This represents a restoration of the protection provided by the original two-dose course. You can read more about this here: www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-phase-3-trial-data-showing

On 8 November 2021, Medsafe approved a booster dose of the Pfizer vaccine for people aged 18 and older, at least six months after completion of the primary course. The Ministry is actively monitoring all emerging data and international evidence on the efficacy of vaccines.

14. A recent report in The Lancet concluded:

"Publicly available data from the Pfizer-BioNTech and Moderna vaccine trials suggest an imbalance in the incidence of Bell's palsy following vaccination compared with the placebo arm of each trial. Combining data from both trials, among nearly 40000 vaccine arm participants, there were seven Bell's palsy cases compared with one Bell's palsy case among placebo arm participants…the observed incidence of Bell's palsy in the vaccine arms is between 3·5-times and 7-times higher than would be expected in the general population."

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Are intended recipients of the vaccine in New Zealand routinely informed of possible side-effects or adverse reactions, or do intended recipients have to ask for such information? What information, if any, is being provided to recipients about the observed incidence of Bell's palsy in vaccine trials?

Given that roll-out of the vaccine has begun, a prompt response to this request would be appreciated.

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
https://www.health.govt.nz/system/files/documents/pages/covid-19-vaccine-what-to-expect-20oct2021.pdf

COVID-19 Vaccine: After your immunisation
https://www.health.govt.nz/system/files/documents/pages/covid-19-vaccine-after-your-vaccination-jan2022.pdf

COVID-19: Need to know brochure
https://www.health.govt.nz/system/files/documents/pages/about-the-pfizer-booster-210122.pdf

Protecting your tamariki
https://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
https://www.health.govt.nz/system/files/documents/pages/covid-19-vaccine-information-12-15-year-olds-20oct2021.pdf

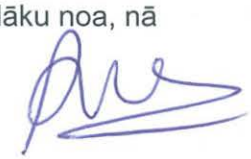
COVID-19 Vaccine: After your child's Pfizer vaccination
https://www.health.govt.nz/system/files/documents/pages/after-your-childs-pfizer-vaccination-210222.pdf

We can confirm that information indicating that Bell's Palsy is a rare side effect is publicly available in the Pfizer datasheet. Information about Bell's palsy as a rare side effect is also available on the Ministry's website:
https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-side-effects-and-reactions

For more information, this part of your request would be best directed to IMAC. Though IMAC are not subject to the Act, they can be contacted with questions here:
https://covid.immune.org.nz/about/contact-us

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.

Nāku noa, nā



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