


5 August 2021

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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 27 July 2021. I will respond to each part of your request in turn.

1. *A comprehensive list of all of the ingredients in the Pfizer injection.*

The ingredients list for the Pfizer vaccine is publicly available here:

www.medsafe.govt.nz/regulatory/ProductDetail.asp?ID=21938.

2. *Comprehensive information about the potential benefits of the Pfizer agent -- will getting this agent prevent my contracting COVID or transmitting COVID? Will it have any effect on my immune response to the flu or other common respiratory viruses?*

Information about the benefits of the Pfizer vaccine is publicly available here:

www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-effectiveness-and-protection; please see also www.medsafe.govt.nz/COVID-19/q-and-a.asp.

The COVID-19 vaccine will not protect against the flu or other common respiratory viruses as these are caused by different viruses.

3. *What are the potential adverse reactions to the Pfizer agent? As of today, how many people worldwide and in New Zealand have reported adverse reactions, how many of these have been major, and how many people have died?*

Known side effects of the Pfizer vaccine are publicly available here:

www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf; see also www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-side-effects-and-reactions.

In New Zealand, adverse reactions are reported to the Centre for Adverse Reactions Monitoring (CARM). CARM's weekly reports on the number of adverse events following immunisation (AEFI) in New Zealand are publicly available here: www.medsafe.govt.nz/COVID-19/vaccine-report-overview.asp.

I am unable to provide you with global statistics on adverse reactions as this information is not held by the Ministry. This part of your request is refused under section 18(g)(i) of the Act as the information requested is not held by the Ministry and there are no grounds for believing it is held by another agency subject to the Act.

4. *What are the medical contraindications to the Pfizer injection?*

This information is publicly available here:

www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf; see also www.health.govt.nz/our-work/immunisation-handbook-2020/5-coronavirus-disease-covid-19#23-6.

5. *How does the Pfizer injection differ from the fully researched and approved vaccines I have received in the past?*

Medsafe evaluates applications for all new medicines, including vaccines, to ensure that they comply with international standards and local requirements for quality, safety and efficacy. Only if the medicine meets these standards will Medsafe recommend approval for use in New Zealand. Medsafe prioritised and streamlined the assessment process for the Pfizer vaccine in order to reach a decision on approval sooner, but did not compromise on the integrity of this process or on the safety requirement of the vaccine. Information about this process is publicly available: www.medsafe.govt.nz/COVID-19/vaccine-approval-process.asp.

6. *What happens to the synthetic mRNA that is injected into a person? Where does it go and how long does it stay within the body?*

7. *Where do the spike proteins travel within the body -- does it cross the blood-brain barrier? Can the spike proteins cause damage on its own? Can this protein trigger an autoimmune response towards vital organs? Is it linked to blood clots? Can the spike proteins be eliminated thoroughly and safely from the body?*

Information on how the Pfizer vaccine works is publicly available here:

www.medsafe.govt.nz/COVID-19/mRNA-vaccines.asp. The mRNA is broken down by the body shortly after vaccination. Animal studies showed that the mRNA in the Pfizer vaccine is broken down within a couple of weeks.

Information on how spike proteins work is also publicly available. Here are some resources which you may find useful:

www.epa.govt.nz/community-involvement/science-corner/sars-cov-2-vaccines-and-the-hsno-act/.

www.nebraskamed.com/COVID/where-mrna-vaccines-and-spike-proteins-go.

The number of reports of blood clots after vaccination is lower than the base rate of blood clots in the general population.

8. *What happens to the lipid nanoparticles that appear to be a part of the Pfizer agent? Where do they travel within the body? What are the potential adverse effects of having these particles within the body? Can they be eliminated?*

Animal studies have indicated that the lipid nanoparticles which contain the mRNA rapidly leave the bloodstream in the first 24 hours following administration. Most of these then are transported to the liver. They are broken down by the body within 2 to 6 weeks. This information is publicly available here: www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf.

9. *Who will assume liability if I develop an adverse reaction? Pfizer? The government? My employer? You?*

The Accident Compensation Corporation (ACC) can provide treatment and support for injuries caused by COVID-19 vaccination if the criteria for treatment injury are met. This means there is a physical injury caused by the vaccination, that is not a necessary part or ordinary consequence of the treatment. For more information see the ACC website: www.acc.co.nz/providers/lodging-claims/lodging-a-claim-for-a-patient/#information-for-specific-injury-types.

10. *I understand that the Pfizer injection is only authorised under provisional consent -- so that questions of long-term efficacy and safety have not yet been answered - am I correct in this?*

The Pfizer vaccine has been granted provisional consent for a period of nine months. This allows a number of conditions to be placed on the consent that require the sponsor company to provide additional information and conduct certain activities. At the end of this period, the vaccine may be given full consent, given renewed provisional consent for a further period of time, or the consent may not be renewed. This decision will be made after review of the additional information provided to Medsafe by the company since provisional consent was initially granted. Medsafe has assessed safety and efficacy data from the six-month follow up point in the pivot clinical trial. This and other clinical studies are currently ongoing, which is normal for a new vaccine.

If so, do you believe, as my doctor, that I should receive this agent without such data available?

11. *If I contract COVID after having received the Pfizer agent, how would you treat me?*

While the Act enables people to request official information from the Ministry, it only applies to information it holds. There is no obligation to create information or compile information it does not hold in order to respond to requests, nor is the Ministry obliged to provide or prove an opinion. Therefore, this part of your request is refused under section 18(g)(i) of the Act, as the information requested is not held by the Ministry and there are no grounds for believing it is held by another agency subject to the Act.

If you have concerns, I encourage you to discuss these with your doctor.

12. *If I become ill after the Pfizer injection, how will you be able to tell that it is caused by the Pfizer injection? Will you automatically report any symptoms/adverse effects that I will experience to CARM?*

It difficult to establish a causal relation between illness or reactions experienced following any vaccine as there are many individual factors at play. Any adverse reactions you experience after receiving the Pfizer vaccine and which you suspect may be linked to your vaccination can be reported to CARM. Your health professional is encouraged to report these on your behalf, although they are not legally required to do so. You are also encouraged to lodge a report yourself. For more information on reporting adverse reactions see:

www.medsafe.govt.nz/COVID-19/monitoring-process.asp.

13. *Are you aware of early treatment protocols for COVID, such as Ivermectin, hydroxychloroquine, zinc, steroids, Vit-D and other medications? Would you be willing to prescribe these agents if I were to contract COVID?*

At present, the only approved medication for COVID-19 is dexamethasone tablets. Medical practitioners are permitted to use any medicine for a particular patient in their care at their discretion; however, unapproved medicines have not been evaluated by Medsafe for safety and efficacy. If your healthcare professional chose to prescribe any of the mentioned agents to treat

a patient with COVID-19 it would be their responsibility to ensure that they are aware of any safety issues and that they communicate the risks and benefits to their patients. See www.medsafe.govt.nz/COVID-19/medicine-approval-process.asp.

14. *If I have no symptoms of a respiratory virus, do you believe I can infect others, and if so, how?*

Flu viruses are well-known to be infectious prior to the development of symptoms. Please see: www.cdc.gov/flu/about/disease/spread.htm.

15. *How dangerous is COVID compared to other common respiratory viruses such as the flu? Can you provide me with some epidemiologic data?*

Information on how COVID-19 and influenza viruses differ can be found here: www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/coronavirus-disease-covid-19-similarities-and-differences-with-influenza.

16. *If I agree to receive the Pfizer injection, will it protect me fully if I am exposed to any variant, current and future, of COVID?*

This information is publicly available here: www.medsafe.govt.nz/COVID-19/q-and-a.asp.

17. *If I have already been exposed to the virus, do I really need the Pfizer injection, and If I do, is there a risk of getting more sick if I am re-exposed again to the virus? I will assume you are aware of the New Zealand Bill of Rights and the Nuremberg Code, which stipulate that a person has a right to refuse medical interventions. Even if a COVID vaccine is developed and fully approved, will you respect my right to decline an invitation to receive it?"*

This information is publicly available at the following link: www.medsafe.govt.nz/COVID-19/q-and-a.asp. Additionally, it is not mandatory to be vaccinated against COVID-19.

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



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Health System Improvement and Innovation