

15 February 2022

s 9(2)(a)

Ref: H202117410

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 10 December 2021 for:

"1. any correspondence, reports, memos, minutes, emails relating to the safety of (a mother) receiving COVID-19 Pfizer vaccine (Comirnaty) while breastfeeding for a baby/child being breastfed; i.e. the safety and risks to the baby/child being breastfed.

2. any correspondence, reports, memos, minutes, emails relating to studies or any other evidence showing whether or not there are any immediate or long term effects on a child if their mother receives COVID-19 Pfizer vaccine (Comirnaty) while breastfeeding.

3. any other information or correspondence (not already covered in the above points) that led to the Ministry of Health determining and providing advice that the COVID-19 Pfizer vaccine (Comirnaty) is safe to receive while breastfeeding.

4. any correspondence, reports, memos, minutes, emails etc that acknowledge the fact that Pfizer's own documentation (last updated 9 December 2021) states that:

"Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion."

Statement is found in 'Pfizer Emergency Use Full Prescribing Info Fact Sheet Pfizer-BioNTECH COVID-19 vaccine' for Health Professionals found here <https://www.pfizer.com/products/product-detail/pfizer-biontech-covid-19-vaccine>"

On 16 December 2021, the Ministry advised that your request was likely to be refused under section 18(f) of the Act as it would require substantial research and collation. On 20 December 2021, you refined your request to:

"1. any reports, memos, minutes relating to the safety of (a mother) receiving COVID-19 Pfizer vaccine (Comirnaty) while breastfeeding for a baby/child being breastfed; i.e. the safety and risks to the baby/child being breastfed.

2. any reports, memos, minutes, relating to studies or any other evidence showing whether or not there are any immediate or long term effects on a child if their mother receives COVID-19 Pfizer vaccine (Comirnaty) while breastfeeding.

3. any other information (not already covered in the above points) that led to the Ministry of Health determining and providing advice

that the COVID-19 Pfizer vaccine (Comirnaty) is safe to receive while breastfeeding.

4. any reports, memos, minutes, etc that acknowledge the fact that Pfizer's own documentation (last updated 9 December 2021) states that:

"Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion."

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On 12 January 2022, the Ministry provided a response to your request (attached as Document 1). On 13 January 2022, you responded as follows:

Points 1 and 2 have not been responded to. Are responses to these going to be provided in a separate response?

One document has been identified in scope of your request and an excerpt has been released in accordance with section 16(1)(e) of the Act, with information deemed out of scope of your request excluded (attached as Document 2).

Point 4 response also does not accurately reflect the request which is seeking copies of minutes, memos, reports that refer to that which is outlined in point 4.

Part 4 of your request is refused under section 18(e) as the information requested does not exist.

As mentioned in the 12 January 2022 response, while data on the effects of vaccination on breastfed babies is limited, studies show there are no additional safety concerns or issues with continuing to breastfeed after vaccination. Information relevant to your request has been published on FYI.org.nz at: www.fyi.org.nz/request/16233/response/62117/attach/3/H202109584%20Response%20Letter.pdf.

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



Jan Torres
Acting Manager, OIA Services
Office of the Director-General

From: OIA Requests
Sent: Wednesday, 12 January 2022 3:08 pm
To: s 9(2)(a)
Cc: OIA Requests
Subject: Response to your official information act request (ref_H202117410)

Tēnā koe s 9(2)

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 10 December 2021 for:

“1. any correspondence, reports, memos, minutes, emails relating to the safety of (a mother) receiving COVID-19 Pfizer vaccine (Comirnaty) while breastfeeding for a baby/child being breastfed; i.e. the safety and risks to the baby/child being breastfed.

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On 16 December 2021, the Ministry advised that your request was likely to be refused under section 18(f) of the Act as it would require substantial research and collation. On 20 December 2021, you refined your request as suggested. I will respond to each part of your request in turn.

1. any reports, memos, minutes relating to the safety of (a mother) receiving COVID-19 Pfizer vaccine (Comirnaty) while breastfeeding for a baby/child being breastfed; i.e. the safety and risks to the baby/child being breastfed.

2. any reports, memos, minutes, relating to studies or any other evidence showing whether or not there are any immediate or long term effects on a child if their mother receives COVID-19 Pfizer vaccine (Comirnaty) while breastfeeding.

3. any other information (not already covered in the above points) that led to the Ministry of Health determining and providing advice that the COVID-19 Pfizer vaccine (Comirnaty) is safe to receive while breastfeeding.

The datasheet for Comirnaty contains some information about breastfeeding. Datasheets contain information about the medicine, including the approved indication and information from clinical trials which have been run. The datasheet for Comirnaty is available at: www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf. I have copied the relevant part for you below:

Lactation

It is unknown whether BNT162b2 [mRNA] is excreted in human milk. A combined fertility and developmental toxicity study in rats did not show harmful effects on offspring development before weaning (see Fertility).

While lactating people were not included in phase III studies, as with all schedule vaccines, there are no safety concerns about vaccinating lactating people with Comirnaty. Information on receiving the COVID-19 vaccine while breastfeeding, including links to relevant clinical studies, is available on the Ministry's website at: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-health-advice/covid-19-vaccine-pregnancy-and-breastfeeding.

*4. any reports, memos, minutes, etc that acknowledge the fact that Pfizer's own documentation (last updated 9 December 2021) states that:
"Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion."
Statement is found in 'Pfizer Emergency Use Full Prescribing Info Fact Sheet Pfizer-BioNTECH COVID-19 vaccine' for Health Professionals found here <https://www.pfizer.com/products/product-detail/pfizer-biontech-covid-19-vaccine>*

As stated above, while data on the effects of vaccination on breastfed babies is limited, studies show there are no additional safety concerns or issues with continuing to breastfeed after vaccination.

You may be interested in the response to a similar request has been published on FYI.org.nz: www.fyi.org.nz/request/16233/response/62117/attach/3/H202109584%20Response%20Letter.pdf.

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.

Nāku noa, nā

OIA Services
Government Services
Office of the Director-General
Ministry of Health
E: oiagr@health.govt.nz



Excerpt A: Request for Advice from Minister Verrall, CV-TAG | Vaccination for COVID-19 in Pregnancy, Version 4 | 11 June 2021

Request outline

- To provide information regarding vaccination against COVID-19 in pregnant or breastfeeding women that Health Professionals can provide to their patients / clients.
- To provide a document which can serve as a template for discussion between relevant professional, public and government agencies so that consistent information can be provided across the maternity sector.

NOTE: The language used in this document is scientific. It is not expected that the responses to the questions will be used word-for-word as information to mothers and whānau.

Organisations with recently updated advice

[RANZCOG \(NZ & AUS\)\[38\]](#)

[ATAGI \(Aus\) \[39\]](#)

Last updated 9th June 2021

A joint statement from The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) and the Australian Technical Advisory Group on Immunisation (ATAGI) recommend that pregnant women are routinely offered COVID-19 vaccination at any stage of pregnancy. This is because the risk of severe outcomes from COVID-19 infection is significantly higher for pregnant women and their unborn baby. Global surveillance data from large numbers of pregnant women have not identified any significant safety concerns with mRNA COVID-19 vaccines given at any stage of pregnancy. Furthermore, there is also evidence of antibody in cord blood and breastmilk, which may offer protection to infants through passive immunity. Pregnant women are encouraged to discuss the decision in relation to timing of vaccination with their health professional. Women who are trying to become pregnant do not need to delay vaccination or avoid becoming pregnant after vaccination.

[RCOG \(UK\)\[40\]](#)

Updated 28th May 2021

The Royal College of Obstetricians and Gynaecologists refers to the latest advice from the Joint Committee on Vaccination and Immunisation (JCVI) which states that:

- COVID-19 vaccines should be offered to pregnant women at the same time as the rest of the population, in line with the age group roll out.
- Women may wish to discuss the benefits and risks of having the vaccine with their healthcare professional and reach a joint decision based on individual circumstances. However, as for the non-pregnant population, pregnant women can receive a COVID-19 vaccine even if they have not had a discussion with a healthcare professional.

- Women should not stop breastfeeding in order to be vaccinated against COVID-19.
- Women trying to become pregnant do not need to avoid pregnancy until after vaccination and there is no evidence to suggest that COVID-19 vaccines will affect fertility.

Public Health England

Updated 30 April 2021

Public Health England provides the following information:

- The COVID-19 vaccines available in the UK have been shown to be effective and to have a good safety profile. These vaccines do not contain live coronavirus and cannot infect a pregnant woman or her unborn baby in the womb. There is no known risk with giving inactivated virus or bacterial vaccines or toxoids during pregnancy or whilst breast-feeding.
- The Joint Committee on Vaccination and Immunisation (JCVI) has advised that pregnant women should be offered COVID-19 vaccines at the same time as people of the same age or risk group.
- Evidence so far reviewed by the Medicines and Healthcare products Regulatory Agency (MHRA), the UK regulatory agency responsible for licencing medicines including vaccines, has raised no specific concerns about safety in pregnancy. Evidence on COVID-19 vaccines is being continuously reviewed by the World Health Organization and the regulatory bodies in the UK, USA, Canada and Europe.

ACOG (US)[41]

Updated 22nd May 2021

The American College of Obstetricians and Gynecologists recommends that pregnant women should have access to COVID-19 vaccines and that COVID-19 vaccines should be offered to lactating individuals. They add that...

- “While a conversation with a clinician may be helpful, it should not be required prior to vaccination, as this may cause unnecessary barriers to access. Pregnancy testing should not be a requirement prior to receiving any EUA-approved COVID-19 vaccine. Unfounded claims linking COVID-19 vaccines to infertility have been scientifically disproven. ACOG recommends vaccination for all eligible people who may consider future pregnancy”.

SOCGC (Canada)[42]

Updated 4 May 2021

The Society of Obstetricians and Gynecologists of Canada provide the following guidelines:

- Pregnant individuals should be offered vaccination at any time during pregnancy or while breastfeeding if no contraindications exist.
- The SOGC supports the use of all available COVID-19 vaccines approved in Canada in any trimester of pregnancy and during breastfeeding in accordance with regional eligibility.

- The decision to be vaccinated is based on the individual's personal values, as well as an understanding that the risk of infection and/or morbidity from COVID-19 outweighs the theorized and undescribed risk of being vaccinated during pregnancy or while breastfeeding.
- Individuals should not be precluded from vaccination based on pregnancy status or breastfeeding.
- Given that pregnant people are at increased risk of morbidity from COVID-19 infection, all pregnant persons should be eligible to receive a COVID-19 vaccination.

The Immunisation Advisory Centre (NZ) [43].

Updated June 2021

The Immunisation Advisory centre has recently reviewed advice for vaccination in pregnancy in line with the advice provided from the organisations above. The IMAC COVID-19 Vaccination pregnancy and lactation fact sheet is published on its website ([link here](#)).

38. RANZCOG, *COVID-19 Vaccination in Pregnant and Breastfeeding Women*. 2021.
39. ATAGI, *Clinical guidance on use of COVID-19 vaccine in Australia in 2021 (v2.0)*. 2021, Australian Technical Advisor Group on Immunisation.
40. RCOG, <https://www.rcog.org.uk/en/guidelines-research-services/coronavirus-covid-19-pregnancy-and-womens-health/covid-19-vaccines-and-pregnancy/covid-19-vaccines-pregnancy-and-breastfeeding/>. 2021.
41. ACOG, *ACOG Practice Ad*

Released under the Official Information Act 1982