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27 March 2026

Alisha Riley

By email: fyi-request-33896-b51448f5@requests.fyi.org.nz
Ref: H2026079420

Tēnā koe Alisha

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 – Manatū Hauora (the Ministry) on 27 February. Please find a response to each part of your request below:

> *My request relates to the regulatory evaluation and subsequent provisional consent process for the Pfizer mRNA COVID-19 vaccine (Comirnaty) in New Zealand, specifically focusing on the period leading up to its referral to the Medicines Assessment Advisory Committee (MAAC).*
>
> *Please provide the following information and documents generated between 1 November 2020 and 10 February 2021:*
>
> *Internal Medsafe communications (including emails, memos, and briefing notes) authored by, sent to, or copying Dr. Chris James regarding the safety, efficacy, and quality evaluation of the Pfizer mRNA vaccine.*

The Ministry considered contacting you in accordance with section 18B of the act, in order to seek a refinement of this part of your request, as how it request is currently worded, would require substantial collation. However, in this instance, any reasonable refinement would mean that the information sought would be then withheld under the following sections of the Act:

- 9(2)(ba)(i) to protect information that is subject to an obligation of confidence and making it available would likely prejudice the supply of similar information, or information from the same source; and
- 9(2)(b)(ii) where its release would likely unreasonably prejudice the commercial position of the person who supplied the information.

Where information is withheld under section 9 of the Act, I have considered the public interest in the release of this information and do not consider that it outweighs the need to withhold it in this case.

> *Official Medsafe reports, drafts, or risk-benefit assessments that detailed "unresolved concerns" or requirements for "additional quality, safety and efficacy data" prior to the provisional consent being granted.*

The information in scope of your request has been published online as a response to a different request made under the Act. This is publicly accessible through the following link: www.health.govt.nz/system/files/2021-10/h202106950_-_response.pdf.

Please refer to Document 17.

> *All correspondence and official documentation between Medsafe and the MAAC regarding the decision to refer the Pfizer vaccine authorization to the MAAC.*

Information in scope of this part of your request is covered by Documents 13 and 14 of the above linked PDF. Document 13 is memo to MAAC referring the administration of the recommendation and Document 14 is a letter to Pfizer describing the decision to refer the application.

> *The final briefing or recommendation document Medsafe provided to the MAAC or the Director-General of Health regarding the Pfizer mRNA vaccine.*

MAAC's recommendations were communicated by memorandum to Chris James, in his capacity as the Minister of Health's delegate, for the purpose of granting consent to the distribution of medicines under sections 20 and 23 of the Medicines Act 1981. This is detailed in Document 15 of the PDF linked above.

If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: oiagr@health.govt.nz.

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

Chris James
Group Manager
Medsafe