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T Baker

By email: fyi-request-14899-4938bd99@requests.fyi.org.nz  
Ref: H202102755

Dear T Baker

### 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 March 2021 for:

*"In Ministry of Health media release (3rd Feb 2021) announcing Medsafe approval of Pfizer/BioNTech vaccine, it was stated Medsafe had completed a 'benefit risk assessment, which allows [Medsafe] to balance the benefits of the vaccine against any known risks such as side effects.'*

*Please provide full details of benefit risk assessment undertaken as part of Pfizer/BioNTech vaccine approval."*

The information you have requested is withheld under sections 9(2)(b)(ii) and 9(2)(ba)(i) of the Act. The release of this information would likely unreasonably prejudice the commercial position of the person who supplied the information. Further to this the information 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.

Please note that the Ministry has published some information that may be of interest to you at the following links:

- <https://www.medsafe.govt.nz/committees/maac/Recommendation109-2February2021.htm>
- <https://www.medsafe.govt.nz/COVID-19/vaccine-approval-process.asp>
- <https://www.medsafe.govt.nz/COVID-19/q-and-a.asp>
- <https://www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Medsafe-Evaluation-Process.asp>

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](mailto: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](http://www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests).

Yours sincerely



Nick Allan  
**Manager, OIA Services**  
**Office of the Director General**