

29 August 2022

Mr T. Baker

By email: fyi-request-20167-4fc48c84@requests.fyi.org.nz
Ref: H2022009578

Dear Mr Baker,

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora (the Ministry of Health) on 7 August 2022 for:

“Regarding Ministry of Health OIA Ref: H202205215, an error appears to have been made in stating that the Ministry of Health (nor any other agency) has not undertaken risk benefit work regarding Pfizer Covid vaccine.

Please clarify the following:

- Did the Ministry of Health undertake a "Risk / Benefit analysis of the vaccine when it was approved"?*
- If not, why did the Ministry of Health state it did in press release of 3rd February 2021?*
- If so, why did the Director of National Immunisation Programme state no risk benefit work had been undertaken as part of their response to OIA Ref: H202205215?"*

The information provided in the response H202205215 was incorrect regarding benefit/risk work. A benefit/risk analysis was undertaken by Medsafe prior to the Pfizer COVID-19 vaccine (Comirnaty) being granted provisional consent for use in New Zealand. The assessment has been released in a previous response under the Act and can be found at: www.health.govt.nz/system/files/documents/information-release/h202106950_response.pdf. Please refer to document 10 on page 94.

Additionally, there are ongoing measures to monitor the safety of COVID-19 vaccines. More information is available at: www.medsafe.govt.nz/COVID-19/safety-monitoring.asp.

The COVID-19 Vaccine Independent Safety Monitoring Board (CV-ISMB) provides expert advice to the Director-General of Health (now the National Director of the National Public Health Service) about the COVID-19 vaccine.

The CV-ISMB continues to review the available safety information on Comirnaty, and they have continued to advise that the benefits of vaccination outweigh the risk of side effects. Please refer to the CV-ISMB media releases and interim report, which are available at: www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-information-health-professionals/covid-19-vaccine-strategy-planning-insights/covid-19-who-were-working#ismb.

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.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Chris James', with a stylized flourish at the end.

Chris James
Group Manager
Medsafe