

9 September 2021

El Zorro

By email: fyi-request-16339-7573f83a@requests.fyi.org.nz

Ref: H202110447

Dear El Zorro

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 12 August for:

*"I'm looking for a Ministry assessment of the pharmacokinetic and toxicity profile of the spike protein. The links you referred me to did not match with the summarized finding of Pfizer's animal study. And the EMA link doesn't exist anymore.
Can you please confirm you are in possession of Pfizer's study:
"SARS-CoV-2 mRNA Vaccine (BNT162, PF-07302048) 2.6.4 Summary state- ment of the pharmacokinetic study 2020."
And if so please release any evaluation regarding it."*

The Ministry has no record of sending you information regarding Pfizer's animal study or an EMA link. It is possible this information was released to you through a request made under a different pseudonym.

Medsafe is unable to confirm that it is in possession of the referenced study as no specific study number has been provided. However, Medsafe does hold pharmacokinetic study data for Comirnaty COVID-19 vaccine provided by Pfizer.

The document *New Medicine Application Evaluation Report – Non-Clinical* is attached as Appendix 1. This is being released with information withheld. Information has been withheld under section 6(b)(ii) of the Act as its release would prejudice information entrusted to the Government of New Zealand on a basis of confidence by any international organisation, section 9(2)(b)(ii) of the Act where its release would likely unreasonably prejudice the commercial position of the person who supplied the information, and section 9(2)(g)(ii) of the Act to maintain the effective conduct of public affairs through the protection of such Ministers, members of organisations, officers, and employees from improper pressure or harassment.

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