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23 February 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H202200582

Dear 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 26 January 2022 for information relating to the Comirnaty (Pfizer) COVID-19 vaccine. I will respond to each part of your request in turn.

> *Consolidated (Medsafe) Further to this OIA request on the FYI website, https://scanmail.trustwave.com/?c=15517&d=w-nw4WIG-nneLRiKlXLXtyKY0e8rA5x-u1fvPshUHg&u=https%3a%2f%2ffyi%2eorg%2enz%2frequest%2f17810%2fresponse%2f69250%2fattach%2fhtml%2f8%2fH202112131%2520Appendix%25201%2epdf%2ehtml I see that there was an independent quality assurance test for the Pfizer/BioNTech 'vaccine'.*
>
> *Please publish the test report/s the minister/ministry received or at least show me where I may find the report online. Please include all reports if there was more than one*

Medsafe's approval process of the COVID-19 vaccine is outlined on Medsafe's website at the following page: www.medsafe.govt.nz/COVID-19/vaccine-approval-process.asp.The Medsafe gazette notice for each vaccine (which are on the Medsafe website for approved vaccines) also provides detail on the clinical evidence that is required for each vaccine after it is given provisional consent. The provisional consent for the Comirnaty (Pfizer) COVID-19 vaccine for adults can be found on Medsafe's website at the following page: www.medsafe.govt.nz/COVID-19/Comirnaty-Gazette-Oct-2021.pdf. The Pfizer paediatric for children can also be found on the following page: www.medsafe.govt.nz/COVID-19/Comirnaty-Gazette-Dec-2021.pdf.

The Ministry of Health's page on the assessment and approval of COVID-19 vaccines in New Zealand provides more details on what happens after Medsafe's provisional approval is given and how cabinet makes their decision. This information can be found on the Ministry's website at the following page: www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-assessing-and-approving-vaccines.

It is a requirement for COVID-19 vaccine suppliers to send Medsafe Certificates of Analysis (CoAs) for the first three shipments of vaccines to New Zealand. The CoA details the quality control testing criteria the vaccine needs to meet before it can be released for distribution and the test results for that particular batch. These certificates of analysis are then checked by the Ministry of Health's logistics quality representative to ensure that they meet all test specifications. These checks include data to demonstrate that the temperature conditions during shipping to New Zealand met storage specifications. There is also a requirement for suppliers to provide Medsafe with batch certificates from international independent testing authorities, such as the European Union Official Control Authority Batch Release (OCABR), upon request.

> *In the above request, Bloomfield states in a letter that "I want to assure you that Medsafe's approval is the culmination of a rigorous assessment over many months to ensure the Pfizer/BioNTech vaccine is safe and effective to use here." Please publish what 'rigorous assessment' data used to ensure the Pfizer/BioNTech vaccine is safe and effective to use here" or show me where I can find that data online. By data I mean the actual data, not a pharmaceutical industry pamphlet that seems to pass for data these days.*

The information that you have requested, relating to the data submitted by Pfizer New Zealand limited to support their application of approval of Comimaty is withheld under section 9(2)(b)(ii) of the Act, where its release would likely prejudice the commercial position of the person who supplied the information. Where information is withheld, please note I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

> *I note that your website states that fees are paid to Medsafe by the pharmaceutical industry for certain activities. Where would I find that fee schedule and amounts paid and by whom and for what? If that is not already published online, please send me the past five years of payments from the pharmaceutical industry, to Medsafe and for what activities*

This information can be found on Medsafe's website at the following page: www.medsafe.govt.nz/regulatory/fees.asp.

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.

Yours sincerely

Chris James
**Group Manager**
**Medsafe**