

26 January 2022

Raff Potter

By email: fyi-request-18127-2d9d0046@requests.fyi.org.nz
Ref: H202200180

Dear Raff

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 10 January 2022 for information relating to the safety data from human trials for people aged 5-11-year-olds for the Comirnaty formula.

You specifically requested:

“Can you please provide the safety data from human trials (trials in which the humans were 5-11 years of age) for the COMIRNATY formula containing the Tris buffer which is to be administered to 5–11-year-olds in New Zealand.

To be clear, I am NOT requesting safety data from the COMIRNATY formula containing the PBS buffer.”

The clinical data submitted to Medsafe by Pfizer to support the application for approval of a new strength and formulation (containing trometamol, also known as tris buffer) of Comirnaty for use in children aged 5 to 11 years old is withheld under section 9(2)(b)(ii) of the Act, where its release would unlikely unreasonably prejudice the commercial position of the person who supplied the information.

Please note that the primary clinical study conducted to support this application used vaccine batches of the same formula as Comirnaty that is used for people aged 12 years and older (i.e., containing PBS buffer). Medsafe considered that the two formulations were sufficiently comparable to allow use of the clinical study to support the safety and efficacy of the new formulation in children aged 5 to 11 years old.

The clinical trial information can be found at: <https://clinicaltrials.gov/ct2/show/NCT04816643>.

An evaluation of the results can be found at:
<https://www.nejm.org/doi/full/10.1056/NEJMoa2116298>.

Further information can be found in the data sheet:
<https://medsafe.govt.nz/profs/Datasheet/c/Comirnaty0.2mlOrangeCapinj.pdf>.

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 black ink, appearing to read 'Derek Fitzgerald', written in a cursive style.

Derek Fitzgerald
(Acting) Group Manager
Medsafe