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M Bell

By email: [fyi-request-15177-161241e9@requests.fyi.org.nz](mailto:fyi-request-15177-161241e9@requests.fyi.org.nz)

Ref: H202104534

Dear M Bell

### Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 15 April 2021 for information relating to provisional consent. You specifically requested:

- “1. What the Urgent clinical need is or is related to*
- 2. A copy of all data, information, statistics and scientific proof which you used to decide provisional consent was required to meet the urgent clinical need described in question 1”*

The urgent clinical need is related to the global COVID-19 pandemic, and the potential need if an outbreak occurs in New Zealand.

Any information relating to provisional consent is withheld in full under 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.

For more information regarding the vaccine approval process please refer to the following link: [www.medsafe.govt.nz/COVID-19/vaccine-approval-process.asp](http://www.medsafe.govt.nz/COVID-19/vaccine-approval-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



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