

01/02/2020

Virginia Crawford

By email: fyi-request-14492-f5b3ebf2@requests.fyi.org.nz

Ref: H202100277

Dear Virginia Crawford

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 20 January 2021 for information relating to Medsafe methods of assessing COVID vaccines.

You asked the following:

"If trials are still in progress, how can Medsafe be sure that these vaccines are "safe and effective" by the time they are used in New Zealand? Already there are reports of very serious side effects (and even deaths) from covid vaccines in various parts of the world.

As New Zealand's medicines regulatory agency, Medsafe decides whether a medicine has acceptable efficacy, safety and quality for use in New Zealand. You can find more information about how this process works here: www.medsafe.govt.nz/consumers/Safety-of-Medicines/Vaccine-safety.asp.

When considering a medicine application, Medsafe reviews all safety aspects of the vaccine as it may not be suitable for use by some people. Whilst Medsafe is prioritising COVID-19 vaccine assessments, the review of safety of any vaccine will not be compromised. Following the Medsafe process, the list of ingredients will be published in a datasheet and CMI on our website, like all other medicines.

As well as following our usual approval processes, Medsafe will continue to monitor the safety and effectiveness of vaccines and other medicines including taking action if it detects a safety issue.

You may also be interested to know that information on the COVID-19 approval process for medicines is available on the Medsafe website at: www.medsafe.govt.nz/COVID-19/medicine-approval-process.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.

Please note that this response, with your personal details removed, may be published on the Ministry website.

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