133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T +64 4 496 2000
W www.medsafe.govt.nz

26 May 2021

Paul Jones

By email: fyi-request-15328-7372abdf@requests.fyi.org.nz
Ref: H202106088

Dear Paul Jones

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 19 May 2021 for:

> *"Provide all documentation and evidence to support the above claims, being;*
> *Provide documentation outlining all the safety steps the COVID-19 vaccines are evaluated against.*
> *Please provide documentation for the criteria that enables Medsafe to determine what is considered "safe".*
> *Please provide documentation for the criteria that enables Medsafe to determine what is considered "effective"*

Medsafe is responsible for the regulation of medicines in New Zealand. It follows international guidelines and standards when assessing the safety and efficacy of new medicines before granting approval. Only if the medicine meets these standards will Medsafe recommend approval for use in New Zealand.

In the case of new COVID-19 vaccines, this has included those issued by international regulatory authorities. These regulatory authorities include the United States Food and Drug Administration (FDA) where information and guidance documents for the industry can be accessed publicly here: www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders, as well as the European Medicines Agency (EMA) where information can be accessed publicly here: www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-vaccines.

> *"Its claimed no shortcuts have been taken but the propaganda brochure does not outline that these vaccines have only been approved under "emergency use". Please clarify the differences ("shortcuts") between approval for emergency use and the regular approval that an MMR vaccine had to go through?"*

Information related to the Medsafe approval process for COVID-19 vaccines, including how this differs from the standard medicines approval process, is publicly available here: www.medsafe.govt.nz/COVID-19/vaccine-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 at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely

Chris James
Group Manager
Medsafe