MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

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10 March 2021

Greg Keen

By email: fyi-request-14713-80d17545@requests.fyi.org.nz
Ref: H202101531

Dear Greg Keen

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 18 February 2021 regarding the COVID-19 vaccine (Comirnaty):

Responses to your questions are set out below.

> *"1) Can you please provide details of robust assessments which were carried out on any COVID-19 vaccines prior to their approval in New Zealand (specifically by Medsafe) to ensure that there are no serious long-term effects on New Zealanders who are injected with any COVID-19 vaccine. For the purposes of clarity I will define 'long-term effects' as any adverse reaction to any COVID-19 vaccine which either persists beyond 6 months following the date of initial vaccination or first presents itself at least 6 months after the date of initial vaccination. To be clear, I am not requesting any information relating to any side effects which present themselves in the weeks following initial vaccination."*

To date, Medsafe has completed the assessment for the Comirnaty vaccine and although there were participants who had been in the study for longer than 6 months, the assessment was based on a median of 2 months follow-up after the 2nd dose. This part of your request is therefore refused under section 18(g) of the Act, as the information is not held by the Ministry.

> *"2) In the event that the long-term adverse effects of any approved COVID-19 vaccines are unknown or have not yet been assessed, what assurance can the Ministry of Health give New Zealanders that their regulatory business unit known as Medsafe is fit for purpose in its role of enhancing the health of New Zealanders by regulating medicines and medical devices to maximise safety and benefit, when there would appear to be a significant risk being taken with the long-term health of New Zealanders at stake?"*

For all medicines, there will be use by patients in real world settings that exceeds that of the clinical trials. For this reason, Medsafe contracts the Centre for Adverse Reactions Monitoring (CARM) at the University of Otago to run the spontaneous reporting system whereby anyone can report their suspicions of an adverse reaction to a medicine (including vaccines). The Ministry has full confidence in Medsafe to administer the requirements of the Medicines Act 1981 and the Medicines Regulations 1984.

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