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27 January 2021

[redacted]

By email: [redacted]
Ref: H202008399

Dear [redacted]

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 23 November 2020 for:

> *"OIA - I'd like to request the following information under the Official Information Act please:*
> *• Will New Zealand be relying on Emergency Use Authorisation from the FDA to adopt fast-tracked vaccines from international pharmaceutical companies?*
> *• What measures does New Zealand have in place to make similar authorisation for emergency use and what is the criteria that must be met to trigger such authorisation?*
> *• What additional systems do the MOH have in place to record, investigate, monitor and report adverse reactions from the upcoming COVID-19 vaccines?*
> *• How will members of the public report suspected reactions and what compensation and/or financial and medical support will be available to them? How will such support be financed?*
> *• Will the pharmaceutical companies providing vaccine products be liable for adverse reactions stemming from the use of their products?*
> *• How will the – 10% reporting rate for adverse events be factored in to assessing the true nature of events experienced?"*

On 21 December 2020 your request was extended in accordance with section 15A of the Act as further consultation was required.

I will respond to each of your questions in turn:

> *"Will New Zealand be relying on Emergency Use Authorisation from the FDA to adopt fast-tracked vaccines from international pharmaceutical companies?"*

Medsafe administers the Medicines Act 1981, available online at: http://www.legislation.govt.nz/act/public/1981/0118/latest/DLM54687.html. There is no provision for emergency use authorisation in this Act.

> *"What measures does New Zealand have in place to make similar authorisation for emergency use and what is the criteria that must be met to trigger such authorisation?"*

Please see above.

> *"What additional systems do the MOH have in place to record, investigate, monitor and report adverse reactions from the upcoming COVID-19 vaccines?"*

The Ministry of Health (the Ministry) does not report adverse reactions. Medsafe will be monitoring the safety of these vaccines through additional monitoring systems. These will be publicised once they are in place nearer the time when a vaccine is rolled out in New Zealand.

> *"How will members of the public report suspected reactions and what compensation and/or financial and medical support will be available to them? How will such support be financed?"*

Any individual (including health professionals and the general public) can report adverse reactions following immunisations to the Centre for Adverse Reactions Monitoring (CARM). Information on how to do this can be found here: https://nzphvc.otago.ac.nz/.

Individuals are covered by the Accident Compensation Corporation (ACC) if they suffer an injury while getting medical treatment from a doctor or other health professional, including injury as a result of vaccination. The cover does not include things that are a necessary part or ordinary consequence of the treatment. Further information on claims for treatment injury can be found on the ACC website.

> *"Will the pharmaceutical companies providing vaccine products be liable for adverse reactions stemming from the use of their products?"*

Information pertaining to this part of your request may be held by the Ministry of Business, Innovation and Employment (MBIE). If you wish to submit a further request to MBIE relating to this part of your request, please contact them at ministerialservices@mbie.govt.nz.

> *"How will the – 10% reporting rate for adverse events be factored in to assessing the true nature of events experienced?"*

There is no evidence to support a 10 per cent reporting rate. We do not need all adverse reactions to be reported to identify safety signals see: https://www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Medicines-Safety-and-Pharmacovigilance.asp and https://www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Vaccine-safety.asp.

For common adverse reactions the rate will be identified in the clinical trials. Individuals can report adverse reactions themselves at: https://nzphvc.otago.ac.nz/consumer-reporting/ or by asking a healthcare professional to do it for them.

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 Medsafe website.

Yours sincerely

Chris James
Group Manager
Medsafe