

9 February 2023

Erika Whittome

By email: fyi-request-21071-b35ac001@requests.fyi.org.nz
Ref: H2023019798

Tēnā koe Erika

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora (the Ministry of Health) on 5 February 2023 as a follow up to information provided to you under ref: H2022016442. You requested:

*"This is a very interesting Ministry of Health response which says that Medsafe does not perform any informed consent process.
If Medsafe does not perform any informed consent process, then....*

- 1 Are Medsafe allowed to discourage informed consent?*
- 2. Are Medsafe allowed to discourage the consideration of risks of a medicine which are outlined in a medicine's safety report?*

*Many Medsafe safety reports for Comirnaty say, "Medsafe advises people NOT to make any decisions about vaccination based on information contained in this report. "
eg <https://www.medsafe.govt.nz/COVID-19/safety-report-45.asp>"*

Your questions and the statements that support them appear designed to engage in a debate about Medsafe's involvement in the informed consent process, rather than a request for official information. The Act does not support requests where an opinion, comment, argument, or hypothetical statement is put to the Ministry for response, couched as a request for information.

As you have been advised, Medsafe is the New Zealand Medicines and Medical Devices Safety Authority and is responsible for the regulation of therapeutic products in New Zealand. Medsafe administers New Zealand legislation in relation to medicines. It is not a healthcare provider. As Medsafe is not involved in the provision of healthcare to any individual patient, it does not perform any informed consent process.

The statement you refer to from the safety reports is not related to an informed consent process. The statement is included because the safety reports cover symptoms that are reported as *suspected* to be related to a medicine and do not represent true side effects.

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.

Nāku noa, nā

A handwritten signature in blue ink, appearing to read 'Chris James', written in a cursive style.

Chris James
Group Manager
Medsafe