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

2 November 2021

Chris McCashin

By email: fyi-request-17034-551ebac1@requests.fyi.org.nz
Ref: H202113613

Dear Chris

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 4 October for information regarding adverse reactions and a suspected adverse reaction to the Pfizer vaccine. I will respond to each part of your request in turn.

> *Medsafe has recorded that the death of a 17 year old following the Covid-19 vaccine but it was potentially another 'suspect medicine' which would be considered by the Medicine Adverse Reactions in Due Course.*
>
> *Can you please name the 'suspect medicine' and the pharmaceutical manufacturer so that the public are aware what the 'suspect medicine' is and people can avoid it?*

This death was reported to the Centre for Adverse Reactions Monitoring (CARM) at the University of Otago. CARM undertakes this work under contract to the Ministry. It has been established that the adverse reaction was not a result of the Pfizer vaccine. Further details are withheld under section 9(2)(a) of the Act, to protect the privacy of natural persons, including deceased natural persons.

> *If it recorded by Medsafe on the death register as a potential side effect of the Pfizer vaccine does that mean the manufacturer of the 'suspect medicine' can not be held liable because it is recorded against the vaccine which Pfizer are indemnified for?*

Medsafe monitors and investigates adverse reactions, including deaths. Neither agency registers deaths. Information about confirming and registering deaths is available at: https://communitylaw.org.nz/community-law-manual/chapter-14-a-death-in-the-family/confirming-and-registering-the-death.

As New Zealand operates a no-fault accident compensation system, there is no requirement to indemnify employers and/or healthcare providers. The Accident Compensation Corporation provides assistance and cover in these situations: www.covid.immune.org.nz/faq/will-acc-provide-cover-covid-19-vaccination-injuries.

> *Last count there were 60 deaths recorded as adverse reactions with these numbers continuing to go up but coincidentally, they remain under investigation. Also of note and recently added to the Medsafe report were that 749 people had died within 21 days of administration of the Pfizer vaccine. How is this not a massive red flag?*
>
> *Given Medsafe approve the vaccine and then investigate the deaths is this is a conflict of interest? How many deaths need to be recorded before Medsafe actually investigate these and provide transparent reporting.*

Surely this is of a national emergency given the government is trying to by stealth force this on 90% of the population including children!

How many deaths are required before an independent agency is appointed to investigate all of these deaths properly? Do we need to get to four figures? Maybe 1,000. One case of the disease (not death) shuts down and bankrupts our country yet 60 deaths likely more from the vaccine we are just told that there is nothing to see here.

While the Act allows people to ask government agencies for information, there is no requirement under the Act for agencies to create new information, compile information they do not hold, or provide an opinion. The Act does not support requests where a statement is put to agency to comment on couched as a request for official information. Most of these questions fall into this category and are therefore refused under section 18(g) of the Act on the grounds that the information is not held by Medsafe or the Ministry.

However, I can advise that there is no conflict between Medsafe's role in independently approving and regulating medicines (including vaccines) and monitoring their safety. The two roles are complementary and is a model used by nations throughout the world. There is more information about medicine safety monitoring at: www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Medicines-Safety-and-Pharmacovigilance.asp.

I can also advise that Medsafe and CARM monitor and investigate all adverse effects following immunisation (AEFI) with COVID-19 vaccines that are reported to them. The form to do is available at: https://report.vaccine.covid19.govt.nz/s/ and anyone – a doctor, nurse, pharmacist, government agency or member of the public – can make a report. Both Medsafe and CARM encourage reports to be made. The results of these reports are publicly reported every week at: www.medsafe.govt.nz/COVID-19/vaccine-report-overview.asp. As these reports outline, Medsafe has determined that one death was likely due to vaccine-induced myocarditis and it has been referred to the coroner – an independent judicial officer – for their consideration.

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