

18 March 2022

§ 9(2)(a)

By email: § 9(2)(a)
Ref: H202203386

Tēnā koe § 9(2)(a)

Thank you for your request under the Official Information Act 1982 (the Act) where parts 8, 9 and 10 were partially transferred from the University of Auckland (the University) to the Ministry of Health (the Ministry) on 2 March 2022. Please find a response to each part of your request below.

8. Provide:- Methodology and explanation of why there is confused and asymmetrical data sets published for background rates 2008-2019 and 2016-2019

The University SAFE project studied adverse events of special interest (AESI) from 2008-2019. However, it did not study all AESI that Medsafe and the Centre for Adverse Reactions Monitoring at the University of Otago monitor closely (shown in table 9 at www.medsafe.govt.nz/COVID-19/safety-report-40.asp#analysis). Therefore, Medsafe decided to generate its hospitalisation background data (yearly average) using the National Minimum Dataset (NMDS) with data ranging from 2016-2019.

9. Provide:- Evidence referenced to support the claim that TTS AESI does not occur with BNT162b2 'occurs only in non-replicating viral vaccines (eg, the AstraZeneca vaccine)'

Your question is based on a false dichotomy as it is scientifically impossible to prove a negative. However, given that more than a billion doses of Pfizer's COVID-19 vaccine Comirnaty have been administered worldwide, there have been no convincing cases of thrombosis with thrombocytopenia syndrome (TTS) associated with the vaccine.

10. Provide: - Evidence and explanation why Lymphadenopathy (10025197) is not classified as AESI and is not listed as a safety signal with 3,611 reports as at 4th December 2021

Lymphadenopathy is an expected immune response to an infection or a virus and is non-serious. Therefore, it does not meet the criteria of an AESI as it is not of special interest. It is a known adverse reaction to the Comirnaty vaccine and is listed in the data sheet which also states that it occurs more often after booster vaccination. The datasheet can be found here: www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf.

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 of Health website at: www.health.govt.nz/about-ministry/information-releases.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'Chris James', with a stylized flourish at the end.

Chris James
Group Manager
Medsafe