MEDSAFE
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7 December 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H2022016737

Dear s 9(2)(a)

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 11 November 2022. Please find a response to each of your requests below.

> *1) information about each of the studies on post PfizerVax injuries referred to in the attached extract from the Covid Independent Safety Monitoring Board monthly Minutes . Please include information about:*
> *a) the design and ethics approval for each study,*
> *b) criteria for participants,*
> *c) source of funding and*
> *d) all reports and progress report whether internal or external*
> *e) any follow up by MinHeath or the Board.*

This information is publicly available on Manatū Hauora website here: www.health.govt.nz/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-side-effects-and-reactions/covid-19-vaccine-myocarditis-and-pericarditis-study

> *2) Please also provide copies of all information that triggered the urgent ad hoc meeting of this Board on 22 April 2021 to investigate any risks of abnormal blood clotting and/ or bleeding associated with the PfizerVax.*

The COVID-19 Vaccine Independent Safety Monitoring Board held an ad-hoc meeting on 22 April 2021 to discuss concerns developing overseas in relation to reports of a link between thrombosis with thrombocytopenia syndrome (TTS) and Vaxevria. The meeting was triggered by publicly available international information. No information was found to link this condition with the COVID-19 Comirnaty (Pfizer) vaccine. As such, this part of your request is refused under section 18(e) of the Act.

> *3) Please also include information to show how information about post vaccine deaths which involved abnormal blood clotting or bleeding (including any heart attacks or strokes etc and any deaths involving heamorhaging) that were caused or may have been caused by blood clots were collected. Please include information to show how active this follow up process was and any internal resourcing and funding and how this information was referred to Medsafe and/ or the Board and any resulting analysis; and*

Reports of adverse events following immunisation (AEFI) which involve blood clotting where it results in death are followed up in the same way as all other reports of death. This process is described on the Medsafe website here: www.medsafe.govt.nz/COVID-19/q-and-a-vaccine-safety.asp.

> *4) any advice from MinHeath, Medsafe or any Board funded or managed by MinHeath to the Minister to alert him/her to possible risks of post PfizerVax bleeding and/ or blood clotting.*

No reports have been provided to the Minister as bleeding and blood clotting are not considered side effects of the COVID-19 Pfizer vaccine. As such, this part of your request is refused under section 18(e) of the Act as the information requested does not exist.

> *5) Please also provide copies of any correspondence with the Coroner or Coroners office and/ or with pathologists or undertakers about any NZ post vaccine deaths including any information showing how Medsafe, MinHeath or any of the Covid Boards and advisors it manages actively sought out and used information about post vaccine deaths.*

In response to this part of your request, Manatū Hauora consulted with the Ministry of Justice (MOJ). On 30 November 2022, in response to a request transferred to MOJ from the Office of the Minister for COVID-19 Response, Hon Dr Ayesha Verrall (MOJ ref: OIA 100462) you were advised that information relating to deaths of people who have received a COVID-19 vaccination is reported to the Office of the Chief Coroner and this information is subject to a Memorandum of Understanding between the Chief Coroner and Manatū Hauora and can only be released with the permission of both parties.

As an arm of government separate from the executive (e.g. Ministers and government departments), the Coroner's Court have their own rules for requesting information. Section 2(6)(a) of the Act excludes courts from the ambit of the Act. As such, this part of your request is refused under section 18(g)(i) as the information requested is not held by Manatū Hauora and there are no grounds for believing it is held by another agency subject to the Act.

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 Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely

Chris James
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Medsafe