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9 August 2022

Chris McCashin

By email: fyi-request-18841-799b20e6@requests.fyi.org.nz
Ref: H2022005652

Dear Chris

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora (Ministry of Health) on 27 June 2022 as a follow up to information you received under reference: H202205723. Specifically, you requested:

> *"Is the below excerpt from the Medsafe reports "misinformation"?*
> *Is this Pfizer report "misinformation"?*
> *https://scanmail.trustwave.com/?c=15517&d=wfe44rQgIGnbDd6Tna0zRhPfs6O6SZqkTk7zr1EFlg&u=https%3a%2f%2fphmpt%2eorg%2fwp-content%2fuploads%2f2021%2f11%2f5%2e3%2e6-postmarketing-experience%2epdf.*
>
> *Summary of reported deaths*
> *Up to and including 30 April 2022, a total of 160 deaths were reported to CARM after the administration of the Comirnaty vaccine. Following medical assessments by CARM and Medsafe it has been determined that:*
>
> *99 of these deaths are unlikely related to the COVID-19 vaccine*
> *48 deaths could not be assessed due to insufficient information*
> *10 cases are still under investigation.*
> *3 deaths were likely due to vaccine induced myocarditis (awaiting Coroner's determination)*
>
> *The above also states that there were 48 deaths that could not be assessed due to insufficient information. Are you able to provide how these deaths are recorded? Please provide the policy documents associated with recording deaths that could not be assessed due to insufficient information.*
>
> *How are these deaths categorised?*
> *Cause of death unknown?*
> *Unexplained?*
> *Sudden Adult Death Syndrome?*
>
> *What dataset will they be categorised in?*
>
> *Depending on what dataset they are categorised in are you able to provide that dataset from 2000-2022"*

The link you attached to your request refers to the publication of a report, Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-Feb-2021, in the United States. Manatū Hauora received several requests about this document and has published a comprehensive response that explains its genesis and relevance to New Zealand. It is publicly available at: www.health.govt.nz/system/files/documents/information-release/h202117570_response_0.pdf.

The Centre for Adverse Reactions Monitoring (CARM) and Medsafe investigate reports of significant events, including those with a fatal outcome. In the first stage of the process, the report is verified to check that there is an identifiable individual who has had a COVID-19 vaccination and the reporter can be contacted. Any report that doesn't meet these criteria is invalid and is not further investigated. Sometimes the initial report doesn't contain enough information for assessment so CARM or Medsafe will seek further information from the reporter. For any report, the reporter may be the person who experienced the event, their friend or relative, or the general practitioner (GP) or other healthcare professional who treated them. Regardless of who reported the significant event, the relevant healthcare professionals will be contacted for more information. If the person died and their GP or doctor reported the death to the coroner, CARM will also contact the coroner or the pathologist.

The investigation process can take some time and may not always be successful if there is no response to requests for information or there is no further information to share. This results in a death being categorised as *could not be assessed due to insufficient information*.

Please note, that the cause of death is investigated and determined by the coroner, not by CARM or Medsafe.

There are no Manatū Hauora or Medsafe 'policy documents' associated with recording deaths that could not be assessed due to insufficient information. Therefore, this part of your request is refused under section 18(e) of the Act as the document requested does not exist. However, information about the follow up process for reports of adverse events with the COVID-19 vaccines, including fatal reports is publicly available on the Medsafe website here: www.medsafe.govt.nz/COVID-19/q-and-a-vaccine-safety.asp.

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: xxxx@xxxxxxxxx.xxxxxxxxxx.xx or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on Manatu Hauorā website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours Sincerely

Chris James
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Medsafe