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11 May 2022

s 9(2)(a)

By email: s 9(2)(a)
Ref: H202205337

Tēnā koe s 9(2)(a)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) received by the Ministry of Health (the Ministry) on 8 April 2022 for information related to adverse events following immunisation (AEFIs). Your request is responded to in turn:

> *33 records Sudden death (10042434) appeared in Medsafe report 39 (12 Jan 22) and 40 (16 Feb 22)*
>
> *Provide:*
>
> *1. Time span in days between injection and sudden death (10042434) for each 33 case record*

The Ministry does not hold this information. Therefore, this part of your request is refused under section 18(g)(ii) of the Act as the information requested is not held by the Ministry and there are no grounds for believing it is held by another agency subject to the Act.

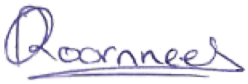
> *2. Documents and details behind the removal of 19 case records sudden death (10042434)*
>
> *3. Documents and details behind alteration of 14 case records from sudden death (10042434)*
>
> *4. Communications held regarding the removal and alteration for all 33 sudden death (10042434) records*
>
> *5. Explanation why 19 records were removed and 14 records altered*
>
> *6. Explanation what has happened with the 19 removed records. Where are the records?*
>
> *7. Explanation of process to alter preferred term and coding of 14 records of sudden death (10042434)*
>
> *8. Do each of the 33 case records remain as death records?*
> *(If not provide case record numbers and explanation for each record as to why/how not death)*

Sudden death is a temporary code used when a death is first reported, this is because reports of death do not often state the cause of death. As a result, the Centre for Adverse Reactions Monitoring (CARM) must obtain follow up information for a medical assessment. Once more information is obtained about the cause of death, the report is re-coded from 'sudden death' to include the cause of death. This is how there could be a perceived 'removal' of sudden death cases, where they are in fact just being re-coded with the cause of death. It is important to understand that death is an outcome and not an adverse event. Therefore, the cause of death, which is the medical event(s) that resulted in death, is what must be coded into CARM for the purposes of pharmacovigilance. Records of this change remain in the CARM system. Your request for documents is refused under section 18(e) of the Act as the documents requested do not exist.

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.

Nāku noa, nā



Astrid Koornneef
Director
National Immunisation Programme