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28 August 2019

[redacted]
By email: [redacted]
Ref: H201906196

Dear [redacted]

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) for:

> *"Can I have a list of all adverse reaction reports related to vaccines that have death as an outcome that have been reported to the MOH and/or CARM since 2000? This list should include reports that have been notified to CARM, and given a CARM number. It appears that not all reports notified are retrieved through SMARS.*
>
> *This list should include the Report#, Date, Gender, Age, Medicine(s), and Reaction(s) as per SMARS outputs.*
>
> *Also, is it possible to extract reports summarising:*
>
> *all notifications related to vaccines and there causality classification?*
>
> *all notifications related to vaccines based on seriousness of the event?"*

Information pertaining to your request is attached to this letter. I trust this information fulfils your request.

You have the right, under section 28 of the Act, to ask the Ombudsman to review any decisions made under this request.

Please note this response (with your personal details removed) may be published on the Ministry of Health website.

Yours sincerely

Chris James
Group Manager
Medsafe

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Report Title: **Deaths related to Vaccines**

Prepared for: [redacted]

Prepared by: **New Zealand Pharmacovigilance Centre**
16 August 2019

Specific Request:

1) a list of all adverse reaction reports related to vaccines that have death as an outcome that have been reported to the MOH and/or CARM since 2000. This list should include reports that have been notified to CARM, and given a CARM number.
2) This list should include the Report#, Date, Gender, Age, Medicine(s) and Reaction(s) as per SMARS outputs.

Contents:

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CAVEAT DOCUMENT

Accompanying statement to data released from the

NEW ZEALAND CENTRE FOR ADVERSE REACTIONS MONITORING

The Centre for Adverse Reactions Monitoring (CARM) has only limited details about each suspected adverse reaction contained in its Database. It is important that the limitations and qualifications which apply to the information and its use are understood.

The data made available represent the collection of spontaneous reports in the CARM database associated with therapeutic products/vaccines granted regulatory approval for use in New Zealand.

Reports have been submitted to the Centre since April 1965 and in many instances describe no more than suspicions which have arisen from observation of an unexpected or unwanted event. This level of reporting is due to CARM encouraging reporters to report events they suspect may be associated with a pharmaceutical product/vaccine irrespective of whether or not they believe it was the cause. CARM accepts all reports and proof of causality is not required when submitting a report to CARM. Coincidental events that may be unrelated to pharmaceutical product/vaccine exposure may be reported. This is particularly possible when the product has widespread use, or is used in targeted strategies such as vaccination campaigns.

In most instances it cannot be proven that a pharmaceutical product or ingredient is the cause of an event in the Database. Reports vary in quality, completeness and detail and may include detail that is incorrect. Consequently, a report in the CARM database of an event does not confirm that the pharmaceutical product/vaccine caused the event.

The volume of reports for a particular product may be influenced by the extent of use of the product, publicity, nature of reactions and other factors which vary over time and from product to product. It is generally accepted internationally that systems such as CARM are subject to under-reporting which may result in scant reports for events perceived by the reporter to be minor or well recognised, whilst more serious or unexpected events are possibly more likely to be reported, even if they are coincidental. Moreover, no information is provided on the number of patients exposed to the product.

The data contained in these tables are further subject to ongoing internal quality controls, review and updating and therefore may be subject to change, particularly if follow-up information is received.

For the above reasons interpretations of adverse reaction data, and particularly those based on comparisons between pharmaceutical products, may be misleading. Any use of this information must take into account at least the above. Although this information is now released, it is strongly recommended that prior to any use of such information, CARM is contacted for interpretation.

Any publication, in whole or in part, of the obtained information must have published with it a statement:

(i) of the source of the information

(ii) that the information is not homogenous at least with respect to origin or likelihood that the pharmaceutical product/vaccine caused the adverse reaction,

(iii) that the information does not represent the opinion of the NZPhvC or CARM.

Director
New Zealand Pharmacovigilance Centre

Vaccine cases reported to CARM – 01 January 2000 to 30 June 2019

Specific Request: **1)** any reports with an outcome of death following vaccination 2000 to 2019

This listing presents details of 48 cases, received by CARM between 2000 and 2019, where a death has occurred following administration of any vaccine whether or not the event is linked to the cause of death and irrespective of age.

Report No	Date Rec'd	Gender	Age	Medicines/Vaccine	Reactions
044838	JUL2000	Male	5m	DTPH HEPATITIS B VACCINE POLIOMYELITIS VACCINE ORAL	PURPURA VOMITING DIARRHOEA SOMNOLENCE PERSISTENT CRYING
052154	JUL2002	Male	73	PNEUMOCOCCAL VACC - 23 FERROUS SULPHATE FLUTICASONE TERBUTALINE OMEPRAZOLE	BRONCHITIS
055368	MAR2003	Male	78	INFLUENZA - TRIVALENT	GUILLAIN-BARRE SYNDROME
057028	JUL2003	Male	4m	HiB/HepB DTaP/IPV	NO REACTION REPORTED
060045	APR2004	Male	1m	HiB/HepB DTaP/IPV AMOXICILLIN	NO REACTION REPORTED
064359	FEB2005	Male	3	MENINGOCOCCAL B	DEMYELINATION PROGRESSION OF DISEASE
064403	FEB2005	Female	12	MENINGOCOCCAL B	PNEUMONIA PROGRESSION OF DISEASE
071269	APR2006	Male	78	INFLUENZA - TRIVALENT	NO REACTION REPORTED
082290	DEC2008	Male	3m	DTaP-Hexa PNEUMOCOCCAL VACC - 7	NO REACTION REPORTED
084614	MAY2009	Male	1m	HPV4-1 VACCINE	MEDICATION ERROR LEUKAEMIA MYELOID
087237	NOV2009	Female	18	HPV4-3 VACCINE DEPO-PROVERA	NO REACTION REPORTED
089896	MAY2010	Male	89	INFLUENZA - TRIVALENT DOXAZOSIN THYROXINE PARACETAMOL	NO REACTION REPORTED

Report No	Date Rec'd	Gender	Age	Medicines/Vaccine	Reactions
090322	JUN2010	Female	15	HPV4-2 VACCINE	SUICIDE
094737	MAR2011	Female	64	INFLUENZA - TRIVALENT	NO REACTION REPORTED
094738	MAR2011	Male	75	INFLUENZA - TRIVALENT	PNEUMONIA SEPSIS
094836	APR2011	Male	1m	DTaP-Hexa PNEUMOCOCCAL VACC - 7	NO REACTION REPORTED
095157	MAY2011	Female	83	INFLUENZA - TRIVALENT OXYCODONE ALENDRONATE + CHOLECALCIFEROL FRUSEMIDE ACETYLSALICYLIC ACID	DYSPNOEA
095467	MAY2011	Female	86	INFLUENZA - TRIVALENT PNEUMOCOCCAL VACC - 23 PREDNISONE ROXITHROMYCIN OXYBUTYNIN	PNEUMONIA SEPSIS RENAL FAILURE ACUTE MYOCARDIAL INFARCTION
095582	MAY2011	Male	66	YELLOW FEVER VACCINE	MULTIPLE ORGAN FAILURE
097321	SEP2011	Female	2m	DTaP-Hexa PNEUMOCOCCAL VACC - 7	NO REACTION REPORTED
104484	NOV2012	Male	4m	DTaP-Hexa PNEUMOCOCCAL VACC - 10	NO REACTION REPORTED
104666	NOV2012	Female		MENINGOCOCCAL B	RASH
105365	JAN2013	Female	2m	DTaP-Hexa PNEUMOCOCCAL VACC - 10	NO REACTION REPORTED
106049	MAR2013	Male	3m	DTaP-Hexa PNEUMOCOCCAL VACC - 10	NO REACTION REPORTED
106839	MAY2013	Female	62	INFLUENZA - TRIVALENT	MYOCARDIAL INFARCTION
109290	DEC2013	Female	16	HPV4-2 VACCINE ORAL CONTRACEPTIVE	NO REACTION REPORTED
109482	JAN2014	Male	5m	DTaP-Hexa PNEUMOCOCCAL VACC - 10	NO REACTION REPORTED
111827	MAY2014	Male	81	INFLUENZA - TRIVALENT CHOLECALCIFEROL DIPYRIDAMOLE THYROXINE ALLOPURINOL	CARDIAC ARREST

Report No	Date Rec'd	Gender	Age	Medicines/Vaccine	Reactions
112848	JUL2014	Male	15m	MEASLES-MUMPS-RUBELLA VACCINE HAEMOPHILUS B (HIBERIX) PNEUMOCOCCAL VACC - 7	NO REACTION REPORTED
113129	AUG2014	Female	4m	DTaP-Hexa PNEUMOCOCCAL VACC - 10	NO REACTION REPORTED
113290	AUG2014	Male	3m	ROTA VIRUS VACCINE DTaP-Hexa PNEUMOCOCCAL VACC - 10	NO REACTION REPORTED
114809	DEC2014	Male	4m	DTaP-Hexa PNEUMOCOCCAL VACC - 10	NO REACTION REPORTED
116202	MAY2015	Female	78	INFLUENZA - TRIVALENT FELODIPINE CHOLECALCIFEROL LACTULOSE MORPHINE SULPHATE	PROGRESSION OF DISEASE EMBOLISM PULMONARY GI HAEMORRHAGE THROMBOPHLEBITIS VENA CAVA INF
116573	MAY2015	Female	96	INFLUENZA - TRIVALENT ALENDRONATE + CHOLECALCIFEROL ACETYLSALICYLIC ACID METOPROLOL FRUSEMIDE	MYOCARDIAL ISCHAEMIA CONGESTIVE HEART FAILURE
117961	SEP2015	Male	2m	ROTA VIRUS VACCINE DTaP-Hexa PNEUMOCOCCAL VACC - 13	NO REACTION REPORTED
118270	OCT2015	Male	6m	ROTA VIRUS VACCINE DTaP-Hexa PNEUMOCOCCAL VACC - 13	NO REACTION REPORTED
118820	NOV2015	Male	46	INFLUENZA - TRIVALENT	SARCOMA
119094	DEC2015	Female	1m	ROTA VIRUS VACCINE DTaP-Hexa PNEUMOCOCCAL VACC - 13	NO REACTION REPORTED
120274	APR2016	Male	16m	MEASLES-MUMPS-RUBELLA VACCINE HAEMOPHILUS B (ACT-HIB) PNEUMOCOCCAL VACC - 13	NO REACTION REPORTED
120924	MAY2016	Male	54	INFLUENZA - TRIVALENT	VASCULITIS MYOCARDIAL INFARCTION
121228	JUN2016	Male	5m	ROTA VIRUS VACCINE DTaP-Hexa PNEUMOCOCCAL VACC - 13	NO REACTION REPORTED
121297	JUN2016	Male	2m	ROTA VIRUS VACCINE DTaP-Hexa PNEUMOCOCCAL VACC - 13	NO REACTION REPORTED
123661	MAR2017	Male	77	INFLUENZA - TRIVALENT	MOTOR NEURONE DISEASE

Report No	Date Rec'd	Gender	Age	Medicines/Vaccine	Reactions
125764	AUG2017	Female	5m	ROTA VIRUS VACCINE DTaP-Hexa PNEUMOCOCCAL VACC - 13	NO REACTION REPORTED
128778	MAY2018	Male	79	VARICELLA VACCINE - SHINGLES INFLUENZA - QUADRIVALENT CILAZAPRIL AMLODIPINE SIMVASTATIN	CARDIAC ARREST
128801	JUN2018	Male	3m	ROTA VIRUS VACCINE DTaP-Hexa PNEUMOCOCCAL VACC - 10	NO REACTION REPORTED
129312	JUL2018	Male	3m	ROTA VIRUS VACCINE DTaP-Hexa PNEUMOCOCCAL VACC - 10	NO REACTION REPORTED
130424	OCT2018	Male	2m	ROTA VIRUS VACCINE DTaP-Hexa PNEUMOCOCCAL VACC - 13	NO REACTION REPORTED