133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
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[redacted]

Ref: H201806709

[redacted]

**Response to your request for official information**

I refer to your request of 3 October 2018 under the Official Information Act 1982 (the Act) for:

> *"1. The total numbers and types of suspected and confirmed adverse reactions to the Gardasil 9 vaccine, since its introduction for use in NZ in January 2017, up until present day, from both of the CARM databaSES.*
> *2. Given that there is no Pregnancy Registry for women who have received Gardasil 4 or Gardasil 9 whilst pregnant, I am seeking information on any suspected adverse reactions for women found to be pregnant, who received these two vaccines, whilst pregnant and the outcomes and untended consequences, or adverse effects for their foetuses, ante and post natally, from both of the CARM databaSES."*

The information relating to this request is itemised below, with copies of documents attached.

| Attachment | Description and decision under OIA |
|---|---|
| 1 | This document is the 'start-up' file which lists your two requests and identifies a separate document (Attachment 2). This contains the answer to question 2 above. This is released in full. |
| 2 | This document contains the response to question 1 above. This is released in full. |

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 under this request.

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

Yours sincerely [redacted]

[redacted]

**Group Manager**
**Medsafe**

ATTACHMENT 1

**New Zealand Pharmacovigilance Centre**
University of Otago
PO Box 913, Dunedin, New Zealand
Telephone: 64-3-479 7185
Fax: 64-3-479 7150
Email: nzphvc@otago.ac.nz
Website: https://nzphvc.otago.ac.nz

**Report Title:** **HPV Vaccine**
**Official Information Act Request**

**Prepared for:** **Medsafe**

**Prepared by:** **New Zealand Pharmacovigilance Centre**
**23 October 2018**

**Specific Request 1.:** The total numbers and types of suspected and confirmed adverse reactions to the **Gardasil 9** vaccine since its introduction for use in NZ in January 2017, up until present day, from both of the CARM databases.

**Specific Request 2.:** Given that there is no Pregnancy Registry for women who have received **Gardasil 4 or Gardasil 9** whilst pregnant, I am seeking information on any suspected adverse reactions for women found to be pregnant, who received these two vaccines, whilst pregnant and the outcomes and untended consequences, or adverse effects for their fetuses, ante and post natally, from both of the CARM databases



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***Results***

**Specific Request 1.:**

Total Reports for **Gardasil 9** received by CARM up to 30 September 2018 169

Refer separate document

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**Specific Request 2.: Gardasil 4**

| | |
|---|---|
| Total Reports for **Gardasil 4** received by CARM up to 30 September 2018 | 692 |
| Number of cases identifying pregnancy associated reactions | 0 |

***Commentary***

CARM has been notified of 20 cases where the Gardasil 4 vaccine has been administered in a patient who has later been identified to have been pregnant at the time of vaccination.

One case documented a Urinary Tract Infection in the third trimester and another documented an ***Elective*** Abortion occurring at some point after vaccination but no further details are available.

In the remaining 18 cases a Drug Exposure in Pregnancy was the only event recorded.



**Specific Request 2.: Gardasil 9**

| | |
|---|---|
| Total Reports for **Gardasil 9** received by CARM up to 30 September 2018 | 169 |
| Number of cases identifying pregnancy associated reactions | 0 |

***Commentary***

CARM has been notified of 3 cases where the Gardasil 9 vaccine has been administered in a patient who has later been identified to have been pregnant at the time of vaccination.

In all 3 cases a Drug Exposure in Pregnancy was the only event recorded.

ATTACHMENT 2

**New Zealand Pharmacovigilance Centre**
University of Otago
PO Box 913, Dunedin, New Zealand
Telephone: 64-3-479 7185
Fax: 64-3-479 7150
Email: nzphvc@otago.ac.nz
Website: https://nzphvc.otago.ac.nz

**Report Title:** **HPV Gardasil 9 - Vaccine**
**Official Information Act Request**

**Prepared for:** **Medsafe**

**Prepared by:** **New Zealand Pharmacovigilance Centre**
**23 October 2018**

**Specific Request 1:** The total numbers and types of suspected and confirmed adverse reactions to the **Gardasil 9** vaccine since its introduction for use in NZ in January 2017, up until present day, from both of the CARM databases.



***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**

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***Background to information***

The reports included in the analyses presented in this OIA response include:

- all cases of adverse events following immunisation with Gardasil 9
- received by CARM in the period from 01 January 2017 to 30 September 2018

Cases are included

- irrespective of whether or not a causal link to the administered vaccine has been established.

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## *Results - Summary of reports*

For the period of 01 January 2017 to 30 September 2018 :

Table 1: The number of cases reported to Gardasil 9

| Date | No. of Reports | Cumulative Total |
|---|---|---|
| **2017** | | |
| January | | 0 |
| February | | 0 |
| March | 4 | 4 |
| April | 11 | 15 |
| May | 15 | 30 |
| June | 8 | 38 |
| July | 11 | 49 |
| August | 12 | 61 |
| September | 15 | 76 |
| October | 13 | 89 |
| November | 14 | 103 |
| December | 8 | 111 |
| **2018** | | |
| January | 6 | 117 |
| February | 9 | 126 |
| March | 13 | 139 |
| April | 9 | 148 |
| May | 5 | 153 |
| June | 3 | 156 |
| July | 0 | 156 |
| August | 2 | 158 |
| September | 11 | 169 |
| | | |

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## *Results - Summary of adverse reactions*

For the period of 01 January 2017 to 30 September 2018 :

### *Adverse events*

Tabulation of occurrences of grouped individual adverse events with gender breakdown, collated from all reports received for Gardasil 9, irrespective of whether or not a causal link to the administered vaccine has been established

Table : Total HPV9 AEFIs at 30/09/2018 - CLASSIC SOC Groupings 1

| | | gender | | |
|---|---|---|---|---|
| | | Female | Male | Total |
| | | N | N | N |
| group | AEFI | | | |
| Alimentary | ABDOMINAL PAIN | 3 | 1 | 4 |
| | APPETITE DECREASED | 1 | 1 | 2 |
| | BURNING SENSATION | | 1 | 1 |
| | DIARRHOEA | 1 | 2 | 3 |
| | DYSPHAGIA | | 1 | 1 |
| | FLATULENCE | 1 | | 1 |
| | LIPS DRY | 2 | | 2 |
| | MOUTH DRY | | 1 | 1 |
| | NAUSEA | 9 | 7 | 16 |
| | VOMITING | 10 | 8 | 18 |
| | *** Total for Group *** | 27 | 22 | 49 |
| Cardiovascular | AEFI | | | |
| | ARRHYTHMIA | | 1 | 1 |
| | BRADYCARDIA | | 1 | 1 |
| | CHEST PAIN | 1 | | 1 |
| | DIZZINESS | 10 | 8 | 18 |
| | FAINTNESS | 1 | 6 | 7 |
| | FLUSHING | 1 | 1 | 2 |
| | HYPOTENSION | | 2 | 2 |
| | SKIN COLD CLAMMY | | 1 | 1 |
| | SYNCOPE | | 1 | 1 |
| | VASOVAGAL REACTION | 9 | 23 | 32 |
| | *** Total for Group *** | 22 | 44 | 66 |
| Haematological | AEFI | | | |
| | EOSINOPHILIA | 1 | | 1 |
| | LYMPHADENITIS | 2 | | 2 |
| | LYMPHADENOPATHY | | 1 | 1 |
| | LYMPHADENOPATHY CERVICAL | | 1 | 1 |
| | THROMBOCYTOPENIA | 1 | | 1 |
| | *** Total for Group *** | 4 | 2 | 6 |

(Continued)

Table 1 Total HPV9 AEFIs at 30/09/2018 - CLASSIC SOC Groupings



| | | gender | | |
|---|---|---|---|---|
| | | Female | Male | Total |
| | | N | N | N |
| group | AEFI | | | |
| Local Reactions | ARM PAIN | 15 | 9 | 24 |
| | INJECTION SITE ABSCESS | 1 | | 1 |
| | INJECTION SITE BRUISING | 1 | 1 | 2 |
| | INJECTION SITE ERYTHEMA | 2 | 2 | 4 |
| | INJECTION SITE INFLAMMATION | 10 | 8 | 18 |
| | INJECTION SITE MASS | 6 | | 6 |
| | INJECTION SITE PAIN | 9 | 4 | 13 |
| | INJECTION SITE PRURITUS | 2 | | 2 |
| | INJECTION SITE REACTION | 1 | 1 | 2 |
| | INJECTION SITE SWELLING | 1 | 1 | 2 |
| | INJECTION SITE URTICARIA | | 1 | 1 |
| | SWELLING LOCALISED | 1 | 1 | 2 |
| | *** Total for Group *** | 49 | 28 | 77 |
| Musculoskeletal | AEFI | | | |
| | ARTHRALGIA | 1 | | 1 |
| | BACK PAIN | 1 | 1 | 2 |
| | CLAVICULAR SWELLING | | 1 | 1 |
| | MOVEMENTS REDUCED | 4 | 2 | 6 |
| | MUSCLE SPASTICITY | | 1 | 1 |
| | MUSCLE STIFFNESS | | 1 | 1 |
| | MUSCLE WEAKNESS | | 1 | 1 |
| | MUSCULOSKELETAL PAIN | 1 | | 1 |
| | MYALGIA | 4 | | 4 |
| | PAIN NECK/SHOULDER | 1 | | 1 |
| | *** Total for Group *** | 12 | 7 | 19 |
| Nervous System | AEFI | | | |
| | ATAXIA | | 1 | 1 |
| | COGNITIVE FUNCTION ABNORMAL | 1 | | 1 |
| | CONCUSSION | | 1 | 1 |
| | CONSCIOUSNESS DECREASED | | 1 | 1 |
| | CONVULSIONS | 1 | 2 | 3 |

(Continued)

| | | gender | | |
|---|---|---|---|---|
| | | Female | Male | Total |
| | | N | N | N |
| group | AEFI | | | |
| Nervous System | CONVULSIONS GRAND MAL | | 1 | 1 |
| | DEMYELINATION | | 1 | 1 |
| | EXHAUSTION | 1 | | 1 |
| | EYES ROLLING | | 1 | 1 |
| | HEADACHE | 6 | 7 | 13 |
| | HYPERTONIA | | 1 | 1 |
| | HYPOAESTHESIA | | 3 | 3 |
| | LIMB WEAKNESS | 1 | 3 | 4 |
| | MIGRAINE | 1 | | 1 |
| | MUSCLE CONTRACTIONS INVOLUNTARY | 1 | 2 | 3 |
| | NUMBNESS LOCALISED | 2 | | 2 |
| | PARAESTHESIA | 2 | | 2 |
| | PARAESTHESIA DISTAL | 3 | 1 | 4 |
| | SHAKING | 2 | 2 | 4 |
| | TWITCHING | | 3 | 3 |
| | WEAKNESS GENERALIZED | 2 | | 2 |
| | *** Total for Group *** | 23 | 30 | 53 |
| Others | AEFI | | | |
| | ANKLE OEDEMA | | 1 | 1 |
| | FALL | 1 | 1 | 2 |
| | FEELING COLD | 1 | 1 | 2 |
| | FEELING HOT AND COLD | 1 | 1 | 2 |
| | FEELING OF WARMTH | 1 | | 1 |
| | FEELING UNWELL | | 3 | 3 |
| | FEVER | 7 | 6 | 13 |
| | HEAVINESS IN LIMBS | 1 | | 1 |
| | INFLUENZA-LIKE SYMPTOMS | 2 | 1 | 3 |
| | LIPS SWELLING NON-SPECIFIC | | 1 | 1 |
| | PALLOR | 1 | 2 | 3 |
| | SHIVERING | | 2 | 2 |
| | SWEATING INCREASED | | 2 | 2 |

(Continued)

Table : Total HPV9 AEFIs at 30/09/2018 - CLASSIC SOC Groupings

| | | gender | | |
|---|---|---|---|---|
| | | Female | Male | Total |
| | | N | N | N |
| group | *** Total for Group *** | | | |
| Others | | 15 | 21 | 36 |
| Procedure Related | AEFI | | | |
| | MEDICATION ERROR | 6 | 4 | 10 |
| | *** Total for Group *** | 6 | 4 | 10 |
| Psychiatric Changes | AEFI | | | |
| | CONCENTRATION IMPAIRED | | 1 | 1 |
| | DEPERSONALIZATION | | 1 | 1 |
| | FATIGUE | 1 | 2 | 3 |
| | JITTERINESS | | 1 | 1 |
| | LETHARGY | 1 | 1 | 2 |
| | SOMNOLENCE | 1 | 2 | 3 |
| | TIREDNESS | 1 | 1 | 2 |
| | *** Total for Group *** | 4 | 9 | 13 |
| Reproductive Disorders | AEFI | | | |
| | DRUG EXPOSURE IN PREGNANCY | 3 | | 3 |
| | INTERMENSTRUAL BLEEDING | 2 | | 2 |
| | MENSTRUAL DISORDER | 1 | | 1 |
| | *** Total for Group *** | 6 | | 6 |
| Respiratory | AEFI | | | |
| | COUGHING | | 1 | 1 |
| | DYSPNOEA | 2 | 1 | 3 |
| | HYPERVENTILATION | 1 | | 1 |
| | NASAL CONGESTION | | 1 | 1 |
| | TACHYPNOEA | 2 | | 2 |
| | THROAT IRRITATION | | 1 | 1 |
| | THROAT TIGHTNESS | 1 | | 1 |
| | *** Total for Group *** | 6 | 4 | 10 |
| Skin and Appendages | AEFI | | | |
| | BULLOUS ERUPTION | | 1 | 1 |
| | ERYTHEMA MULTIFORME | | 1 | 1 |
| | MACULAR RASH | 1 | | 1 |

(Continued)

| | | gender | | |
|---|---|---|---|---|
| | | Female | Male | Total |
| | | N | N | N |
| group | AEFI | | | |
| Skin and Appendages | PRURITUS | 1 | | 1 |
| | RASH | | 3 | 3 |
| | RASH MACULO-PAPULAR | 1 | 1 | 2 |
| | RASH PRURITIC | 3 | 1 | 4 |
| | SKIN DRY | 2 | | 2 |
| | SKIN EXFOLIATION | 2 | | 2 |
| | URTICARIA | | 2 | 2 |
| | *** Total for Group *** | 10 | 9 | 19 |
| Special Senses | AEFI | | | |
| | MYDRIASIS | | 1 | 1 |
| | PHOTOPHOBIA | | 1 | 1 |
| | TASTE METALLIC | | 1 | 1 |
| | VISION BLURRED | | 1 | 1 |
| | VISUAL DISTURBANCE | | 1 | 1 |
| | *** Total for Group *** | | 5 | 5 |
| Urinary | AEFI | | | |
| | EPIDIDYMITIS | | 1 | 1 |
| | *** Total for Group *** | | 1 | 1 |
| Total AEFIs | | 184 | 186 | 370 |