133 Molesworth Street
PO Box 5013
Wellington 6145, New Zealand
T +64 4 496 2000

6 November 2017

[redacted]

Ref: H201703776

Dear [redacted]

Response to your request for official information

Thank you for your request of 7 October 2017 under the Official Information Act 1982 (the Act) for

> *"I am writing to request under the NZ FOIA, the complete numbers regarding suspected adverse reactions reported in boys and men, to CARM, from January 2017 until October 2017, with Gardasil 9.*
>
> *I would also like to request complete numbers of adverse reactions reported in girls and women from January 2017 to October 2017, with Gardasil 9.*
>
> *I would request the numbers of any reports of adverse reactions, that have been removed from the public database, for the Gardasil 9 vaccine for boys and men and girls and women, for period January 2017 to October 2017".*

The information relating to this request is itemised below, with a copy of the document titled 'HPV Gardasil 9 - Vaccine' prepared by the New Zealand Pharmacovigilance Centre on 24 October 2017 attached. Please note that the search period used was 1 January 2017 to 30 September 2017 as complete data for the month of October 2017 were not yet available at the time of compiling this response.

Some of the information you request is already in the public domain. I have provided details of where this information can be accessed in the table below.

Request	**Response**
Complete numbers regarding suspected adverse reactions reported in boys and men, to CARM, from January 2017 until October 2017, with Gardasil 9.	Please refer to Tables 1 and 2 of the attached document.

Complete numbers of adverse reactions reported in girls and women from January 2017 to October 2017, with Gardasil 9.	Please refer to Tables 1 and 2 of the attached document.
Numbers of any reports of adverse reactions, that have been removed from the public database, for the Gardasil 9 vaccine for boys and men and girls and women, for period January 2017 to October 2017	Please refer to Table 3 of the attached document. All valid reports as defined in the *Guidelines on the Regulation of Therapeutic Products in New Zealand, Part 8: Pharmacovigilance* (www.medsafe.govt.nz/regulatory/current-guidelines.asp) of suspected adverse reactions are entered into the CARM database. There is only one database. However, only certain categories of reports are included in the Suspected Medicine Adverse Reaction Search (SMARS) as noted on page 3 of the attached document and on the SMARS disclaimer page (www.medsafe.govt.nz/projects/B1/ADRDisclaimer.asp). The process is as follows: • CARM review all the cases reported to them according to the World Health Organization (WHO) causality assessment procedure. This procedure is a tool used to help detect signals of problems with medicines, including vaccines. • CARM transmit cases that they consider describe a link between a medicine and adverse reaction to Medsafe. • Medsafe publishes this information which is accessible using SMARS as this is considered to be of public interest. Please note that cases in SMARS are published in arrears therefore the figures provided will not match the current SMARS figures.

I trust this information fulfils your request. You have the right, under section 28 of the Act, to ask the Ombudsman to review my decision to withhold information under this request.

Yours sincerely

[redacted]

Acting Group Manager
Medsafe

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 H201703776**

Prepared by: **New Zealand Pharmacovigilance Centre**
24 October 2017

Specific Request:

1) The complete numbers regarding suspected adverse reactions reported in boys and men, to CARM, from January 2017 until October 2017, with Gardasil 9.

2) The complete numbers of adverse reactions reported in girls and women from January 2017 until October 2017, with Gardasil 9.

3) The numbers of any reports of adverse reactions, that have been removed from the public database, for the Gardasil 9 vaccine for boys and men and girls and women for the period January 2017 to October 2017.

Contents:

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

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

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

Background to information

a) The cases included in the analyses presented in this OIA response include all cases of adverse events following immunisation with Gardasil 9 irrespective of whether or not a causal link to the administered vaccine has been established.

b) The public database SMARS is populated with all cases, up to three months previous, where there is an assessed causal link with the medicine or vaccine.

Cases which are **not included** are:

- Cases where a causal link has not been determined
- Cases recording a vaccination which has been administered in error with no associated reaction
- Cases received in the most recent three months

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

Results

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

Request 1)

Table 1: The number of cases reported to Gardasil 9

Date	No. of Reports	Cumulative Total
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

Request 2)

Table 2: Gardasil 9 - Age Distribution by Gender

Age (Years)	Females	Males	TOTAL
10	1		**1**
11	2	2	**4**
12	13	11	**24**
13	1	6	**7**
14		5	**5**
15		7	**7**
16	2	9	**11**
17	1	2	**3**
18		1	**1**
19	3		**3**
20			**0**
Over 20	8	2	**10**
Unknown			**0**
Total	**31**	**45**	**76**

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

Request 3)

There are no cases removed from the public database.

However, as noted in (b) of *Background to Information* [page 3] only certain categories are included on the SMARS database.

Table 3: The number of cases reported to Gardasil 9 which are not included on SMARS at 30 September 2017

Type of case	Females	Males	TOTAL
Non-Causal	2	5	7
Administration error	3	3	6
3 months time-locked causal cases*	10	20	30

* As the SMARS database is populated 3 months in arrears, these cases will be updated monthly with the September cases only populating the SMARS database in the January 2018 update.