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23 MAY 2016

Ref: H201601585

Dear

**Response to your request for official information**

Thank you for your request of 21 April 2016 under the Official Information Act 1982 (the Act) for

“Assistance under the NZ FOIA, in obtaining the CARM statistical reports, pertaining to Gardasil vaccine adverse reports, specifically for the Christchurch, Canterbury Region. I would like the data that covers reports from the period of time of commencement of use of Gardasil in NZ, to present day, for this region.

I would be most obliged, if I could have a break down of those reported events which have been deemed related to Gardasil, by CARM and of these, how many were deemed serious. I would hope that the types of adverse events are also recorded. I am also wanting to know how many, if any claimants, have received ACC payments, as a result of Gardasil vaccine related injury”.

The information relating to this request is itemised below, with a copy of the document attached.

Request	Response
<p><i>CARM statistical reports, pertaining to Gardasil vaccine adverse reports, specifically for the Christchurch, Canterbury Region. I would like the data that covers reports from the period of time of commencement of use of Gardasil in NZ, to present day, for this region.</i></p>	<p>Attached is:            1. A report titled ‘HPV Vaccine – Official Information Act Request’ with a period of 01 September 2008 to 31 March 2016.</p>
<p><i>I would be most obliged, if I could have a break down of those reported events which have been deemed related to Gardasil, by CARM and of these, how many were deemed serious. I would hope that the types of adverse events are also recorded.</i></p>	<p>Attached is:            2. A report titled ‘HPV Vaccine – Official Information Act Request’ with a period of 01 September 2008 to 31 March 2016.</p>

*I am also wanting to know how many, if any claimants, have received ACC payments, as a result of Gardasil vaccine related injury.*

*This part of the request has been transferred to ACC.*

I trust this information fulfils your request.

Yours sincerely

Acting Group Manager  
Medsafe



Report Title: HPV Vaccine  
Official Information Act Request

Prepared for:

Prepared by: Centre for Adverse Reactions Monitoring (CARM)  
New Zealand Pharmacovigilance Centre  
May 2016

Request: (NZPhvC interpretation of emailed request dated 21 April 2016)

1. Number of cases reported to CARM for Gardasil vaccine that meet the following criteria
  - a. From Christchurch, Canterbury Region
  - b. Period: 01 September 2008 to 31 March 2016
  - c. Assessed by CARM as 'related to Gardasil' ( See Note 1 )
2. Number of cases categorised serious ( See Note 2 )
3. Types of Adverse Events Following Immunisation (AEFIs ) ( See Note 3 )
4. Number of ACC payments for Gardasil related injury

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### Summary

Data Lock Point:	31 March 2016	
	Total Reports from Christchurch, Canterbury	46
	Total AEFIs from Christchurch, Canterbury	97
	Serious cases	2
	Number of ACC payments	Unknown to CARM



**Summary**

Data Lock Point: 31 March 2016

1. **Number of cases reported to CARM for Gardasil HPV vaccine that meet the following criteria**
  - a. From Christchurch, Canterbury Region
  - b. Period : 01 September 2008 to 31 March 2016
  - c. Assessed by CARM as 'related to Gardasil' ( See Note 1)

Year	Number of cases
2008	46
2009	3
2010	2
2011	8
2012	5
2013	3
2014	3
2015	4
2016 (31/03/2016)	16
<b>Total</b>	<b>101</b>

Note 1: Causality is assessed using a 6 level scale

- |   |   |
|---|---|
| 1 | Definitely  |
| 2 | Probably  |
| 3 | Possibly  |
| 4 | Unlikely  |
| 5 | Awaiting further information to enable assessment |
| 6 | Insufficient information to enable assessment     |

Related cases are those where the adverse events are assessed as

- |    |                       |
|----|-----------------------|
|    | Definitely            |
| or | Probably              |
| or | Possibly              |
|    | linked to the vaccine |

2. **Number of cases categorised serious? ( See Note 2 )**

Serious Cases 2

Note 2:

Definition of Seriousness

The following codes are used to define seriousness in accordance with international criteria as detailed in the ICH E2D guidelines:

- C = Congenital abnormality
- D = Died
- H = Hospitalisation or prolonged hospitalisation
- L = Life Threatening
- O = Intervention required to avoid permanent harm
- P = Persisting disability (at the time of the report)

Seriousness is assessed for each report based on the 'result/outcome of the adverse event(s)'; the individual events are not separately assessed for seriousness.



3. Types of Adverse Events (AEFIs) ( See Note 3 )

Table: HPV Vaccine – AEFIs per System Organ Class

Individual AEFIs by SOC ▼	Total
Alimentary	8
Injection Site	12
Cardiovascular	13
Haematological	1
Musculoskeletal	12
Nervous System	22
Others	6
Psychiatric Changes	7
Respiratory	3
Skin and Appendages	10
Special Senses	3
<b>Total</b>	<b>97</b>

The number of occurrences of each individual AEFI is in the appended listing

Note 3:

AEFI = Adverse Event Following Immunisation

group	AEFI	region		
		Canterbury	Christchurch	Total
		N	N	N
Alimentary	NAUSEA	2	4	6
	VOMITING	1	1	2
	*** Total for Group ***	3	5	8
	Application Site	AEFI		
	INJECTION SITE BRUISING	1	1	1
	INJECTION SITE ERYTHEMA		1	1
	INJECTION SITE INFLAMMATION		4	4
	INJECTION SITE MASS		1	1
	INJECTION SITE PAIN	3	4	4
	INJECTION SITE PRURITUS		1	1
	*** Total for Group ***	2	10	12
Cardiovascular	AEFI			
	BRADYCARDIA		1	1
	CHEST PAIN		1	1
	DIZZINESS		3	3
	FAINTNESS		1	1
	TACHYCARDIA		1	1
	VASOVAGAL REACTION	3	3	6
	*** Total for Group ***	3	10	13
	Haematological	AEFI		
LYMPHOPENIA			1	1
*** Total for Group ***			1	1
Musculoskeletal	AEFI			
	ARM PAIN	1	3	4
	ARTHRALGIA		1	1
	BURSITIS	1		1
	MYALGIA	2	2	4
	PAIN NECK/SHOULDER	2		2

(Continued)

group	*** Total for Group ***	region		Total
		Canterbury	Christchurch	
		N	N	
Musculoskeletal		6	6	12
Nervous System	AEFI			
	DYSAESTHESIA		2	2
	HEADACHE	4	8	12
	NUMBNESS LOCALISED	2	2	4
	PAIN		1	1
	PARAESTHESIA DISTAL		1	1
	SHAKING		1	1
	TWITCHING		1	1
	*** Total for Group ***	6	16	22
	Others	AEFI		
ANAPHYLACTIC REACTION			1	1
FEELING OF WARMTH			1	1
FEVER			3	3
PALLOR			1	1
*** Total for Group ***			6	6
Psychiatric Changes	AEFI			
	FATIGUE		1	1
	LETHARGY	1		1
	NERVOUSNESS		1	1
	SOMNOLENCE	1	1	2
	TIREDNESS	1	1	2
	*** Total for Group ***	3	4	7
Respiratory	AEFI			
	BRONCHOSPASM		1	1
	COUGHING		1	1
	THROAT SORE	1		1
	*** Total for Group ***	1	2	3

(Continued)

group	AEFI	region		
		Canterbury	Christchurch	Total
		N	N	N
Skin and Appendages	MORBILLIFORM RASH		1	1
	PRURITUS		1	1
	RASH	2	3	5
	RASH PRURITIC	1		2
	URTICARIA		1	1
	*** Total for Group ***	3	7	10
	Special Senses	AEFI		
EYE PAIN			1	1
MYDRIASIS			1	1
PHOTOPHOBIA		1		1
*** Total for Group ***		1	2	3
Total AEFIs		28	69	97

RELEASED UNDER THE OFFICIAL INFORMATION ACT