MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

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- 8 DEC 2017

[redacted]

Ref: H201704040

Dear [redacted]

Response to your request for official information

Thank you for your request of 10 November 2017 under the Official Information Act 1982 (the Act) for

> *"It was remiss of me to not also request the types of, or nature of the adverse events that were reported, regarding my FOIA, so I would like to do so now. i.e. types of adverse events, suspected or linked, or any 'types' of that have been compensated thus far, for Gardasil 9 in NZ. I would also like clarification as to what administration events meant on the response.*
>
> *What, if any follow up of these reported events is there and is it ongoing, through CARM, or any other organisation, with these reported adverse events with Gardasil 9?*
>
> *Have any NZ women found they were pregnant whilst receiving Gardasil and what monitoring is in place for them? The USA has a Special Pregnancy Registry for women found to be pregnant, if they have received the vaccine, whilst pregnant".*

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 attached. 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**
Types of adverse events, suspected or linked, or any 'types' of that have been compensated thus far, for Gardasil 9 in NZ.	There were a total of 76 cases received by the Centre for Adverse Reactions Monitoring (CARM) during the period 1 January 2017 to 30 September 2017. This total figure of 76 cases was provided to you in response to your previous request under the Act (H201703776).

	Of these 76 cases, 6 were of 'Administration events' (see below for an explanation of what these events mean). Individual adverse events as reported in the remaining 70 cases are contained in the table of the attached document. These adverse events are listed in vaccine groups and broken down by gender. Medsafe and the Ministry of Health do not hold information on compensation as a result of treatment injury. Please contact the Accident Compensation Corporation (ACC) for information on compensation regarding Gardasil 9.
Clarification as to what administration events meant on the response.	As stated on the first page of the attached document, administration events are cases recording a vaccination which has been administered in error – incorrect time gap between first and second vaccination – with no associated reaction.
What, if any follow up of these reported events is there and is it ongoing, through CARM, or any other organisation, with these reported adverse events with Gardasil 9?	Follow up of reported events is the responsibility of the patient's healthcare professional. The spontaneous reporting system is not a clinical study, but an alerting system. CARM may follow up with the reporter if they require further details in order to validate the case. Medsafe is the medicines regulator and is unable to provide health advice to individuals.
Have any NZ women found they were pregnant whilst receiving Gardasil and what monitoring is in place for them?	CARM has identified one case of 'Drug exposure in pregnancy' where the patient received the vaccine on 21 July 2017 and found she was pregnant on 2 August 2017. Further HPV vaccination has been delayed until after the baby is born and there are no adverse reactions.

The USA has a Special Pregnancy Registry for women found to be pregnant, if they have received the vaccine, whilst pregnant	Merck Sharp & Dohme (MSD) is the sponsor of Gardasil 9 in New Zealand. MSD has planned enhanced pharmacovigilance activities to monitor pregnancy exposures. As you have noted, this includes an enhanced surveillance program of pregnancy exposures to Gardasil 9 reported in the United States. Because of the small population size in New Zealand and the age at which Gardasil 9 is given, the number of exposed pregnancies is too small for a pregnancy register to be successful. A published study by Bonde et al 2016 is an example of international research regarding HPV vaccine safety during pregnancy. This article is publicly available from this link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4994723/.

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

Prepared for: **Medsafe H201704040**

Prepared by: **New Zealand Pharmacovigilance Centre**
27 November 2017

Specific Request:

Follow-up to H201703776 – HPV9 reports January 2017 to October 2017 for the numbers of reports of adverse reactions with Gardasil 9 per gender

1) Detail of the adverse events reported with Gardasil 9 per gender.

2) Clarification of 'administration events'

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.

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Adverse events
Tabulation of occurrences of grouped individual adverse events with gender breakdown

		gender		
		Female	Male	Total
		N	N	N
vacc_group	AEFI			
CARDIOVASCULAR	BRADYCARDIA		1	1
	CHEST PAIN	1		1
	HYPOTENSION		2	2
	*** Total for Group ***	1	3	4
HYPERSENSITIVITY	AEFI			
	BULLOUS ERUPTION		1	1
	DYSPNOEA	2	1	3
	LIPS SWELLING NON-SPECIFIC		1	1
	MACULAR RASH	1		1
	NASAL CONGESTION		1	1
	NUMBNESS LOCALISED	1		1
	PARAESTHESIA	1		1
	PARAESTHESIA DISTAL	1	1	2
	RASH MACULO-PAPULAR	1	1	2
	RASH PRURITIC	1		1
	TACHYPNOEA	2		2
	THROAT IRRITATION		1	1
	*** Total for Group ***	10	7	17
Injury	AEFI			
	CONCUSSION		1	1
	FALL		1	1
	*** Total for Group ***		2	2
LOCAL REACTION	AEFI			
	ARM PAIN	6	4	10
	INJECTION SITE ABSCESS	1		1
	INJECTION SITE INFLAMMATION	4	1	5
	INJECTION SITE PAIN	3		3
	INJECTION SITE PRURITUS	1		1
	SWELLING LOCALISED		1	1
	*** Total for Group ***	15	6	21

(Continued)

		gender		
		Female	Male	Total
		N	N	N
vacc_group	AEFI			
MISCELLANEOUS	BURNING SENSATION		1	1
	CLAVICULAR SWELLING		1	1
	DRUG EXPOSURE IN PREGNANCY	1		1
	INTERMENSTRUAL BLEEDING	2		2
	MEDICATION ERROR	1		1
	MYDRIASIS		1	1
	TASTE METALLIC		1	1
	VISION BLURRED		1	1
	*** Total for Group ***	4	5	9
NEUROLOGICAL	AEFI			
	CONCENTRATION IMPAIRED		1	1
	CONSCIOUSNESS DECREASED		1	1
	CONVULSIONS		2	2
	CONVULSIONS GRAND MAL		1	1
	EYES ROLLING		1	1
	JITTERINESS		1	1
	MUSCLE CONTRACTIONS INVOLUNTARY		1	1
	MUSCLE SPASTICITY		1	1
	TWITCHING		1	1
	*** Total for Group ***		10	10
PSYCHIATRIC	AEFI			
	SOMNOLENCE		1	1
	*** Total for Group ***		1	1
SOMATIC RESPONSES	AEFI			
	ABDOMINAL PAIN		2	2
	BACK PAIN	1		1
	DIARRHOEA	1		1
	EXHAUSTION	1		1
	FATIGUE	1	1	2
	FEELING COLD		1	1
	FEELING HOT AND COLD	1	1	2

(Continued)

		gender		
		Female	Male	Total
		N	N	N
vacc_group	AEFI			
SOMATIC RESPONSES	FEELING OF WARMTH	1		1
	FEELING UNWELL		2	2
	FEVER	1	2	3
	HEADACHE	2	3	5
	INFLUENZA-LIKE SYMPTOMS	1		1
	LETHARGY		1	1
	LIMB WEAKNESS	1		1
	LYMPHADENITIS	1		1
	LYMPHADENOPATHY CERVICAL		1	1
	MOVEMENTS REDUCED	1		1
	MUSCLE WEAKNESS		1	1
	MUSCULOSKELETAL PAIN	1		1
	MYALGIA	2		2
	NAUSEA	3	4	7
	SHIVERING		1	1
	TIREDNESS	1		1
	VOMITING	7	3	10
	WEAKNESS GENERALIZED	1		1
	*** Total for Group ***	28	23	51
VACCINE ANXIETY	AEFI			
	DIZZINESS	5	3	8
	FAINTNESS		5	5
	HYPERVENTILATION	1		1
	PALLOR		2	2
	SHAKING		2	2
	SKIN COLD CLAMMY		1	1
	SYNCOPE		2	2
	VASOVAGAL REACTION	4	14	18
	*** Total for Group ***	10	29	39
Total AEFIs		68	86	154