

12 JUL 2019

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[REDACTED]

Ref: H201903752

Dear [REDACTED]

Response to your request for official information

Thank you for your request for information under the Official Information Act 1982 (the Act) on 3 June 2019 for:

"Please could you provide details regarding Gardasil including the details listed below for the dates September to December 2016/September to December 2017 and for January to December 2018. Please ensure that the same format is used as for Ref H20150303369

CARM case number

Date of report

Age

Gender

Dose number after which report made (ie first second third dose) and any other vaccine administered concominantly

Reaction reported"

On 12 June 2019 you refined your request to include both Gardasil and Gardasil 9.

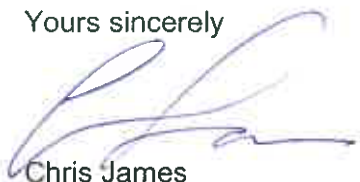
The report for the HPV-4 Gardasil contains information on cases of suspected adverse reactions reported to the Centre for Adverse Reactions Monitoring (CARM). This report covers the time period from 1 September 2016 to 31 December 2018, and is attached as Appendix 1 to this letter.

The report for the HPV Gardasil 9 contains information on cases of suspected adverse reactions reported to CARM. This report covers the time period from 1 January 2017 to 31 December 2018, and is attached as Appendix 2 to this letter. There were no Gardasil 9 cases reported prior to March 2017.

I trust that this information fulfils your request. Under section 28(3) of the Act you have the right to ask the Ombudsman to review any decisions made under this request.

Please note that this response, with your personal details removed, may be published on the Medsafe website.

Yours sincerely



Chris James
Group Manager
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Report Title: HPV-4 Gardasil Vaccine
Official Information Act Request

Prepared for: Medsafe

Prepared by: New Zealand Pharmacovigilance Centre
July 2019

Specific Request 1: "Please could you provide details regarding Gardasil including the details listed below for the dates September to December 2016/September to December 2017 and for January to December 2018. Please ensure that the same format is used as for Ref H20150303369
 CARM case number
 Date of report
 Age
 Gender
 Dose number after which report made (ie first second third dose) and
 any other vaccine administered concominantly
 Reaction reported."

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

Prepared for: Medsafe

Prepared by: New Zealand Pharmacovigilance Centre
 July 2019

Specific Request 1: "Please could you provide details regarding Gardasil including the details listed below for the dates September to December 2016/September to December 2017 and for January to December 2018. Please ensure that the same format is used as for Ref H20150303369
 CARM case number
 Date of report
 Age
 Gender
 Dose number after which report made (ie first second third dose) and
 any other vaccine administered concominantly
 Reaction reported."

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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



New Zealand Pharmacovigilance Centre

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Background to information

The details 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 31 December 2018

Cases are included

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

Released under the Official Information Act 1982



Results - Summary of reports

For the period of 01 January 2017 to 31 December 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
October	3	172
November	20	192
December	10	202

HPV 9 Vaccine cases reported to CARM – 01 January 2017 to 31 December 2018

This listing includes all assessed Adverse Events Following Immunisation (AEFIs) for each case irrespective of causality.

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
123710	MAR2017	Male	12	* HPV9-1 VACCINE	MUSCLE CONTRACTIONS INVOLUNTARY SHAKING HEADACHE FAINTNESS TWITCHING
123835	MAR2017	Female	12	* HPV9-1 VACCINE	DIZZINESS FEELING OF WARMTH NAUSEA VOMITING
123867	MAR2017	Male	12	* HPV9-1 VACCINE	MUSCLE SPASTICITY ARM PAIN FAINTNESS
123903	MAR2017	Female	23	* HPV9-1 VACCINE	DIARRHOEA VOMITING MYALGIA HEADACHE
123942	APR2017	Female	16	* HPV9-1 VACCINE	INJECTION SITE INFLAMMATION INJECTION SITE PAIN
123943	APR2017	Female	12	* HPV9-1 VACCINE	VASOVAGAL REACTION
123944	APR2017	Male	12	* HPV9-1 VACCINE	VASOVAGAL REACTION
123985	APR2017	Male	12	* HPV9-1 VACCINE	VASOVAGAL REACTION
124026	APR2017	Female	12	* HPV9-1 VACCINE	DIZZINESS TACHYPNOEA VASOVAGAL REACTION
124027	APR2017	Female	12	* HPV9-1 VACCINE	DYSPNOEA TACHYPNOEA PARAESTHESIA DISTAL HYPERVENTILATION
124028	APR2017	Female	12	* HPV9-1 VACCINE	ARM PAIN DIZZINESS NAUSEA HEADACHE INJECTION SITE PRURITUS
124029	APR2017	Female	12	* HPV9-1 VACCINE	FEELING HOT AND COLD VOMITING

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
124030	APR2017	Male	15	* HPV9-1 VACCINE ASCORBIC ACID INFLUENZA - TRIVALENT	BURNING SENSATION PALLOR FAINTNESS
124112	APR2017	Female	12	* HPV9-1 VACCINE	ARM PAIN FEVER MUSCULOSKELETAL PAIN EXHAUSTION TIREDNESS
124165	APR2017	Male	12	* HPV9-1 VACCINE SALBUTAMOL FLUTICASONE	RASH MACULO-PAPULAR
124234	MAY2017	Male	12	* HPV9-1 VACCINE VALPROATE SODIUM CARBAMAZEPINE PIZOTIFEN CLOBAZAM	CONVULSIONS SOMNOLENCE FATIGUE
124247	MAY2017	Female	23	* HPV4-1 VACCINE * HPV9-1 VACCINE	INJECTION SITE ABSCESS ARM PAIN
124248	MAY2017	Female	13	* HPV9-1 VACCINE	DIZZINESS NAUSEA VOMITING WEAKNESS GENERALIZED
124335	MAY2017	Male	13	* HPV9-1 VACCINE	HEADACHE VISION BLURRED CONCENTRATION IMPAIRED
124336	MAY2017	Female	26	* HPV9-1 VACCINE	ARM PAIN LYMPHADENITIS
124351	MAY2017	Female	12	* HPV9-1 VACCINE MELATONIN	DIZZINESS VOMITING
124352	MAY2017	Male	16	* HPV9-1 VACCINE	VASOVAGAL REACTION
124385	MAY2017	Male	14	* HPV9-1 VACCINE	ARM PAIN MUSCLE WEAKNESS SWELLING LOCALISED
124418	MAY2017	Male	12	* HPV9-1 VACCINE CETOMACROGOL CREAM AQUEOUS CREAM LORATADINE	BULLOUS ERUPTION
124608	MAY2017	Male	14	* HPV9-1 VACCINE	VASOVAGAL REACTION
124609	MAY2017	Male	12	* HPV9-1 VACCINE	VASOVAGAL REACTION

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
124659	MAY2017	Male	16	* HPV9-1 VACCINE	PARAESTHESIA DISTAL
124660	MAY2017	Male	16	* HPV9-1 VACCINE	VASOVAGAL REACTION
124661	MAY2017	Male	17	* HPV9-1 VACCINE	DIZZINESS
124662	MAY2017	Male	16	* HPV9-1 VACCINE	DIZZINESS PALLOR
124760	JUN2017	Male	16	* HPV9-1 VACCINE	LIPS SWELLING NON-SPECIFIC THROAT IRRITATION
124807	JUN2017	Male	15	* HPV9-2 VACCINE	DIZZINESS NAUSEA
124820	JUN2017	Male	16	* HPV9-1 VACCINE	VASOVAGAL REACTION
124869	JUN2017	Male	11	* HPV9-1 VACCINE	CONVULSIONS GRAND MAL
124975	JUN2017	Female	17	* HPV9-1 VACCINE MERCILON	VASOVAGAL REACTION
124976	JUN2017	Female	12	* HPV9-1 VACCINE	INJECTION SITE INFLAMMATION
124977	JUN2017	Female	25	* HPV9-2 VACCINE	INJECTION SITE PAIN INFLUENZA-LIKE SYMPTOMS
125013	JUN2017	Female	21	* HPV9-1 VACCINE FLUOXETINE	MOVEMENTS REDUCED ARM PAIN
125070	JUL2017	Male	15	* HPV9-1 VACCINE * INFLUENZA - TRIVALENT	NAUSEA EYES ROLLING FAINTNESS
125071	JUL2017	Male	11	* HPV9-1 VACCINE * Tdap	VASOVAGAL REACTION MYDRIASIS
125093	JUL2017	Male	16	* HPV9-2 VACCINE GABAPENTIN	INJECTION SITE INFLAMMATION
125149	JUL2017	Male	25	* HPV9 VACCINE	VASOVAGAL REACTION
125169	JUL2017	Female	12	* HPV9-1 VACCINE * INFLUENZA - TRIVALENT	MACULAR RASH
125194	JUL2017	Female	12	* HPV9-1 VACCINE	MYALGIA FATIGUE

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
125195	JUL2017	Female	19	* HPV9-1 VACCINE HPV4-2 VACCINE HPV4-1 VACCINE	VASOVAGAL REACTION VOMITING
125284	JUL2017	Male	12	* HPV9-2 VACCINE	MEDICATION ERROR
125285	JUL2017	Female	12	* HPV9-2 VACCINE	MEDICATION ERROR
125286	JUL2017	Female	12	* HPV9-2 VACCINE	MEDICATION ERROR
125287	JUL2017	Male	12	* HPV9-2 VACCINE SALBUTAMOL	MEDICATION ERROR
125544	AUG2017	Female	28	* HPV9-1 VACCINE	DRUG EXPOSURE IN PREGNANCY
125612	AUG2017	Male	15	* HPV9-2 VACCINE	NAUSEA VOMITING ABDOMINAL PAIN FEVER ARM PAIN
125613	AUG2017	Male	14	* HPV9-1 VACCINE	VASOVAGAL REACTION
125614	AUG2017	Male	15	* HPV9 VACCINE	SYNCOPE
125623	AUG2017	Male	14	* HPV9-1 VACCINE	FAINTNESS
125624	AUG2017	Male	13	* HPV9-1 VACCINE	VASOVAGAL REACTION
125625	AUG2017	Male	14	* HPV9-1 VACCINE	VASOVAGAL REACTION
125626	AUG2017	Male	15	* HPV9 VACCINE	FALL VASOVAGAL REACTION CONCUSSION
125647	AUG2017	Male	16	* HPV9-1 VACCINE	FEELING UNWELL
125648	AUG2017	Male	16	* HPV9-2 VACCINE	FEELING UNWELL
125656	AUG2017	Female	16	* HPV9-1 VACCINE * Tdap	ARM PAIN INJECTION SITE INFLAMMATION
125744	AUG2017	Male	13	* HPV9 VACCINE	VASOVAGAL REACTION VOMITING
125818	SEP2017	Female	10	* HPV9-1 VACCINE LAX-SACHETS	RASH MACULO-PAPULAR RASH PRURITIC

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
125831	SEP2017	Female	19	* HPV9-1 VACCINE HPV4 VACCINE HPV4-3 VACCINE HPV4-2 VACCINE HPV4-1 VACCINE	CHEST PAIN DYSPNOEA MEDICATION ERROR BACK PAIN VOMITING
125881	SEP2017	Male	13	* HPV9 VACCINE * Tdap	FEVER HEADACHE JITTERINESS
125982	SEP2017	Female	26	* HPV9-1 VACCINE PARACETAMOL	INJECTION SITE INFLAMMATION INJECTION SITE PAIN
125989	SEP2017	Male	13	* HPV9-1 VACCINE	CLAVICULAR SWELLING LYMPHADENOPATHY CERVICAL
126003	SEP2017	Female	11	* HPV9-1 VACCINE Tdap	INTERMENSTRUAL BLEEDING
126028	SEP2017	Female	11	* HPV9-2 VACCINE	INTERMENSTRUAL BLEEDING
126029	SEP2017	Female	19	* HPV9 VACCINE AVA 30 ED	NUMBNESS LOCALISED PARAESTHESIA LIMB WEAKNESS
126040	SEP2017	Male	17	* HPV9-2 VACCINE	ARM PAIN
126041	SEP2017	Male	23	* HPV9-1 VACCINE	VASOVAGAL REACTION
126063	SEP2017	Male	12	* HPV9-2 VACCINE	HYPOTENSION CONVULSIONS CONSCIOUSNESS DECREASED
126064	SEP2017	Male	13	* HPV9 VACCINE SALBUTAMOL	MEDICATION ERROR
126078	SEP2017	Female	24	* HPV9-1 VACCINE HPV4-3 VACCINE HPV4-2 VACCINE HPV4-1 VACCINE	EOSINOPHILIA MYALGIA FEVER MEDICATION ERROR
126113	SEP2017	Male	15	* HPV9-2 VACCINE	FEELING COLD SHIVERING NAUSEA VOMITING LETHARGY
126124	SEP2017	Male	18	* HPV9-2 VACCINE	DYSPNOEA FEELING HOT AND COLD TASTE METALLIC SHAKING NASAL CONGESTION

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
126149	OCT2017	Male	17	* HPV9-2 VACCINE	EPIDIDYMITIS
126169	OCT2017	Male	14	* HPV9-1 VACCINE	ARM PAIN
126191	OCT2017	Female	12	* HPV9-1 VACCINE	VASOVAGAL REACTION
126300	OCT2017	Male	17	* HPV9-2 VACCINE	INJECTION SITE ERYTHEMA
126370	OCT2017	Male	12	* HPV9-2 VACCINE	ARM PAIN HEADACHE
126371	OCT2017	Female	13	* HPV9-2 VACCINE	NAUSEA HEADACHE LETHARGY FEVER
126387	OCT2017	Male	27	* HPV9 VACCINE	VASOVAGAL REACTION
126403	OCT2017	Female	23	* HPV9-3 VACCINE	INJECTION SITE MASS INJECTION SITE PAIN MOVEMENTS REDUCED
126413	OCT2017	Female	24	* HPV9-1 VACCINE	FEELING COLD VOMITING SHAKING FEVER ARTHRALGIA
126414	OCT2017	Male	13	* HPV9-2 VACCINE	LYMPHADENOPATHY
126415	OCT2017	Male	12	* HPV9-1 VACCINE	HYPOAESTHESIA LIMB WEAKNESS
126420	OCT2017	Female	12	* HPV9-1 VACCINE	INJECTION SITE INFLAMMATION NAUSEA ARM PAIN FEVER
126421	OCT2017	Female	12	* HPV9-1 VACCINE FLUTICASONE SALBUTAMOL LORATADINE	INJECTION SITE INFLAMMATION
126463	NOV2017	Female	16	* HPV9-1 VACCINE	ARM PAIN MOVEMENTS REDUCED
126488	NOV2017	Male	12	* HPV9-2 VACCINE	LIMB WEAKNESS HYPOAESTHESIA INJECTION SITE INFLAMMATION
126489	NOV2017	Male	13	* HPV9-2 VACCINE	INFLUENZA-LIKE SYMPTOMS FATIGUE

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
126500	NOV2017	Female	13	* HPV9-2 VACCINE	ARM PAIN INJECTION SITE SWELLING
126536	NOV2017	Female	25	* HPV9 VACCINE ANTIHISTAMINES UNCLASSIFIED	INFLUENZA-LIKE SYMPTOMS MENSTRUAL DISORDER
126567	NOV2017	Female	12	* HPV9-1 VACCINE	SKIN DRY LIPS DRY SKIN EXFOLIATION
126568	NOV2017	Female	13	* HPV9-2 VACCINE	SKIN DRY LIPS DRY SKIN EXFOLIATION
126591	NOV2017	Female	25	* HPV9 VACCINE	INJECTION SITE PAIN INJECTION SITE MASS
126592	NOV2017	Male	12	* HPV9 VACCINE * Tdap	DIARRHOEA VOMITING ANKLE OEDEMA
126593	NOV2017	Male	26	* HPV9 VACCINE	HEADACHE PHOTOPHOBIA SWEATING INCREASED SHIVERING NAUSEA
126617	NOV2017	Male	13	* HPV9-2 VACCINE	URTICARIA
126623	NOV2017	Male	13	* HPV9-1 VACCINE	INJECTION SITE INFLAMMATION ARM PAIN MOVEMENTS REDUCED
126645	NOV2017	Female	16	* HPV9-2 VACCINE HPV9-1 VACCINE HPV4-2 VACCINE HPV4-1 VACCINE	MEDICATION ERROR
126684	NOV2017	Female	12	* HPV9-2 VACCINE	FEVER HEAVINESS IN LIMBS ABDOMINAL PAIN HEADACHE
126719	DEC2017	Male	13	* HPV9-2 VACCINE	RASH
126767	DEC2017	Male	15	* HPV9 VACCINE	FEVER RASH
126778	DEC2017	Male	12	* HPV9-2 VACCINE	MEDICATION ERROR

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
126793	DEC2017	Female	26	* HPV9-3 VACCINE GINET 84	ARM PAIN NAUSEA SOMNOLENCE PALLOR DIZZINESS
126803	DEC2017	Female	24	* HPV9 VACCINE HEPATITIS B VACCINE	INJECTION SITE PRURITUS INJECTION SITE INFLAMMATION ARM PAIN INJECTION SITE MASS
126820	DEC2017	Male	13	* HPV9-1 VACCINE	RASH PRURITIC
126923	DEC2017	Female	20	* HPV9-1 VACCINE	ARM PAIN INJECTION SITE INFLAMMATION
126924	DEC2017	Male	15	* HPV9-1 VACCINE	VOMITING RASH FLUSHING
126947	JAN2018	Female	15	* HPV9-1 VACCINE	FAINTNESS VOMITING ABDOMINAL PAIN FLATULENCE WEAKNESS GENERALIZED
126983	JAN2018	Male	13	* HPV9-2 VACCINE	INJECTION SITE INFLAMMATION ARM PAIN MOVEMENTS REDUCED
127048	JAN2018	Female	13	* HPV9 VACCINE	INJECTION SITE PAIN INJECTION SITE ERYTHEMA FEVER VOMITING
127110	JAN2018	Female	14	* Tdap * HPV9-1 VACCINE HPV4-3 VACCINE HPV4-2 VACCINE HPV4-1 VACCINE	MEDICATION ERROR
127226	JAN2018	Male	13	* HPV9-2 VACCINE	INJECTION SITE URTICARIA HEADACHE FEVER
127227	JAN2018	Female	14	* HPV9-2 VACCINE	VASOVAGAL REACTION
127229	FEB2018	Male	12	* HPV9-2 VACCINE	VASOVAGAL REACTION
127243	FEB2018	Female	12	* HPV9-2 VACCINE	VASOVAGAL REACTION
127300	FEB2018	Male	27	* HPV9-3 VACCINE	INJECTION SITE SWELLING INJECTION SITE PAIN

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
127323	FEB2018	Female	19	* HPV9-3 VACCINE DEPO-PROVERA	INJECTION SITE INFLAMMATION INJECTION SITE PAIN
127397	FEB2018	Female	20	* HPV9-2 VACCINE KONSYL D GINET 84 VITAMIN B12	INJECTION SITE INFLAMMATION ARM PAIN PARAESTHESIA DISTAL RASH PRURITIC
127408	FEB2018	Male	23	* HPV9-1 VACCINE * Tdap	VASOVAGAL REACTION
127409	FEB2018	Female	20	* HPV9-1 VACCINE	INJECTION SITE MASS INJECTION SITE PAIN
127419	FEB2018	Female	19	* HPV9-1 VACCINE	PRURITUS SWELLING LOCALISED
127478	FEB2018	Female	16	* HPV9-1 VACCINE	VASOVAGAL REACTION
127562	MAR2018	Male	22	* HPV9 VACCINE	MUSCLE CONTRACTIONS INVOLUNTARY
127667	MAR2018	Male	17	* HPV9-1 VACCINE	VASOVAGAL REACTION
127711	MAR2018	Male	26	* HPV9-3 VACCINE	INJECTION SITE PAIN INJECTION SITE INFLAMMATION
127731	MAR2018	Female	20	* HPV9-1 VACCINE	ARM PAIN PARAESTHESIA DISTAL NUMBNESS LOCALISED MOVEMENTS REDUCED INJECTION SITE BRUISING
127758	MAR2018	Male	14	* HPV9-2 VACCINE	DIZZINESS
127759	MAR2018	Male	14	* HPV9-2 VACCINE	TWITCHING MUSCLE STIFFNESS FEELING UNWELL
127760	MAR2018	Male	14	* HPV9-2 VACCINE	VASOVAGAL REACTION
127761	MAR2018	Male	13	* HPV9-2 VACCINE	DIZZINESS
127826	MAR2018	Male	12	* HPV9 VACCINE	INJECTION SITE BRUISING URTICARIA
127827	MAR2018	Female	26	* HPV9-2 VACCINE	DRUG EXPOSURE IN PREGNANCY
127833	MAR2018	Male	12	* HPV9-1 VACCINE	DIZZINESS

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
127891	MAR2018	Female	18	* HPV9-2 VACCINE	INJECTION SITE MASS INJECTION SITE PAIN
127892	MAR2018	Male	12	* HPV9-1 VACCINE	VOMITING DIARRHOEA
127910	APR2018	Male	24	* HPV9-1 VACCINE * ADT (ADULT/DOUBLE) VACCINE * POLIOMYELITIS VACCINE INACTIVE	VASOVAGAL REACTION
127914	APR2018	Male	11	* Tdap * HPV9-1 VACCINE PARACETAMOL	INJECTION SITE INFLAMMATION
127926	APR2018	Female	12	* HPV9-1 VACCINE	VASOVAGAL REACTION FALL
127978	APR2018	Male	12	* HPV9-1 VACCINE	VASOVAGAL REACTION
128002	APR2018	Female	12	* HPV9-1 VACCINE	DIZZINESS CONVULSIONS MUSCLE CONTRACTIONS INVOLUNTARY HEADACHE ABDOMINAL PAIN
128040	APR2018	Female	12	* HPV9-1 VACCINE	ARM PAIN INJECTION SITE ERYTHEMA
128101	APR2018	Male	17	* HPV9-1 VACCINE	MOUTH DRY VOMITING HYPOTENSION ATAXIA VISUAL DISTURBANCE
128128	APR2018	Female	11	* HPV9-1 VACCINE	INJECTION SITE MASS
128246	APR2018	Male	24	* HPV9-3 VACCINE	DEMYELINATION COUGHING LIMB WEAKNESS DYSPHAGIA
128426	MAY2018	Male	13	* HPV9-1 VACCINE	DIZZINESS FAINTNESS ARRHYTHMIA NAUSEA BRADYCARDIA
128446	MAY2018	Female	12	* HPV9-1 VACCINE	NAUSEA DIZZINESS
128448	MAY2018	Female	12	* HPV9-1 VACCINE	INJECTION SITE REACTION SHAKING

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
128510	MAY2018	Male	12	* HPV9 VACCINE	DIZZINESS TIREDNESS INJECTION SITE REACTION
128614	MAY2018	Male	15	* HPV9-1 VACCINE	VASOVAGAL REACTION
128787	JUN2018	Female	12	* HPV9-1 VACCINE	PAIN NECK/SHOULDER
129083	JUN2018	Female	12	* HPV9-1 VACCINE	THROMBOCYTOPENIA
129084	JUN2018	Female	14	* HPV9 VACCINE	HEADACHE NAUSEA APPETITE DECREASED MYALGIA DIZZINESS
129623	AUG2018	Female	12	* HPV9-1 VACCINE	LYMPHADENITIS
129788	AUG2018	Male	12	* HPV9-2 VACCINE	FEVER APPETITE DECREASED
129823	SEP2018	Female	15	* HPV9-2 VACCINE HYDROXOCOBALAMIN	MIGRAINE PARAESTHESIA
129852	SEP2018	Female	12	* HPV9-2 VACCINE OMEPRAZOLE	RASH PRURITIC FLUSHING THROAT TIGHTNESS
129944	SEP2018	Male	11	* HPV9-1 VACCINE * Tdap	ERYTHEMA MULTIFORME
129995	SEP2018	Male	13	* HPV9-2 VACCINE	INJECTION SITE ERYTHEMA
130025	SEP2018	Female	13	* HPV9-2 VACCINE	NAUSEA DIZZINESS COGNITIVE FUNCTION ABNORMAL
130026	SEP2018	Female	27	* HPV9-2 VACCINE ADT (ADULT/DOUBLE) VACCINE	DRUG EXPOSURE IN PREGNANCY
130064	SEP2018	Male	13	* HPV9-2 VACCINE	SWEATING INCREASED SKIN COLD CLAMMY TWITCHING HYPERTONIA DEPERSONALIZATION
130148	SEP2018	Male	12	* HPV9-2 VACCINE	SOMNOLENCE FEVER VOMITING
130149	SEP2018	Male	13	* HPV9-2 VACCINE	ARM PAIN HYPOAESTHESIA

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
130150	SEP2018	Male	13	* HPV9-2 VACCINE	INJECTION SITE INFLAMMATION INJECTION SITE PAIN NAUSEA HEADACHE BACK PAIN
130151	SEP2018	Male	12	* HPV9-2 VACCINE FLUOXETINE MELATONIN - Circadin METHYLPHENIDATE ER	INJECTION SITE INFLAMMATION INJECTION SITE PAIN
130515	OCT2018	Female	12	* HPV9-2 VACCINE	MUSCLE CONTRACTIONS INVOLUNTARY
130554	OCT2018	Female	13	* HPV9-2 VACCINE	INJECTION SITE INFLAMMATION
130664	OCT2018	Female	22	* HPV9-2 VACCINE	DIZZINESS FEVER MYALGIA HEADACHE VOMITING
130727	NOV2018	Female	12	* HPV9-2 VACCINE	BACK PAIN FEVER
130770	NOV2018	Female	24	* HPV9-1 VACCINE	INJECTION SITE REACTION HEADACHE FEELING HOT AND COLD NAUSEA FAINTNESS
130818	NOV2018	Female	12	* HPV9-2 VACCINE	PALLOR VOMITING
130831	NOV2018	Male	13	* HPV9-2 VACCINE	VASOVAGAL REACTION
130847	NOV2018	Female	12	* HPV9-2 VACCINE	MEDICATION ERROR
130848	NOV2018	Female	12	* HPV9-2 VACCINE BUDESONIDE/EFORMOTEROL CETIRIZINE IBUPROFEN SPIRULINA	HEADACHE ARM PAIN FAINTNESS CONCENTRATION IMPAIRED ATAXIA
130860	NOV2018	Male	18	* HPV9-3 VACCINE	FEVER NAUSEA PHOTOPHOBIA ARM PAIN
130890	NOV2018	Female	13	* HPV9-2 VACCINE	INJECTION SITE INFLAMMATION INJECTION SITE PAIN MOVEMENTS REDUCED

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
130906	NOV2018	Female	22	* HPV9-3 VACCINE	INJECTION SITE MASS INJECTION SITE BRUISING INJECTION SITE INFLAMMATION
130923	NOV2018	Male	19	* HPV9-2 VACCINE	URTICARIA
130970	NOV2018	Female	13	* HPV9-2 VACCINE	NAUSEA RASH MACULO-PAPULAR RASH PRURITIC
130987	NOV2018	Female	12	* HPV9-1 VACCINE BUDESONIDE/EFORMOTEROL CETIRIZINE IBUPROFEN SPIRULINA	HEADACHE ARM PAIN
130988	NOV2018	Male	17	* HPV9-2 VACCINE CETIRIZINE	CONSCIOUSNESS DECREASED CONVULSIONS VASOVAGAL REACTION
130994	NOV2018	Male	12	* HPV9-3 VACCINE	MEDICATION ERROR
130995	NOV2018	Female	13	* HPV9-2 VACCINE	ARM PAIN MOVEMENTS REDUCED
130996	NOV2018	Male	27	* HPV9 VACCINE	FATIGUE PARAESTHESIA MYALGIA WEAKNESS GENERALIZED
130997	NOV2018	Male	12	* HPV9-2 VACCINE	HEADACHE FEVER MYALGIA EYE PAIN VOMITING
130998	NOV2018	Female	29	* HPV9-3 VACCINE	INJECTION SITE PAIN INJECTION SITE SWELLING
131024	NOV2018	Female	16	* HPV9-3 VACCINE * HEPATITIS B VACCINE * Tdap	C-REACTIVE PROTEIN POSITIVE FEVER VOMITING ABDOMINAL PAIN COUGHING
131025	NOV2018	Male	13	* HPV9-2 VACCINE	VASOVAGAL REACTION ANXIETY ABDOMINAL PAIN COUGHING
131115	DEC2018	Female	13	* HPV9-2 VACCINE	VOMITING SWEATING INCREASED VISION ABNORMAL PALLOR BRADYCARDIA

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
131126	DEC2018	Male	11	* HPV9-1 VACCINE * Tdap * VARICELLA VIRUS VACCINE	VASOVAGAL REACTION CONVULSIONS
131127	DEC2018	Female	13	* HPV9-3 VACCINE	MEDICATION ERROR
131153	DEC2018	Male	11	* HPV9-1 VACCINE	FEVER LYMPHADENOPATHY APPETITE DECREASED
131154	DEC2018	Female	21	* HPV9-2 VACCINE LEVLEN ED	INJECTION SITE PAIN INJECTION SITE INFLAMMATION MYALGIA
131184	DEC2018	Male	22	* HPV9-1 VACCINE	VASOVAGAL REACTION
131188	DEC2018	Female	13	* HPV9-2 VACCINE	HEADACHE MORBILLIFORM RASH NUMBNESS LOCALISED
131249	DEC2018	Male	16	* HPV9-1 VACCINE	DIZZINESS
131263	DEC2018	Female	13	* HPV9-2 VACCINE CLOTRIMAZOLE	HYPERVENTILATION THROAT SWELLING NON-SPECIFIC FLUSHING RASH HEADACHE
131320	DEC2018	Male	16	* HPV9-1 VACCINE	HEADACHE DEPERSONALIZATION SOMNOLENCE LETHARGY WEIGHT DECREASE



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 details presented in this OIA response include:

- all cases of adverse events following immunisation with Gardasil 4
- received by CARM in the period from 01 September 2016 to 31 December 2018

Cases are included

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

Released under the Official Information Act 1982



Results - Summary of reports

For the period of 01 September 2016 to 31 December 2018 :

Table 1: The number of cases reported to Gardasil 4

Date	No. of Reports	Cumulative Total
2016		
September	2	2
October	2	4
November	4	8
December	2	10
2017		
January	1	1
February	7	8
March	5	13
April	2	15
May	2	17
June	2	19
July	1	20
August	0	20
September	1	21
October	0	21
November	0	21
December	0	21
2018		
January	5	5
February	2	7
March	1	8
April	0	8
May	1	9
June	0	9
July	0	9
August	1	10
September	0	10
October	0	10
November	0	10
December	0	10

HPV-4 Vaccine cases reported to CARM – 01 September 2016 to 31 December 2018

This listing includes all assessed Adverse Events Following Immunisation (AEFIs) for each case irrespective of causality.

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
122177	SEP2016	Female	12	* HPV4-3 VACCINE	RASH PRURITUS
122219	SEP2016	Female	18	* HPV4-2 VACCINE IBUPROFEN	HEADACHE MYALGIA FEELING HOT AND COLD SWEATING INCREASED NAUSEA
122438	OCT2016	Female	19	* HPV4-3 VACCINE	VASOVAGAL REACTION
122521	OCT2016	Female	12	* HPV4-3 VACCINE	INJECTION SITE INFLAMMATION ARM PAIN
122625	NOV2016	Female	12	HPV4-1 VACCINE HPV4-2 VACCINE * HPV4-1 VACCINE HPV4-3 VACCINE * HPV4-2 VACCINE	MEDICATION ERROR
122626	NOV2016	Female	12	* HPV4-3 VACCINE	FATIGUE FEVER
122718	NOV2016	Female	13	* HPV4-2 VACCINE	SENSORY DISTURBANCE ARTHRALGIA MYALGIA RASH SKIN EXFOLIATION
122865	NOV2016	Female	12	* HPV4-2 VACCINE	VASOVAGAL REACTION
122982	DEC2016	Female	15	* HPV4-2 VACCINE	VASOVAGAL REACTION BRADYCARDIA
123006	DEC2016	Female	20	* HPV4-3 VACCINE	SHIVERING FEVER STOOLS LOOSE NAUSEA

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
123255	JAN2017	Female	11	* HPV4-3 VACCINE	VASOVAGAL REACTION MYDRIASIS SHAKING
123407	FEB2017	Female	13	* HPV4-1 VACCINE	VASOVAGAL REACTION
123487	FEB2017	Female	12	* HPV4-1 VACCINE PARACETAMOL	INFLUENZA-LIKE SYMPTOMS ANOREXIA NAUSEA
123488	FEB2017	Female	13	* HPV4-2 VACCINE PARACETAMOL	INFLUENZA-LIKE SYMPTOMS NAUSEA ANOREXIA
123519	FEB2017	Female	26	* HPV4-1 VACCINE DEPO-PROVERA	INJECTION SITE INFLAMMATION INJECTION SITE PAIN THROAT SWELLING NON-SPECIFIC TONGUE SWELLING NON-SPECIFIC NUMBNESS LOCALISED
123540	FEB2017	Female	13	* HPV4-3 VACCINE	LYMPHADENOPATHY CERVICAL
123568	FEB2017	Female	18	HPV4-1 VACCINE HPV4-2 VACCINE HPV4-3 VACCINE * HPV4-1 VACCINE * HPV4-2 VACCINE	MEDICATION ERROR FEELING UNWELL
123601	FEB2017	Female	17	* HPV4-1 VACCINE	HEADACHE NAUSEA VOMITING FURUNCULOSIS ACNE
123708	MAR2017	Female	12	* HPV4-1 VACCINE	DIZZINESS FAINTNESS HEADACHE
123709	MAR2017	Male	19	* HPV4-1 VACCINE	VASOVAGAL REACTION NAUSEA TIREDNESS
123787	MAR2017	Male	20	* HPV4-1 VACCINE	VASOVAGAL REACTION HALLUCINATION
123917	MAR2017	Female	11	* HPV4-1 VACCINE Tdap	VASOVAGAL REACTION
123927	MAR2017	Female	21	* HPV4-3 VACCINE AVA 20 ED	GENITAL WART VACCINE FAILURE
124166	APR2017	Male	13	* HPV4-1 VACCINE	LYMPHADENOPATHY

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
124193	APR2017	Female	16	* HPV4-3 VACCINE IBUPROFEN PARACETAMOL	PELVIC PAIN ABDOMINAL PAIN CHEST PAIN ASCITES NAUSEA
124290	MAY2017	Female	20	* HPV4-2 VACCINE * INFLUENZA - TRIVALENT	PRURITUS DYSAESTHESIA RASH HEADACHE CHEST TIGHTNESS
124306	MAY2017	Female	22	* HPV4-1 VACCINE	NAUSEA VOMITING
124693	JUN2017	Male	16	* HPV4-1 VACCINE	HEADACHE NAUSEA ARM PAIN INFLUENZA-LIKE SYMPTOMS NASAL CONGESTION
124901	JUN2017	Female	13	* HPV4-1 VACCINE	MEDICATION ERROR
125140	JUL2017	Male	26	* HPV4-1 VACCINE	NEURITIS PARAESTHESIA DISTAL
126030	SEP2017	Female	19	* HPV4 VACCINE	VASOVAGAL REACTION

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
127038	JAN2018	Female	11	* HPV4-1 VACCINE	ALOPECIA
127039	JAN2018	Female	13	* HPV4-1 VACCINE	ALOPECIA
127074	JAN2018	Female	26	* HPV4-1 VACCINE	DRUG EXPOSURE IN PREGNANCY
127089	JAN2018	Female	12	* HPV4-3 VACCINE	GLUTEN SENSITIVITY
127114	JAN2018	Female	16	* HPV4 VACCINE	FATIGUE GASTRO-INTESTINAL DISORDER NOS HEADACHE CHEST PAIN FIBROMYALGIA
127301	FEB2018	Female	25	* HPV4-2 VACCINE	INJECTION SITE SWELLING INJECTION SITE INFLAMMATION INJECTION SITE PAIN
127379	FEB2018	Female	21	* HPV4-2 VACCINE	DIZZINESS FAINTNESS NAUSEA
127512	MAR2018	Female	19	* HPV4-2 VACCINE	ARM PAIN INJECTION SITE SWELLING
128447	MAY2018	Male	12	* HPV4-1 VACCINE	INJECTION SITE ERYTHEMA
129451	AUG2018	Female	9	* HPV4 VACCINE	DEPRESSION EYE ABNORMALITY PROLONGED FATIGUE-LIKE CONDITION MENSTRUAL DISORDER