



Office of Hon Dr Jonathan Coleman

Minister of Health

Minister for Sport and Recreation

Member of Parliament for Northcote

30 NOV 2016



Ref: H201604437

Dear 

Response to your request for official information

Thank you for your request of 8 November 2016 under the Official Information Act 1982 (the Act) for

"1. I would like to request under the NZ FOIA, all up to date data on the NZ CARM statistics, that relate to adverse events for Gardasil. I would like all data base information, as I am aware, that there are a number of these data bases, having been informed recently by a parent, whose daughter is probably among one of the most seriously injured girls post Gardasil in NZ, that her case 'has been removed' from the CARM public data base. This is most disturbing, because if this has occurred, then anyone looking at the CARM data base, will not be viewing an accurate representation of the data. If cases are being downplayed, then patterns will not be recognised. If this is taking place, then signals will not be detected and further investigations will not be initiated. The result will be that health professionals, will be in the dark about adverse events and this has ramifications for the public, who trust their doctors to be up to date and informed. This is not best practice, safe, or I would think, legal and has implications for the Informed Consent process and the NZ Bill of Rights, among other things. This girl, has suffered paralysis, encephalitis (confirmed on CT) and a myriad of other debilitating new medical conditions post Gardasil vaccination. She has not recovered fully and faces an uncertain future in respect to her health. If her case is not considered to be 'serious,' then I would questions the point of having a CARM data base. She appears to have met the criteria.

2. I am also aware, that a medical expert who advises ACC on these types of cases, has declined a suspected Gardasil adverse event by another girl and requested that his name not be disclosed to the Health and Disability Commission, as having advised ACC, on this HPV vaccine Gardasil CARM/ACC claim. Why would this be Minister? On what grounds could name non disclosure possibly be justified? I would like this question answered under the NZ FOIA.

3. I would also like to request information on erectile dysfunction, which I am aware is being reported globally, in young boys following Gardasil.

In view of the impending fully funded Gardasil vaccination for New Zealand boys in 2017, it would surely be prudent and responsible, to establish any risk regarding male reproductive health, given the paucity of scientific evaluation, that took place in the clinical trials for Gardasil and since. This would be a time to

exercise the Precautionary Principle. I would hope that you agree as Minister of Health and as medical doctor.

4. Please provide any information you have regarding monitoring for ovarian failure in NZ girls, in regard to the HPV vaccine Gardasil, as I am aware that no ovarian studies were carried out during the clinical trials, or have been since. Given that this vaccine is being offered to prepubescent and pubescent girls, this can in no way be considered best practice. I would like this information provided under the NZ FOIA and whether health professionals are being made aware of this fact regarding no ovarian evaluations having been carried out and are seeing an increase in girls with reproductive disturbance, which they relate to Gardasil.

What current testing/diagnostics are carried out to investigate ovarian function in these cases? Do you anticipate in the future that funding will be made available, for girls who wish to store eggs as a precautionary measure, in the absence of ovarian evaluation during the clinical trials for the HPV vaccine Gardasil? What if any thoughts has your Ministry given, to compensation and assistance with IVF? How useful this will be if they are found to be sterile and what provisions have been made to accommodate men, who may also face fertility issues in the future?

5. Please indicate why you do not think that it is not necessary to have scientific evaluations, that demonstrate that the recombinant HPV DNA fragments, which constitute a contamination, do not have the potential for carcinogenicity. With no recalls and no further evaluations regarding the contamination, how can you say that this vaccine is safe? Under the NZ FOIA, I request any information your Ministry of Health Medsafe or Pharmac has, regarding this matter.

Professor Joseph Cummins of the Institute of Science in Society, has written at length regarding this matter, indicating that at least one yeast gene product in the HPV vaccine Gardasil, is capable of inactivating the cancer suppressor gene P53. This indicates the potential for other cancers to develop in multicellular organisms.

6. Under the NZ FOIA, I would also request information that the NZ MOH, Medsafe or Pharmac has, regarding the content of the non alum or carrier solution, used as a placebo, named in the HPV Gardasil vaccine clinical trials.

I am aware that AAHS, or amorphous aluminium hydroxyphosphate sulphate, was used as the adjuvant in the vaccine and at the same time, it was used as a so called placebo, something that is not in keeping with the WHO Gold Standards, for recommendations for placebo use in new vaccine trials. AAHS, was also a novel proprietary adjuvant at that time.

I am aware that other 'vaccines' were also used as 'placebos' and that in protocol 018, the only time that saline was used, the only true placebo used, only benign effects were reported, as one would expect. However, the serious adverse events data that were reported in the adjuvant group (AAHS), were then combined with the saline placebo groups minor outcomes and presented as one column of data, thus skewing reported safety information for adverse events reported. These serious adverse events were also the same as those reported in the Gardasil cohorts.

The general public is not informed about this and I suggest that most health professionals do not know this either, or are aware, of the growing international scientific concerns being raised about the neurotoxic effects of AAHS.”.

I will respond to each of your points in turn. A summary of the information released is summarised in the table below, with copies of documents attached. Some of the information you request is already in the public domain. The location of this information is also included in the summary table.

Part 1- Request for CARM reports

Please find attached a report containing information on cases of suspected adverse reactions to HPV vaccine reported to the Centre for Adverse Reactions Monitoring (CARM) in association with HPV vaccination. This report covers the time period 1 July 2015 to 30 September 2016.

Data on cases reported up to 1 July 2015 is refused under section 18(d) of the Act as the information requested is publicly available at:

www.medsafe.govt.nz/publications/OIA/HPVVaccineCasesAug2015.pdf

www.medsafe.govt.nz/publications/OIA/HPVVaccineCasesOIA14September2015.pdf.

Individual case details have been withheld under section 9(2)(a) of the Act to protect the privacy of natural persons. The withholding of the private details is not outweighed by other considerations which render it desirable, in the public interest, to make this information available.

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/Guideline/GRTPNZ/part-8-pharmacovigilance.pdf)

of suspected adverse reactions are entered into the CARM database. There is only one database. CARM review all the cases reported to them according to the 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 who publish this information as this is considered to be of public interest. The case you mention (Ref 115471) is not included in the public view of the CARM database as it did not meet the criteria to be considered linked to the HPV vaccine. The case is still included in the CARM database.

The known adverse reactions to medicines including vaccines are published in the medicine data sheet. Healthcare professionals are expected to review data sheets or similar sources of information such as the New Zealand Formulary or the Immunisation Handbook for information on adverse reactions to medicines. They are not expected to individually make risk assessments based on raw CARM data as this is a specialist task.

Part 2 ACC queries.

I am not in a position to answer any queries about ACC processes. I suggest you direct your queries to ACC directly.

Part 3 Erectile dysfunction following Gardasil vaccination

This request is refused under section 18(g) of the Act, as the information requested (ie, information on erectile dysfunction in young boys following Gardasil use) is not held by the Ministry of Health. The Ministry of Health has received no reports of erectile dysfunction as a response to HPV vaccination in New Zealand.

Officials have informed me that Gardasil vaccine has been used extensively in boys in both the US and Australia. Information on the safety of Gardasil in boys has been published by the Therapeutic Goods Administration (TGA) and the Centres for Disease Control (CDC). Gardasil and Gardasil 9 vaccines were given to boys and men in clinical trials and erectile dysfunction was not found to be a problem in any of these studies.

Part 4 Ovarian failure following Gardasil vaccination.

This request is refused under section 18(g) of the Act, as the information requested (data on monitoring for ovarian failure in NZ girls who have been vaccinated with HPV vaccine) is not held by the Ministry of Health.

There have been no reports of ovarian failure following HPV vaccination in New Zealand. The Ministry has considered international cases of ovarian failure and published its findings at www.medsafe.govt.nz/profs/adverse/Minutes164.htm. The TGA have also investigated and found no association between Gardasil vaccination and ovarian failure (www.tga.gov.au/alert/gardasil-quadrivalent-human-papillomavirus-vaccine-update-2).

Pre-clinical studies performed with Gardasil 9 in rats did not show any effect on mating performance, fertility or embryonic/fetal survival (www.medsafe.govt.nz/profs/Datasheet/g/gardasil9inj.pdf).

Since no association between Gardasil or Gardasil 9 vaccination and decreased fertility has been demonstrated there is no need for monitoring or preventative actions.

Part 5 HPV DNA fragments in the vaccine

This request is refused under section 18(d) of the Act as the information requested is publicly available. The information can be found at: www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm276859.htm.

Part 6 Aluminium adjuvant

This request is refused under section 18(d) of the Act, as the information requested is publicly available at: www.medsafe.govt.nz/publications/OIA/Gardasil%20December%202015/Contents.asp.

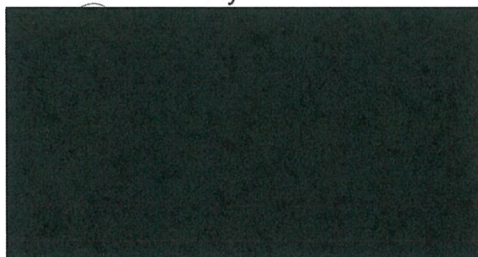
The safety of excipients is taken into consideration during the assessment of a new medicine application. The international requirements as interpreted by the European Medicines Agency (EMA) can be found at: www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003382.pdf

Summary table

Request	Response
1. <i>all up to date data on the NZ CARM statistics, that relate to adverse events for Gardasil</i>	Attached is: 'HPV vaccine total reports'. This covers the time period 1 July 2015 to 30 September 2016. Data prior to this time period is refused under section 18(d) of the Act as the information is publicly available: www.medsafe.govt.nz/publications/OIA/HPVVaccineCasesAug2015.pdf www.medsafe.govt.nz/publications/OIA/HPVVaccineCasesOIA14September2015.pdf
2. ACC	No information released
3. <i>Erectile dysfunction</i>	Information refused under 18(g) of the Act as the information requested is not held by the Ministry
4. <i>Ovarian failure</i>	Information refused under 18(g) of the Act, the information requested is not held by the Ministry Information is available at: www.medsafe.govt.nz/profs/adverse/Minutes164.htm www.tga.gov.au/alert/gardasil-quadrivalent-human-papillomavirus-vaccine-update-2 www.medsafe.govt.nz/profs/Datasheet/g/gardasil9inj.pdf
5. <i>HPV DNA fragments</i>	Information refused under section 18(d) of the Act as the information requested is publicly available. Information is available at: www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm276859.htm
6. <i>Aluminium adjuvant</i>	Information refused under section 18(d) of the Act as the information requested is publicly available. Information is available at: www.medsafe.govt.nz/publications/OIA/Gardasil%20December%202015/Contents.asp www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003382.pdf

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





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 – Total Reports
Official Information Act Request

Prepared for: Medsafe

Prepared by: New Zealand Pharmacovigilance Centre
24 November 2016

Specific Request: Details of all adverse reactions reported to CARM
relating to Gardasil from 01 July 2015 to 30 September 2016

Summary

Total Reports 84

RELEASED UNDER THE
OFFICIAL INFORMATION ACT

HPV Vaccine cases reported to CARM – 01 July 2015 to 30 September 2016

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

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
117051	JUL2015	Female	19	* HPV VACCINE	NAUSEA ERYTHEMA PRURITUS
117067	JUL2015	Female	12	* HPV VACCINE	LYMPHADENOPATHY CERVICAL
117068	JUL2015	Female	12	* HPV VACCINE	LYMPHADENOPATHY CERVICAL
117069	JUL2015	Female	12	* HPV VACCINE HPV VACCINE HPV VACCINE	NAUSEA HEADACHE PROLONGED FATIGUE-LIKE CONDITION JOINT PAIN HYPOTENSION ORTHOSTATIC
117094	JUL2015	Female	12	* HPV VACCINE	SHIVERING NAUSEA VOMITING
117129	JUL2015	Female	12	* HPV VACCINE	TWITCHING
117189	JUL2015	Female	12	* HPV VACCINE	TWITCHING
117258	JUL2015	Female	14	* HPV VACCINE * HEPATITIS B VACCINE	HEADACHE EYE PAIN
117328	JUL2015	Female	16	* HPV VACCINE	VASOVAGAL REACTION MEDICATION ERROR
117352	AUG2015	Female	16	* HPV VACCINE	VASOVAGAL REACTION
117656	AUG2015	Female	18	* HPV VACCINE	HAIR LOSS
117841	SEP2015	Female	12	* HPV VACCINE	FEELING UNWELL DEPERSONALIZATION
117855	SEP2015	Female	12	* HPV VACCINE	OEDEMA PERIORBITAL
117868	SEP2015	Female	12	* HPV VACCINE	FEELING UNWELL DEPERSONALIZATION
118064	SEP2015	Female	12	* HPV VACCINE	INJECTION SITE INFLAMMATION ARM PAIN ABDOMINAL DISCOMFORT

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
118108	OCT2015	Female	12	* HPV VACCINE	INJECTION SITE INFLAMMATION ARM PAIN ABDOMINAL DISCOMFORT
118269	OCT2015	Female	17	* HPV VACCINE	HEADACHE DIARRHOEA THROAT SORE
118382	OCT2015	Female	13	* HPV VACCINE HYDROXOCOBALAMIN FOLIC ACID FLUTICASONE/SALMETEROL	NUMBNESS LOCALISED
118393	OCT2015	Female	12	* HPV VACCINE	PAIN NECK/SHOULDER DIZZINESS
118394	OCT2015	Female	18	* HPV VACCINE	PRURITUS ERYTHEMA INJECTION SITE ERYTHEMA
118454	OCT2015	Female	12	* HPV VACCINE	FEVER FATIGUE SOMNOLENCE NECK STIFFNESS
118490	NOV2015	Female	13	* HPV VACCINE	VASOVAGAL REACTION
118519	NOV2015	Female	13	* HPV VACCINE	NUMBNESS LOCALISED NUMBNESS ORAL LABORATORY TEST ABNORMAL
118615	NOV2015	Female	12	* HPV VACCINE	VASOVAGAL REACTION MOBILITY DECREASED MIGRAINE
118616	NOV2015	Female	11	* HPV VACCINE	COMPLEX REGIONAL PAIN SYNDROME LEG PAIN
118675	NOV2015	Female	12	* HPV VACCINE	BACK PAIN LEG PAIN HYPOAESTHESIA MUSCLE WEAKNESS
118676	NOV2015	Female	12	* HPV VACCINE	FEVER HEADACHE ARM PAIN INJECTION SITE ERYTHEMA
118677	NOV2015	Female	12	* HPV VACCINE * HPV VACCINE	ABDOMINAL PAIN
118689	NOV2015	Female	12	* HPV VACCINE	HAIR LOSS

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
118707	NOV2015	Female	12	* HPV VACCINE	HEADACHE
118708	NOV2015	Female	12	* HPV VACCINE	HEADACHE
118709	NOV2015	Female	13	* HPV VACCINE	HEADACHE FEVER RIGORS ARM PAIN CHILLS
118840	DEC2015	Female	12	* HPV VACCINE	VASOVAGAL REACTION
119468	FEB2016	Male	16	* HPV VACCINE LORATADINE	RASH PRURITIC
119759	MAR2016	Female	15	* HPV VACCINE MELATONIN ESCITALOPRAM FOLIC ACID	INJECTION SITE INFLAMMATION INJECTION SITE PAIN HEADACHE NAUSEA FAINTNESS
119807	MAR2016	Female	14	* HPV VACCINE MULTIVITAMINS	VASOVAGAL REACTION
119861	MAR2016	Female	11	* Tdap * HPV VACCINE	VASOVAGAL REACTION
119875	MAR2016	Female	12	* HPV VACCINE	ANAPHYLACTIC REACTION LARYNGOTRACHEAL OEDEMA
119887	MAR2016	Female	14	* HPV VACCINE	ABDOMINAL PAIN DEPRESSION PARAESTHESIA PARALYSIS CONVULSIONS
119909	MAR2016	Female	11	* HPV VACCINE	VASOVAGAL REACTION NAUSEA VOMITING
119910	MAR2016	Female	12	* HPV VACCINE	DIZZINESS FAINTNESS
119911	MAR2016	Female	12	* HPV VACCINE	ANXIETY FEELING OF WARMTH
119912	MAR2016	Female	11	* HPV VACCINE	ANXIETY DIZZINESS
119913	MAR2016	Female	12	* HPV VACCINE	FAINTNESS NAUSEA HEADACHE

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
119933	MAR2016	Female	12	* HPV VACCINE SALBUTAMOL BUDESONIDE/EFORMOTEROL	INJECTION SITE INFLAMMATION INJECTION SITE PAIN SHAKING
119994	MAR2016	Female	12	* HPV VACCINE	PAIN NECK/SHOULDER BACK PAIN
120017	MAR2016	Female	11	* HPV VACCINE PARACETAMOL PROBIOTICS NOS	HEADACHE THROAT SORE
120018	MAR2016	Female	11	* HPV VACCINE SALBUTAMOL FLUTICASONE	HEADACHE NAUSEA TASTE PERVERSION
120019	MAR2016	Female	11	* HPV VACCINE * Tdap	FEVER MALAISE MOUTH ULCERATION
120031	MAR2016	Female	14	* HPV VACCINE	ALLERGY
120044	MAR2016	Female	14	* HPV VACCINE	MEDICATION ERROR
120059	MAR2016	Female	12	* HPV VACCINE	DIZZINESS ABDOMINAL PAIN
120070	MAR2016	Female	12	* HPV VACCINE	VASOVAGAL REACTION
120108	MAR2016	Female	12	* HPV VACCINE	MEDICATION ERROR
120109	MAR2016	Female	12	* HPV VACCINE	VASOVAGAL REACTION
120110	MAR2016	Female	11	* HPV VACCINE	DIZZINESS NAUSEA VISION BLURRED DISORIENTATION VOMITING
120111	MAR2016	Female	13	* HPV VACCINE	VASOVAGAL REACTION
120136	APR2016	Female	12	* HPV VACCINE	ARM PAIN INJECTION SITE SWELLING VERTIGO VOMITING ABDOMINAL PAIN
120155	APR2016	Female	12	* HPV VACCINE	INJECTION SITE INFLAMMATION DIZZINESS HEADACHE

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
120189	APR2016	Female	12	* HPV VACCINE SALBUTAMOL	VASOVAGAL REACTION
120240	APR2016	Female	12	* HPV VACCINE	ABDOMINAL PAIN DIZZINESS PAIN NECK/SHOULDER BACK PAIN ARM PAIN
120303	APR2016	Female	17	* HPV VACCINE	MYALGIA HEADACHE NAUSEA PALLOR INJECTION SITE INFLAMMATION
120380	APR2016	Female	13	* HPV VACCINE VITAMIN B12	DIZZINESS HEADACHE ABDOMINAL PAIN MYALGIA
120456	APR2016	Female	12	* HPV VACCINE FLUTICASON CETIRIZINE	URTICARIA
120504	APR2016	Female	15	* HPV VACCINE * HPV VACCINE	FEVER HEADACHE ARM PAIN PROLONGED FATIGUE-LIKE CONDITION IRRITABLE BOWEL SYNDROME
120618	MAY2016	Female	12	* HPV VACCINE	HEADACHE FEVER VOMITING
120689	MAY2016	Female	12	* HPV VACCINE	ABDOMINAL PAIN VOMITING DIZZINESS
120691	MAY2016	Female	11	* HPV VACCINE	HEADACHE DIZZINESS NAUSEA
120705	MAY2016	Female	13	* HPV VACCINE PARACETAMOL IBUPROFEN	OEDEMA PERIORBITAL DIZZINESS PARAESTHESIA LIPS NAUSEA HEADACHE
120760	MAY2016	Female	12	* HPV VACCINE	SOMNOLENCE FAINTNESS NAUSEA INJECTION SITE ERYTHEMA
120761	MAY2016	Female	13	* HPV VACCINE	SYNCOPE

Report No	Date	Gender	Age	Medicines/Vaccine	Reactions
120836	MAY2016	Female	12	* HPV VACCINE	OEDEMA PERIORBITAL NUMBNESS LOCALISED THROAT SORE DYSPNOEA
120875	MAY2016	Female	22	* HPV VACCINE	ARM PAIN INJECTION SITE MASS
120907	MAY2016	Female	14	* HPV VACCINE	HEADACHE
121021	JUN2016	Female	12	* HPV VACCINE	PRURITUS
121022	JUN2016	Female	12	* HPV VACCINE	PRURITUS
121135	JUN2016	Female	12	* HPV VACCINE	MEDICATION ERROR
121222	JUN2016	Female	12	* HPV VACCINE HPV VACCINE HPV VACCINE	FATIGUE DIZZINESS PROLONGED FATIGUE-LIKE CONDITION
121460	JUL2016	Female	14	* HPV VACCINE HPV VACCINE HPV VACCINE	DEPRESSION SUICIDAL IDEATION MOOD SWINGS JOINT PAIN CHEST PAIN
121592	JUL2016	Female	12	* HPV VACCINE	LEG PAIN ARM PAIN NUMBNESS LOCALISED
121681	AUG2016	Female	12	* HPV VACCINE	HEADACHE FEVER SHIVERING CHEST PAIN
121905	AUG2016	Female	16	* HPV VACCINE	LYMPHADENOPATHY
122177	SEP2016	Female	12	* HPV VACCINE	RASH PRURITUS
122219	SEP2016	Female	18	* HPV VACCINE IBUPROFEN	HEADACHE MYALGIA FEELING HOT AND COLD SWEATING INCREASED NAUSEA