MINISTRY OF HEALTH
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Ref. No _____

Thank you for your email of 19 July 2011 requesting information under the Official Information Act 1982 about the total and serious adverse events reported in association with Gardasil and how many doses have been administered since the beginning of the HPV vaccine program.

Since the beginning of the HPV program up to 20 June 2011, 404,389 people have received at least one dose of Gardasil vaccine in New Zealand.

Since Gardasil was approved for use in New Zealand the Centre for Adverse Reactions Monitoring (CARM) has received a total of 376 reports of *suspected* adverse reactions in association with Gardasil. The number of reports per year is shown in table 1. Reporters are encouraged to report suspected adverse reactions to medicines. This means that the reporter dose not have to be sure that the vaccine caused the reaction; therefore the reports may or may not be true adverse reactions to the vaccine. It is expected that a number of co-incidental events will be reported for all vaccines.

Table 1 number of reports received by CARM in association with Gardasil per year

Year	Number of reports
2007	5
2008	20
2009	211
2010	118
2011	22

Of the 376 reports CARM consider that 27 were serious according to the criteria:

- Congenital abnormality
- Died
- Hospitalisation or prolonged hospitalisation
- Life Threatening
- Intervention required to avoid permanent harm
- Persisting disability

It is important to note that serious is not the same as severe and that for two people having the same reaction one case may be considered serious and the other case non-serious.

Of the 27 serious reports the reasons for considering the report to be serious were as shown in table 2.

Table 2 Overview of serious reports

Seriousness	Number of reports
Non-serious	349
Hospitalisation	11
Life threatening	2
Intervention Required	2
Died	2
Congenital anomaly	0
Persisting disability	10

For the two reports of death, CARM considers that the death was not related to Gardasil in one report and of unknown relationship in one report.

When reviewing this data it is also important to note that for many reports information to support the diagnosis is not provided to CARM. Therefore although the report is coded with the reported suspected reaction it does not necessarily mean that the person actually had the reaction. This is particularly true of reports of convulsions which are often confused with faints.

It should also be noted that the final outcome of many cases is not known. For the cases of persisting disability not all the reported suspected reactions reported for that case were persisting at the time of the report.

As requested the reported serious reactions are outlined in table 3. The terms presented are those used by CARM.

Table 3 Suspected reactions reported in association with Gardasil

Number	Reactions	Other Reported Medicines	Outcome
Hospitalised cases			
1	Arthropathy, hypertension, myalgia, diabetes mellitus aggravated, uveitis	None reported	Not recovered at the time of report
2	Convulsions	None reported	Recovered
3	Vasovagal reaction, headache	None reported	Not recovered at the time of report
4	Leukaemia	None reported	Not recovered at the time of report
5	Headache, myalgia, tachycardia, fever, lymphopenia	None reported	Recovered

6	Leg pain, neuropathy, headache, chest pain, syncope	Microgynon 20ED	Not recovered at the time of report
7	Ataxia, photophobia, paraesthesia, behaviour abnormal, consciousness decreased	None reported	Not recovered at the time of report
8	Headache, nausea, fever, vomiting, urticaria	None reported	Not recovered at the time of report
9	Henloch-Schonlein Purpura	None reported	Recovered
10	Serum sickness-line disorder	Fluoxetine	Recovered
11	Paraesthesia	None reported	Not recovered at the time of report
Life-threatening			
12	Pallor, nausea, tongue swelling non-specific	None reported	Recovered
13	Rash pruritic angioedema circulatory failure hypotension	None reported	Recovered
Intervention Required			
14	Injection site abscess	None reported	Not recovered at the time of report
15	Genital wart	None reported	Unknown
Died			
16	Paraesthesia, cognitive function abnormal, muscle weakness, night sweats, sudden death	Depo-provera	Not applicable
17	Suicide	None reported	Not applicable
Persisting Disability			
18	Rigors, insomnia, anxiety, fatigue	None reported	Not recovered at the time of report
19	C-reactive protein positive, paraesthesia, headache, fever, myalgia	None reported	Not recovered at the time of report
20	Paraesthesia, lymphadenopathy, arthralgia, headache, muscle weakness	None reported	Not recovered at the time of report
21	Alopecia	Fluticasone, salbutamol, ferrous sulphate, Estelle 35	Not recovered at the time of report
22	Abdominal pain, pelvic inflammation	None reported	Not recovered at the time of report
23	Nausea, faintness, muscle weakness, twitching, memory loss	None reported	Not recovered at the time of report
24	Headache, dizziness, fever	None reported	Not recovered at the time of report
25	Headache	Noriday 28	Not recovered at the time of report

26	Neuropathy, headache, concentration impaired, behaviour abnormal, lethargy	Citalopram, metoclopramide	Not recovered at the time of report
27	Syncope, consciousness decreased	Budesonide/ eformoterol, salbutamol	Not recovered at the time of report

Please also see attached a copy of further information available on this issue published on the Medsafe website.

Yours sincerely

Dr Don Mackie
Chief Medical Officer
Clinical Leadership, Protection and Regulation Business Unit