

**Minutes of the
Adverse Drug Reactions
Advisory Committee**

318th meeting

30 October 2009

10.1.4	Consumer report of reactions to HPV vaccine.....	15
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3.5.1 Minutes of the 56th (June 2009) Meeting of the NDPSC

Members noted discussions on the following:

- Human papillomavirus vaccine

No recommendations were made.

10.1.4 Consumer report of reactions to HPV vaccine

Report 254343 submitted by a father concerned about the behaviour and physical well-being of his daughter after she received HPV vaccine was discussed. The ADRAC noted the patient's complex medical history prior to HPV vaccination, and, the consequent difficulty in discerning a clear causative role of the vaccine in the events that occurred post vaccination.

10.2 Vaccine reports

During the period from 22 July to 09 September 2009, 144 reports of vaccine adverse reactions were lodged. This represents about 9% of the reports lodged for the period.

Reports of vaccines other than HPV vaccine alone

122 of the vaccine reports describe reactions to vaccines other than single-injection HPV vaccine (including 1 where HPV vaccine was administered together with another vaccine – [REDACTED])

83 of the reports were received from States, Territories or Local Government Councils, 23 were from health professionals, 9 were from sponsors; 6 were from the AVN and 1 was from the AMEL. 97 reports related to children, 23 related to adults and age was not stated in 2.

The case reports for vaccines other than HPV vaccine alone are at Paper 10.2.1; a case line listing of these reports was provided.

HPV vaccine reports:

22 of the vaccine reports described reactions to HPV vaccine when given as a single vaccine. These were received from VIC (9), NSW (4 – including 2 from the AVN), QLD (4), SA (1), WA (2), ACT (1) or from an unidentified State *via* the sponsor (1).

Reports in association with HPV vaccine received from July 22 to Sept 9 2009 are at Paper 10.2.2; a case line listing of these reports was provided.

Number of reports and events

The number of reports received in association with the majority of the vaccines is shown below:

Vaccine	No. reports	Vaccine	No. reports
		Human papilloma virus	22

Other events

Summarised details of other specific reactions associated with vaccines are shown in the Tables, below.

Seizures/convulsions (10 reports)						
Note: onset time (if stated on report) is in days; an onset time of 0 indicates the reaction occurred on the day of vaccination						
Number Source	Sex	Age	Onset Time	Outcome	Trade Name Description	Reactions
254644 ACT	F	15	1.5 months; 2 weeks	Recovered	Gardasil	Girl experienced seizure about 1.5 months after her first HPV vaccine and about 2 weeks after her second dose.

Seizures/convulsions (10 reports)						
Note: onset time (if stated on report) is in days; an onset time of 0 indicates the reaction occurred on the day of vaccination						
Number Source	Sex	Age	Onset Time	Outcome	Trade Name Description	Reactions
255876 Sponsor	F	13	1 mo	Unknown	Gardasil	Girl who had received Gardasil 1 month previously and was heavily bullied at school developed seizures lasting 4 months
255877 NSW	F	12			Gardasil	Fainting, grand mal seizure. After 1 st and 2 nd doses, girl became faint at school. Five weeks after 2 nd dose she experienced her 1 st grand mal tonic-clonic seizure, 10 days later another seizure occurred resulting in hospital admission.

Other serious neurological cases (3 reports)						
Number Source	Sex	Age	Onset Time	Outcome	Trade Name Description	Reactions
265445 NSW	F	12	24 days	Not yet recovered	Gardasil	Father reports that after 2 nd dose, girl has experienced on-going illness, including severe migraines, dizziness, loss of balance, pins and needles in hands, arms, face, and inability to walk. Has been under care of neurologist but report does not specify the diagnosis or test outcomes. Further information has been requested.
255954 AVN	F	23	Morning after	Not yet recovered	Gardasil	Arthralgia, myalgia, paraesthesia