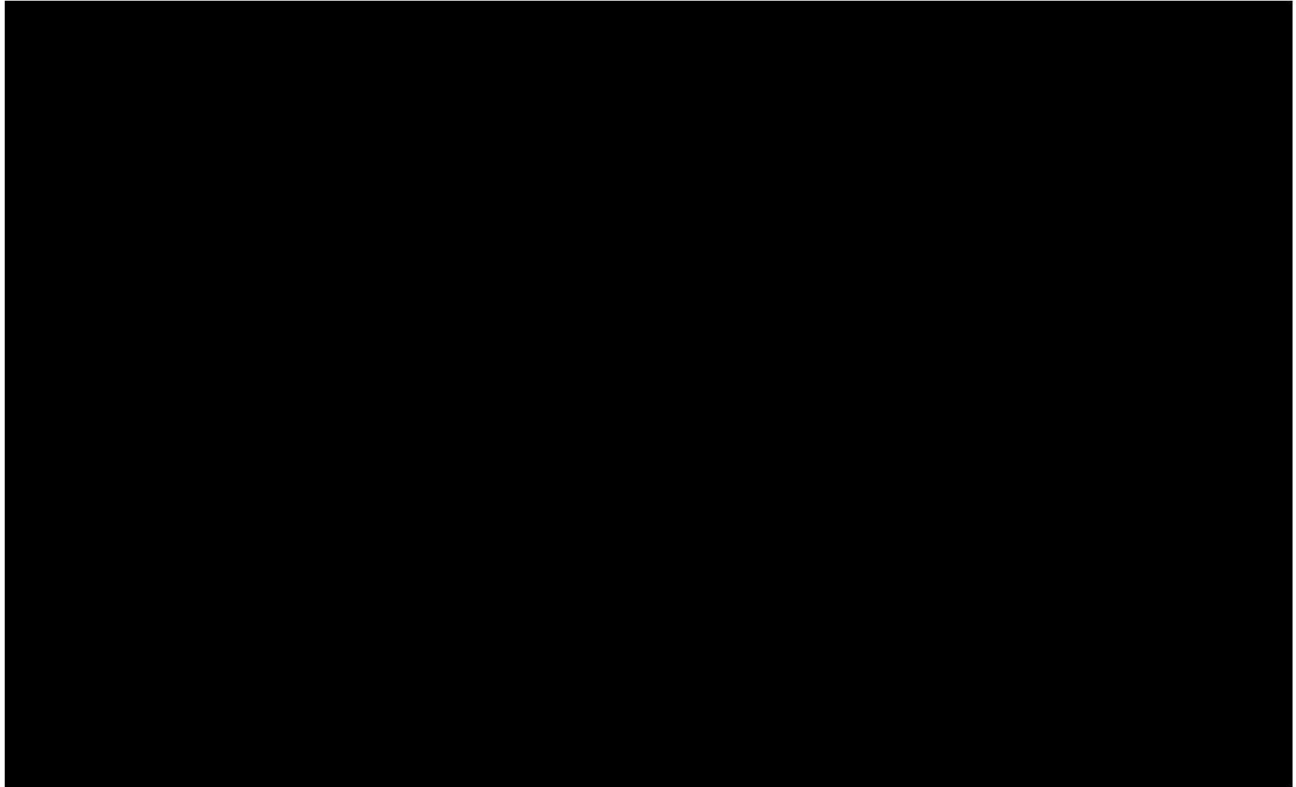


ADRAC 302

Item 10 – Vaccines

The review of this item will be led by [REDACTED]

10.1 Vaccine issues and published articles



10.1.2 Adverse events to human papilloma virus vaccine (Gardasil)

Background

Gardasil (quadrivalent human papilloma virus vaccine) was registered on 24 July 2006. From April 2007 Gardasil has been available to girls via a schools-based vaccination campaign and this is to be extended to women aged to 26 years from July 2007. ADEC Minutes relating to the registration of Gardasil are at Paper 10.1.2.1.



ADRAC data

To 17 July 2007 the TGA had received 224 ADR reports describing 639 reactions.

[REDACTED]

[REDACTED]

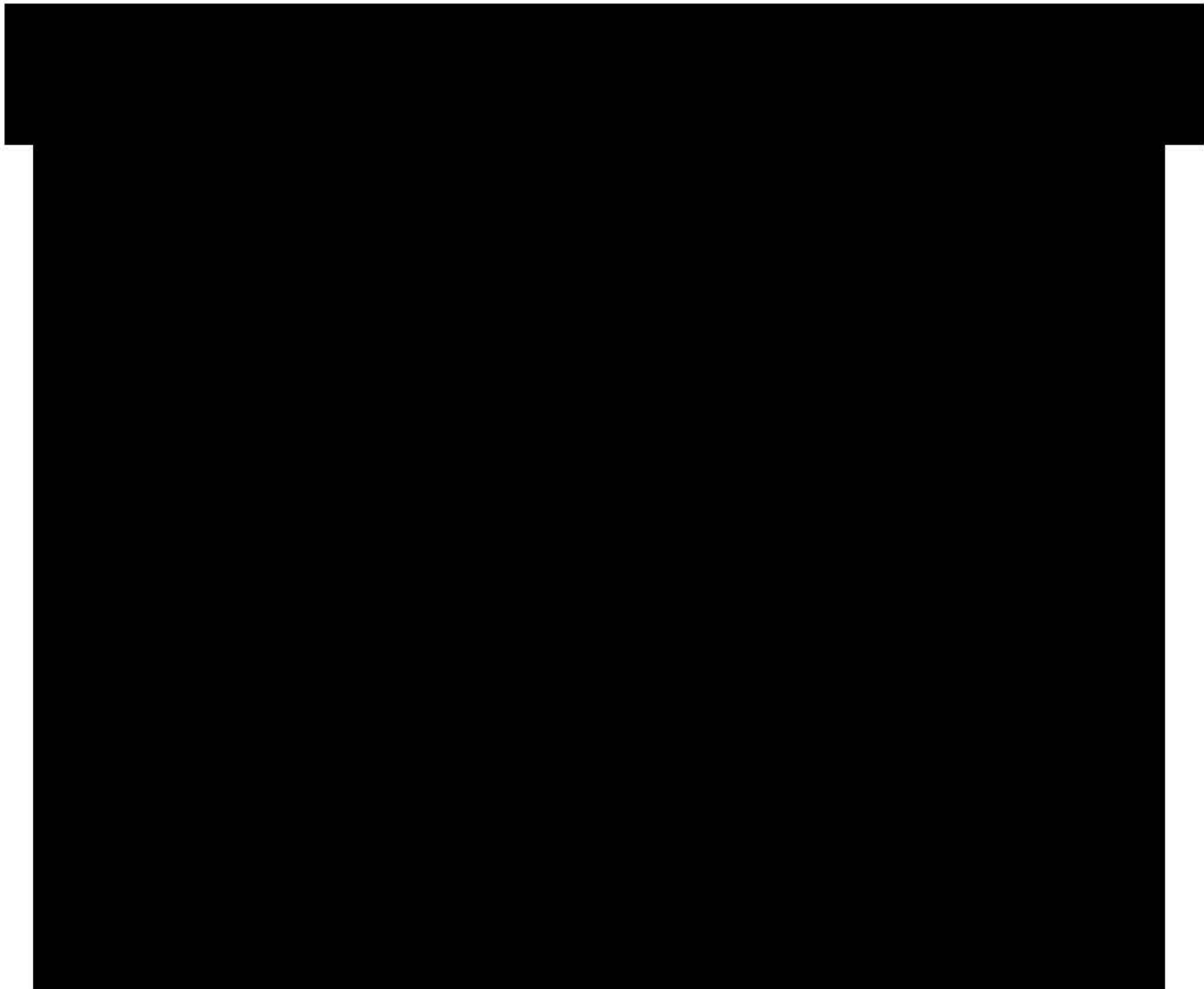
The following are reactions of interest:

Reaction	No reports	Sole suspected
Syncope/vasovagal	25	24
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

An initial cluster of 5 reports of syncope/vasovagal syncope originated from Vic. [REDACTED]

[REDACTED] This last consumer report was taken from a talk back radio program in which a woman stated that a student at the school her daughter attended had fainting and a convulsion. It is unclear if this was witnessed by the reporter and could be considered as hearsay rather than a genuine report. One of these reports involved a teenage girl who fainted within 30 minutes of receiving the injection and continued with 12 syncopal episodes over the next 13 days. She had been referred to her GP and a cardiologist. In the 3 weeks to 17 July a further 13 reports of syncope were received. The PI was updated to include information on syncope.

[REDACTED]



Conclusion and Recommendation

[REDACTED], syncope [REDACTED] have arisen as potential safety issues with Gardasil. The sponsor should write to GPs advising of changes to the PI, and reminding them to maintain vigilance and monitor patients after vaccination. Information on safe immunisation practices should be included with this correspondence. The Government should ensure that adequate post-market programs are in place to monitor the safety of HPV vaccine. Adverse reactions with human papilloma virus vaccine should be kept on the agenda as a standing item until further notice.

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

10.2 Vaccine reports

[REDACTED]

179 of the reports related to HPV vaccine (Gardasil), which has been discussed above. Virtually all of the Gardasil reports are for teenaged girls given the vaccine via school-based programs.

[REDACTED]

[REDACTED]

The case reports for vaccines other than Gardasil are at Paper 10.2.1. Reports for Gardasil are at Paper 10.2.2.

[REDACTED]

Vaccine	No. reports	Inject. site reaction	Convulsion seizure	Fever/pyrexia	Dyspnoea/apnoea	HHE	Other notable reports/important reactions / comments
Human papilloma virus (Gardasil)	179						58 rpts of dizziness/syncope