

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

302nd Meeting

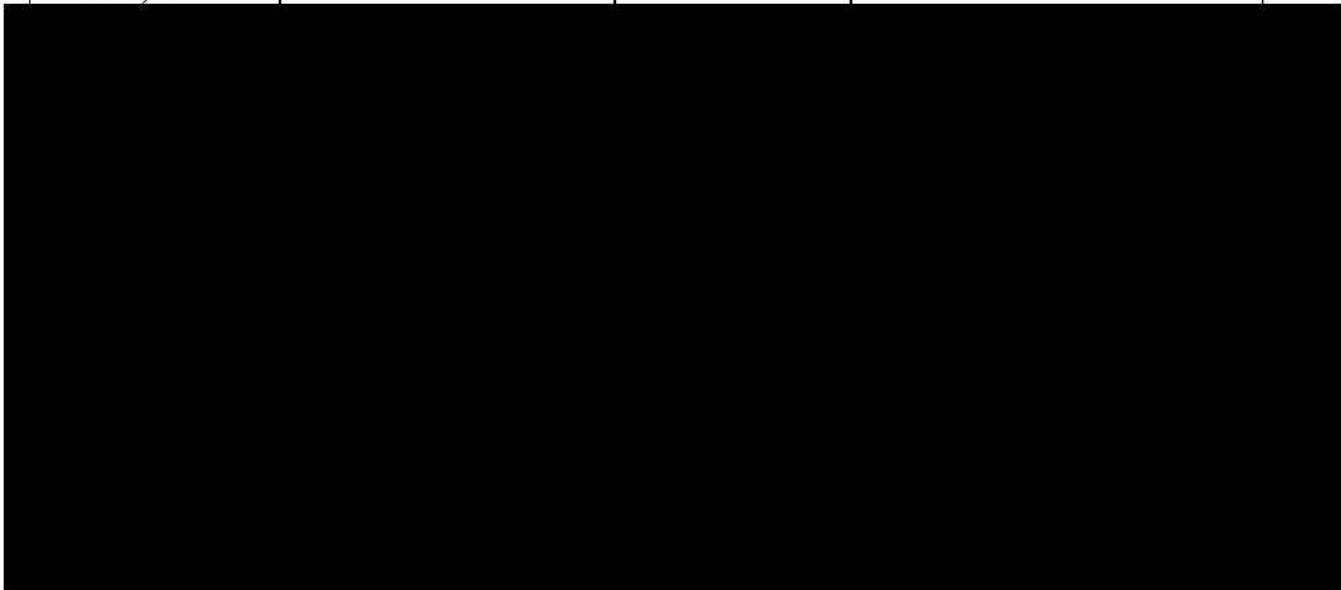
10 August 2007

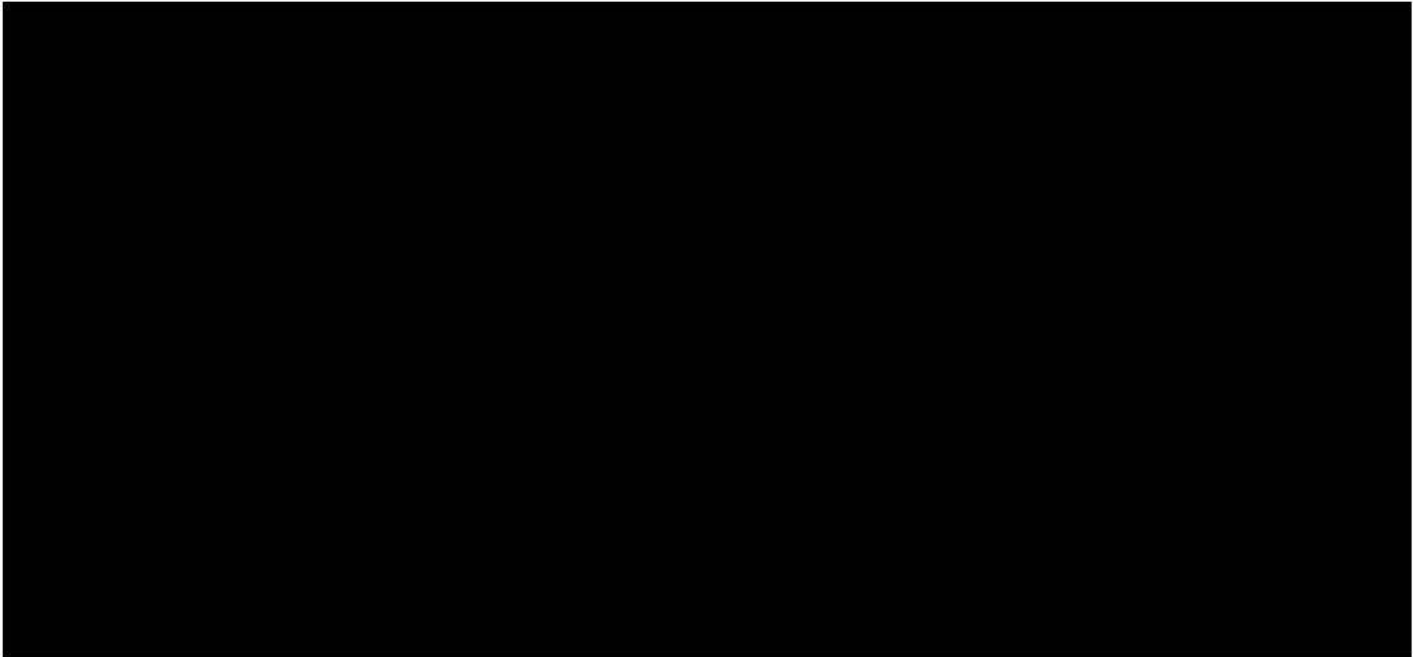


8 Summary of reports for review

The line listing of reports lodged in the period covered by this Meeting (16 May – 30 June 2007) with proportional reporting ratios was provided. The following associations were highlighted at the Meeting:

Medicine	Adverse reaction	Reports in database (sole suspected)	Comment
Gardasil (HPV vaccine)	various		See item 10.1.2





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 was extended to women aged to 26 years from July 2007.

[Redacted]

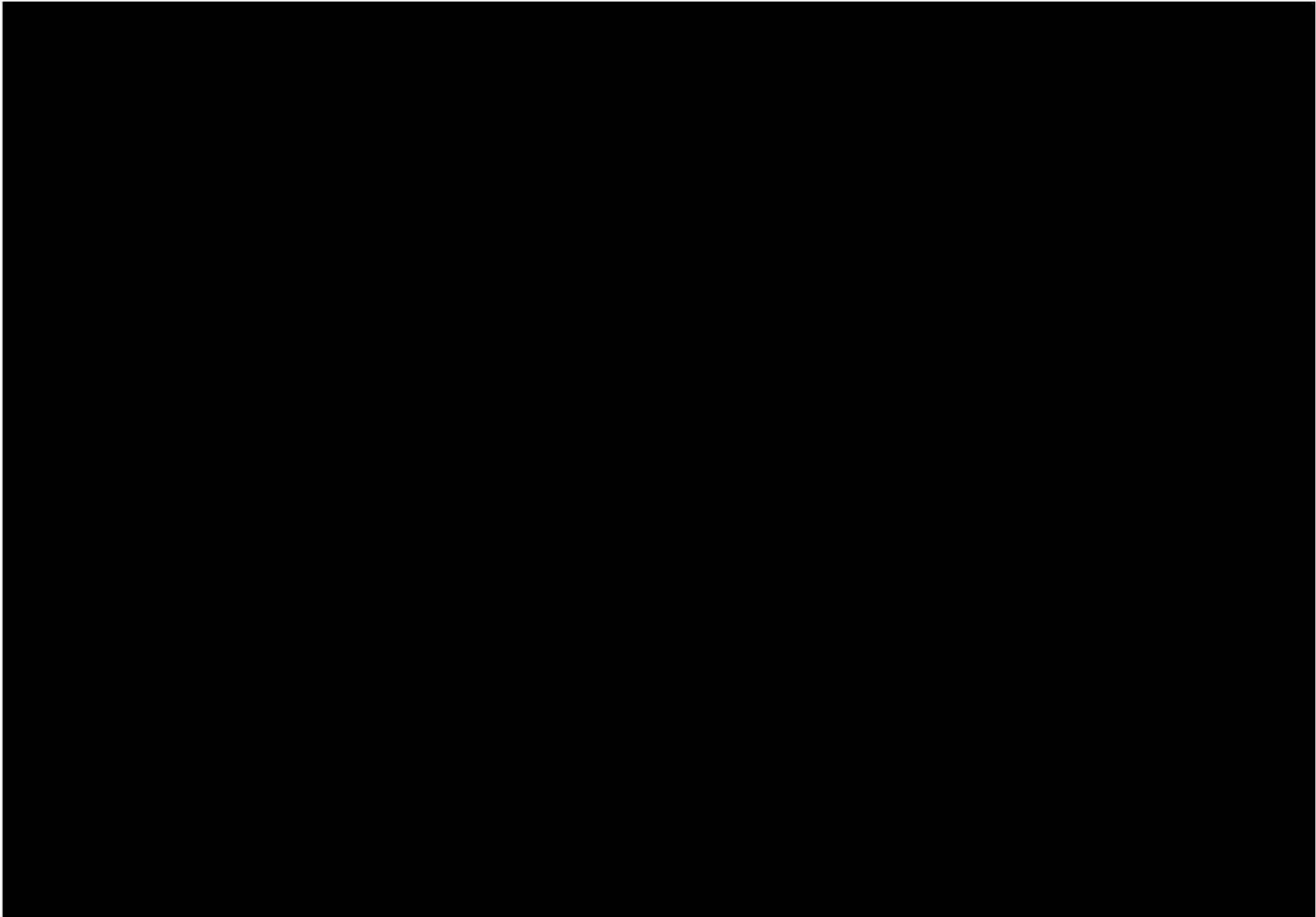
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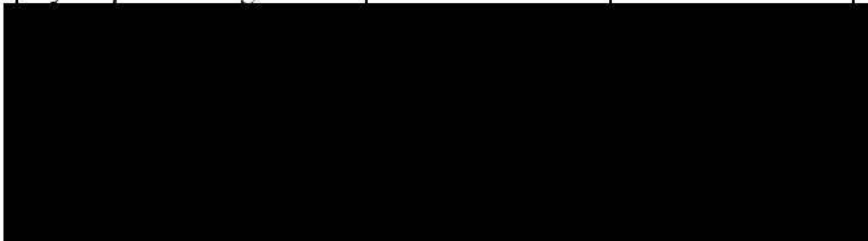
ADRAC data

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

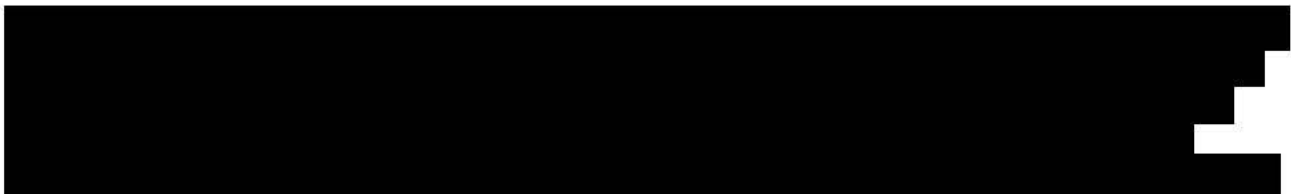


The following were reactions of interest:

Reaction	No reports	Sole suspected
Syncope/vasovagal	25	24



An initial cluster of 5 reports of syncope/vasovagal syncope originated from [redacted] but in the 3 weeks to 17 July a further 13 reports of syncope were received and the PI was updated to include information on syncope.



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Update on actions taken since the teleconference:

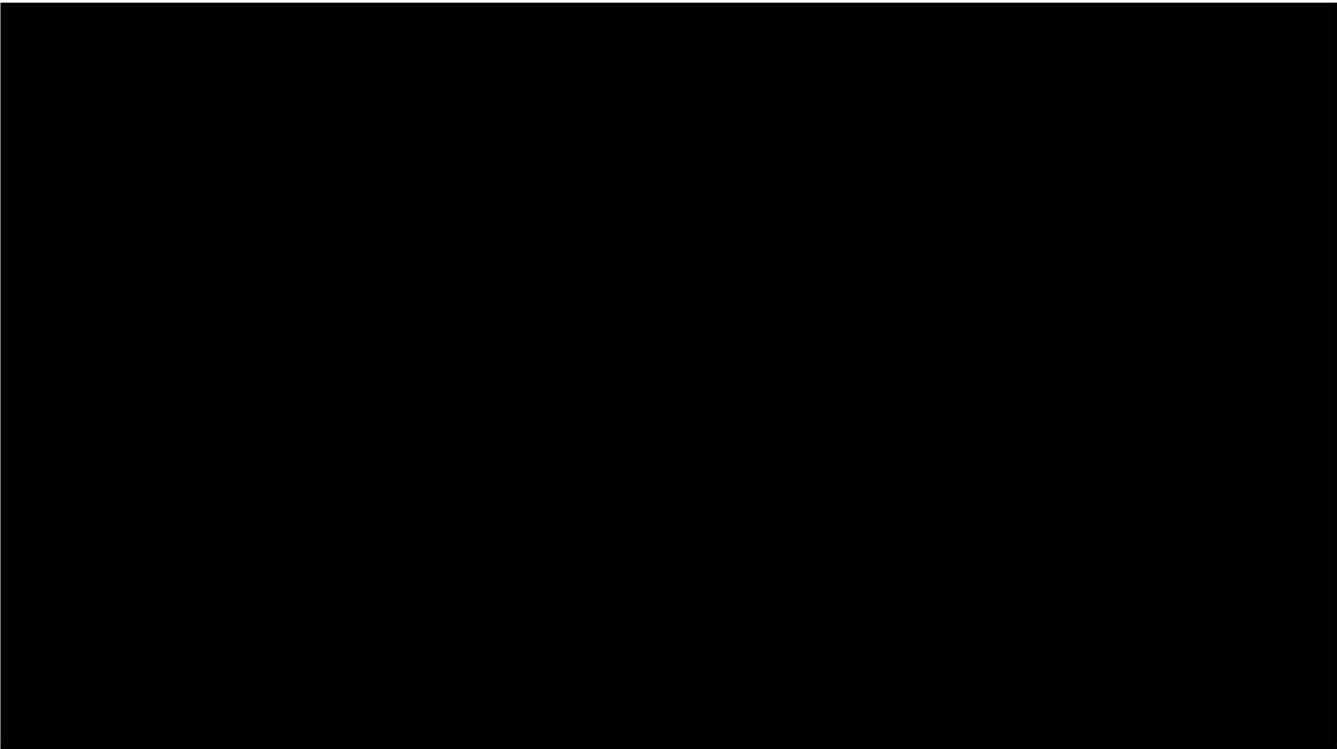
[REDACTED]

The sponsor will also be issuing to prescribers general information on safe immunisation practices, and will review the incidence of ADRs to Gardasil in the context of rates of ADRs with vaccines in comparable mass-vaccination programs. The most recent PI and CMI documents for Gardasil were provided.

[REDACTED]

[REDACTED]

[REDACTED]



Discussion

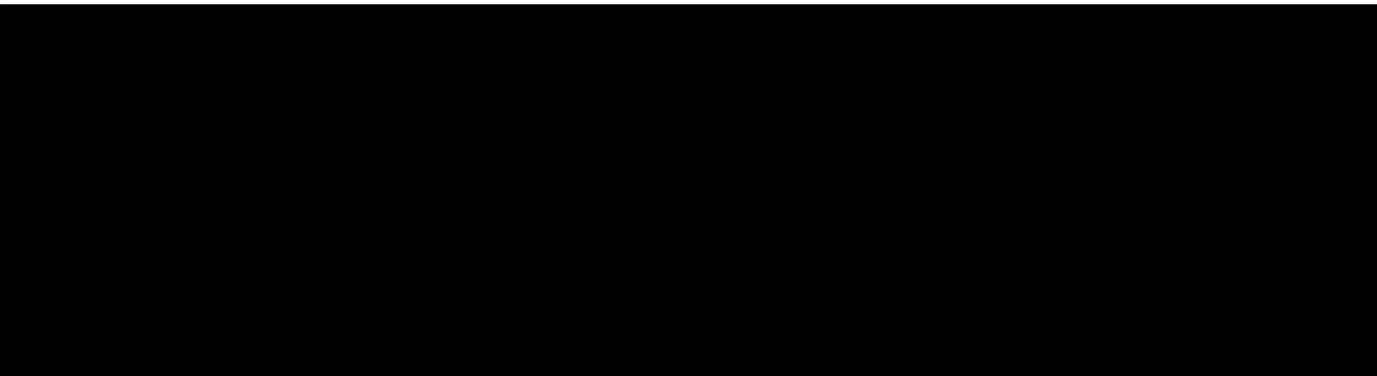
Members noted there were three main groups of adverse reactions reported with Gardasil:

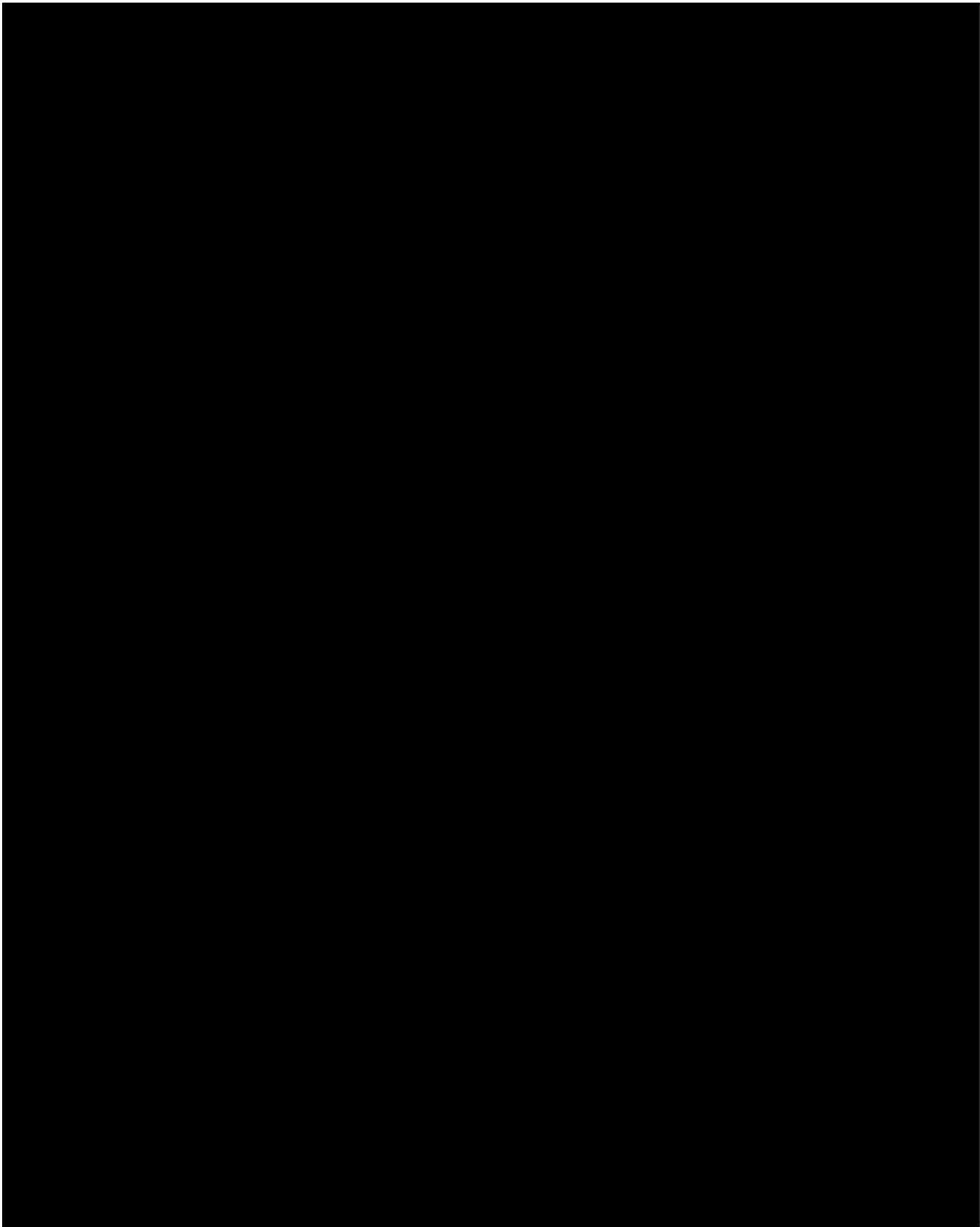
- Conversion-type reactions, with symptoms of fainting, dizziness, syncope and headache, sometimes associated with hypoaesthesia

• [Redacted]

[Redacted]

Members considered that current post-market safety monitoring strategies for Gardasil appeared to be adequate at this time. ADRAC noted plans by the sponsor to 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 would be included with this correspondence. In NSW, the Government had established post-market programs to monitor the safety of HPV vaccine, and ADRAC would continue to actively monitor the safety of Gardasil *via* the spontaneous reporting system. No further action by the Committee was warranted at this time. **ADRAC requested adverse reactions with human papilloma virus vaccine should be kept as a standing item on the agenda until further notice.**





10.2 Vaccine reports

During the 6-week period from 16 May to 30 June 2007

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

[REDACTED]

[REDACTED]

[REDACTED]

Case reports for all vaccines received in the period were provided to the Committee

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