



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

294th ADRAC Meeting

Minutes of the

Adverse Drug Reactions

Advisory Committee

294th meeting

18 August 2006



10 Vaccines

10.1 Vaccine issues and published articles

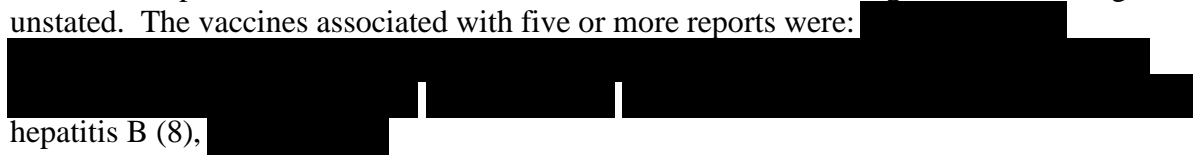


10.2 Vaccine reports

During the 6-week period from 16 May to 30 June 2006, 139 reports of vaccine adverse reactions were lodged. This represents 13% of the reports lodged for the period.

Of the 139 reports, 89 related to children and 45 to adults, with the age in 5 cases being unstated. The vaccines associated with five or more reports were:

hepatitis B (8),



About 52% of the reports describe injection site reactions and another 17% described rash, urticaria or pruritus. Details of reactions associated with individual vaccines are shown in the Table, below. There were no deaths and no reports of anaphylaxis, but there were 2 reports of

convulsions – 218819 and 219130, both associated with Hepatitis B vaccine - and 1 of seizure - report 219597, involving a male baby given Infanrix Penta, [REDACTED].

About 55% of the reports were received from States, Territories or Local Government Shire Councils; 35% were received from health professionals; 10% of the reports were received from sponsors, and none were from the Australian Vaccination Network.

Vaccine	Inject. site reaction	Urticaria / rash /pruritus	Anorexia	Irritability malaise	Fever/pyrexia	Dyspnoea/apnoea	Pallor	HHE	Others of potential interest
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	1	0	0	0	0	0	0	0	Lethargy, muscle weakness, arthralgia, eczema
/Hepatitis B									
Hepatitis B	3	1	0	0	0	0	2	0	2 x convulsions; 4 x syncope; 2 x dizziness; 1 x loss of consciousness; 2 x paresthesia; 1 x cyanosis; 3 x muscular disorder
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

