



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

ADRAC 289

Adverse Drug Reactions Advisory Committee

289th meeting

16 December 2005

10.2 Vaccine reports

During the 6-week period from 01 October to 15 November 2005, 93 reports of vaccine adverse reactions were lodged. This represents 7.5% of the reports lodged for the period.

Of the 93 reports, 61 related to children and 31 to adults with the age in 1 case being unknown. The vaccines associated with five or more reports were [REDACTED]

⁵ Watson JM, Cordier JF, Nicholson KG. Does influenza immunisation cause exacerbations of chronic airflow obstruction or asthma? *Thorax* 1997; 52: 190-94.

⁶ Park CL, Frank A. Does influenza vaccination exacerbate asthma? *Drug Safety* 1998; 19: 83-88.

[REDACTED] and hepatitis B (5)'

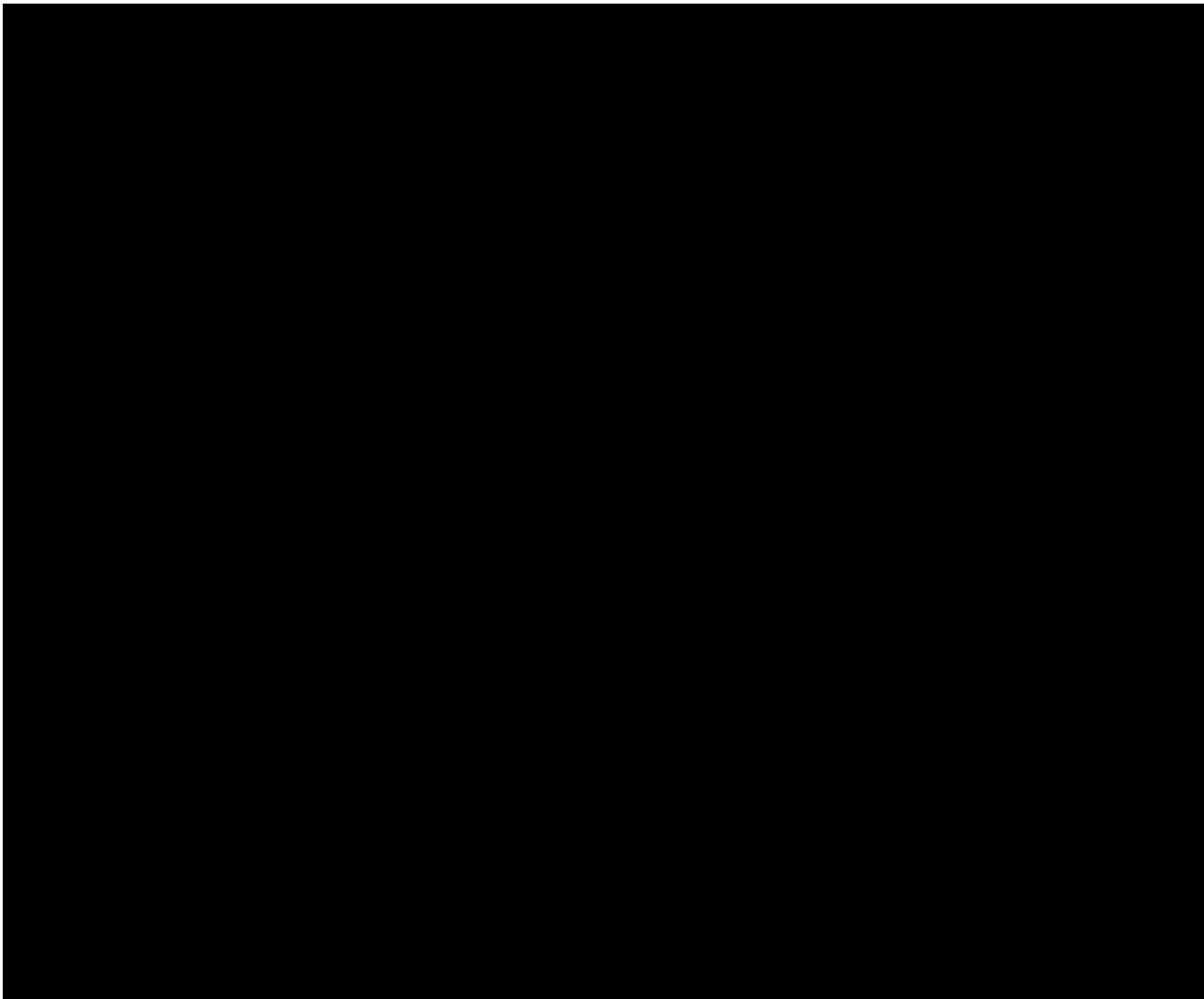
Forty seven (50%) of the 93 reports were of injection site reactions and another 11 (12%) described rash, urticaria or pruritus. There were no reports of anaphylaxis, and only 1 report of convulsion (in an infant aged ≤ 1 year who received hepatitis B vaccine and subsequently recovered).

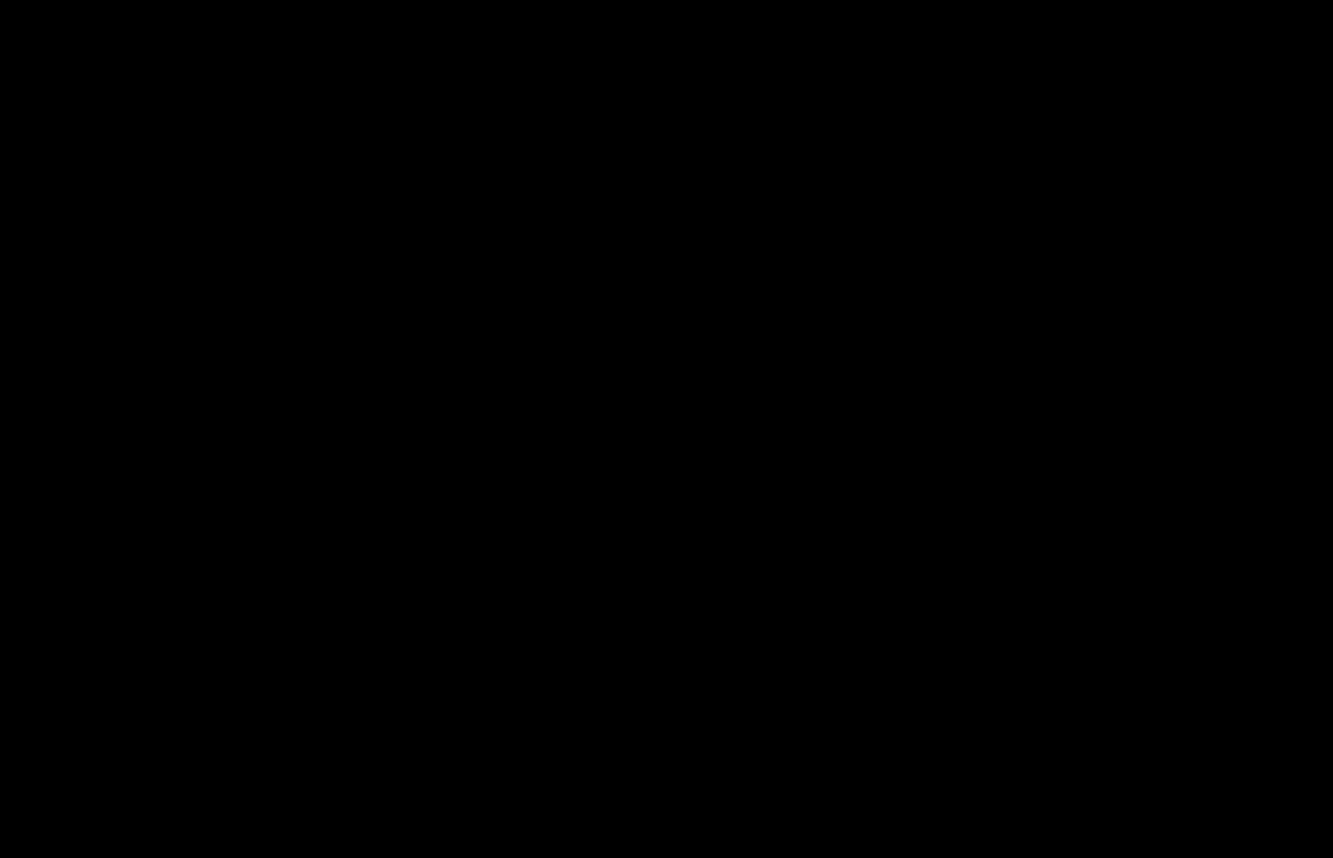
About half of the reports (47) were received from health professionals and just under half (42) were received from States, Territories or Local Government Shire Councils; 1 was received from a sponsor, and the remaining 3 reports were from the Australian Vaccination Network. The case reports for vaccines were provided in the agenda papers.

10.2.1 [REDACTED], Hep B, [REDACTED]

Report 212331

A 2 month old baby with previously healthy bowels developed constipation following vaccination. Members commented that they had rarely seen reports of constipation with vaccines.





10.2.3 Hep B and febrile seizures

Report 212285

Eight hours after administration of Hep B vaccine, a 3 day old baby developed high fever and convulsions and became unconscious. Members noted that Hep B was usually given at birth, rather than on day 3 as indicated in the report.

ADRAC considered this report should be coded ‘possible’ rather than ‘probable’, since the temporal relationship was not convincing. There have also been good studies showing that Hep B usually does not cause fever.



10.2.6 Hep B and anaphylaxis

Report 213068

A 13 year old female developed anaphylactic-type reactions 7-10 min after vaccination with Hep B, from which she recovered well. This was not remarkable.

