

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2011-2012, 19 October 2011

Question: E11-288

OUTCOME 1: Population health

Topic: CSL

Written Question on Notice

Senator Fierravanti-Wells asked:

- a) Did the CSL notify the TGA in 2005 and September 2006 of the two serious adverse events involving febrile convulsions and hospital admissions in the 2005 CSL Clinical Trial for paediatric flu vaccine?
- b) What action did the TGA take when they were made aware of these serious adverse events?

Answer:

- a) CSL notified the Therapeutic Goods on the 27 March 2006 and 30 March 2006 of two suspected serious adverse reactions. Only one of these included a febrile convulsion.
- b) No medicines are free from side-effects. Reactions such as the ones described, while unfortunate, are within the accepted safety profile for this type of medicine. The report was not indicative of a wider safety issue with the vaccine.