

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2011-2012, 19 October 2011

Question: E11-154

OUTCOME 1: Population Health

Topic: PEER REVIEW JOURNAL

Hansard Page: CA 44

Senator Xenophon asked:

- a) Can you provide details of when the TGA first became aware of the peer-reviewed article?
- b) At what point was action taken?
- c) Did the TGA embark on other inquiries as a result of that peer-reviewed article?
- d) Do you agree with Peter Collignon's view? It is:
"The TGA should be ensuring companies do update their data – it should be compulsory that the TGA should be informed of any new information, and the TGA should ensure the product information is updated to reflect that".

Answer:

- a) The Therapeutic Goods Administration (TGA) was aware of the study in late 2009.
- b) Some data from the 2009 Nolan study were included in the product information document for Fluvax and Fluvax Junior in 2010 and 2011. The product information document for 2012 will include the updated information on the rate of fever reported in the Nolan study.

It should be noted that the CSL seasonal vaccine used in the Nolan study was used in Australia between 2005 and 2009. The rates of febrile convulsions in this period were lower than those reported for the 2010 CSL vaccine which suggests there were unique features of the 2010 vaccine that were responsible for the higher than expected rates of adverse reactions observed in the 2010 flu season.

A detailed response on all actions taken by TGA in relation to the higher than expected rates of adverse events in children following administration of CSL's 2010 seasonal vaccine 'Fluvax' is given in the answer to E11-253.

- c) As detailed in response E11-253, TGA commenced in depth investigations prior to becoming aware of the journal article.
- d) There is a requirement for sponsors to report all significant safety related data to TGA in a timely and expeditious manner.