

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2011-2012, 19 October 2011

Question: E11-253

OUTCOME 1: Population Health

Topic: CSL FLUVAX VACCINE

Written Question on Notice

Senator Xenophon asked:

- a) When did the TGA first become aware of problems with the CSL Fluvax vaccine?
- b) When were these first reported to the public?
- c) When was the first alert issued?
- d) The TGA has since raised the minimum recommended usage age from 5 to 9 years old. Was a new bulletin or alert issued for this? When? It does not appear to be on the TGA website.
- e) How did the TGA become aware of these problems?
- f) Was the TGA involved with CSL's investigation into the cause of the problems?
- g) How was the TGA involved?
- h) If not, why not?

Answer:

a-c) and e)-h)

The TGA first became aware of increased rates of adverse reactions in children following administration of CSL Fluvax in April 2010. A comprehensive report, including all relevant timelines, is available on the TGA website at <http://www.tga.gov.au/safety/alerts-medicine-seasonal-flu-101008.htm>. A copy of this report is attached.

d)

Changes to preclude use of Fluvax in children under the age of five years were approved by the TGA in October 2010. This followed the advice given by the Chief Medical Officer in April 2010 that Fluvax should not be used in children unless there was a clear clinical need. The advice was posted on the TGA website prior to the 2011 flu season - <http://www.tga.gov.au/safety/alerts-medicine-seasonal-flu-110310.htm>. As well, the product information for Fluvax was required to have a 'black box' warning notifying users that the vaccine was not for use in children.