Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2012-2013, 30 & 31 May and 1 June 2012

Question: E12-297

OUTCOME 1: Population Health

Topic: Therapeutic Goods Administration

Type of Question: Written Question on Notice

Number of pages: 1

Senator: Senator Fierravanti-Wells

Question:

What are the latest findings of the ongoing TGA investigation into the cause of the Fluvax febrile convulsions in children in 2010?

Answer:

To date, a conclusive and definitive root cause has not been established to explain the higher than expected rates of fevers and febrile convulsions observed in children under five years who received Fluvax in 2010.

The combination of the particular influenza vaccine viruses contained in the 2010 vaccine and the specific methodology used by Commonwealth Serum Laboratories to manufacture Fluvax broadly appears to explain the difference in the frequency of these adverse events between Fluvax and other brands of influenza vaccine, where there was not a higher rate of fevers and febrile convulsions observed in children under five years of age.

Extensive investigations have sought to identify the specific factors within the manufacturing process and the biology of the influenza virus that may have contributed to this increased rate of adverse events. While preliminary scientific findings point to some possible causes, the data is still not sufficiently robust to be conclusive. These investigations are on-going and, meanwhile, Fluvax is not licensed for use in children aged under five years and is only recommended for at-risk children aged between five and nine years if no other licensed influenza vaccine is available.