Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2010-11, 20 October 2010

Question: E10-030

OUTCOME 1: Population Health

Topic: ADVERSE EVENTS REPORTING

Written Question on Notice

Senator Siewert asked:

The Australian Technical Advisory Group on Immunisation (ATAGI) and TGA Joint Working Group reported on 28 September 2010 that 'the overall rate of febrile convulsions post Panvax/Panvax Junior is estimated to lie between 7 and 18 per 100,000 doses nationally'.

a) How does this conclusion fit with the research published in the journal Eurosurveillance showing Fluvax may have caused two to three hospital admissions due to seizure for every admission from flu it prevented?

b) What steps is the TGA taking to improve its adverse events reporting systems in light of the Fluvax issue?

Answer:

a) The rate of febrile convulsions quoted by ATAGI is reported in association with Panvax and Panvax Junior monovalent H1N1 pandemic vaccine. The article in Eurosurveillance outlines an estimation of hospital admissions associated with a febrile convulsions following immunisation with seasonal influenza vaccine (Fluvax). The two figures are not related as they refer to different vaccines.

b) The TGA is working with the National Immunisation Committee to improve the timeliness and consistency of reporting adverse events following immunisation. This includes the development of a single national reporting form and improved protocols for transmission of information to and from state-based vaccine programs. The TGA has written to key stakeholder groups (consumers, healthcare professionals, state and territory departments of health and industry) to detail current mechanisms for reporting adverse events and to enlist their support in raising awareness of the mechanisms for and need for reporting of adverse reactions.