

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: E12-295

OUTCOME 1: Population Health

Topic: Therapeutic Goods Administration

Type of Question: Written Question on Notice

Number of pages: 1

Senator: Senator Fierravanti-Wells

Question:

Is the TGA satisfied that CSL has rectified the manufacturing deficiencies identified by the US Food and Drug Administration?

Answer:

The major manufacturing issue identified by Therapeutic Goods Administration (TGA) and the US Food and Drug Administration is the extent to which Commonwealth Serum Laboratories (CSL) investigates manufacturing deviations. TGA is continuing to actively monitor improvements in the way CSL undertakes these investigations and ensure that product released to the market is not adversely affected.