

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Supplementary Budget Estimates 2014 - 2015, 22 October 2014

Ref No: SQ14-001256

OUTCOME: 7 - Health Infrastructure, Regulation, Safety and Quality

Topic: Poly Implant Prothese Breast Implants

Type of Question: Written Question on Notice

Senator: Xenophon, Nick

Question:

Was the TGA aware of problems with PIP breast implants and Medical Vision Australia, including allegations of fraud, since 2008 as reported by Dr Fleming? If so, why was this information withheld from the 2012 Senate Inquiry?

Answer:

The TGA is not aware of any allegation of fraud by the Australian sponsor, Medical Vision Australia, relating to Poly Implant Prothese (PIP) breast implants. The Therapeutic Goods Administration first became aware that unauthorised gel was being used by the French manufacturer, Poly Implant Prothese, in a report from the then French regulatory agency dated 31 March 2010. The PIP breast implants were formally recalled in Australia on 6 April 2010 and they were cancelled from the Australian Register of Therapeutic Goods shortly after.