

**Senate Community Affairs Committee**

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

**Supplementary Budget Estimates 2014 - 2015, 22 October 2014**

**Ref No:** SQ14-001259

**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:**

In August 2009, why did the TGA approve Medical Vision Australia's application to vary the inclusion of PIP breast implants on the Australian Register of Therapeutic Goods from TGA certification (which was due to expire October 2009) to European certification, if the TGA were aware that there were allegations of fraud by Medical Vision Australia relating to PIP breast implants?

**Answer:**

The Therapeutic Goods Administration (TGA) was not aware of allegations of fraud (please see response provided to Question on Notice SQ14-001256).

In relation to the change in certification for the Poly Implant Prothese breast implants, the manufacturer held certification for supply in Europe and elsewhere from an accredited European assessment body. The TGA recognises this type of certification for medical devices supplied in Australia.