

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Supplementary Budget Estimates 2014-2015, 22 October 2014

Ref No: SQ14-001257

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 September 2004, the Medical Devices Evaluation Committee approved PIP implants to be listed on the Australian Register of Therapeutic Goods “subject to the provision of comprehensive annual post market reports to the TGA for a period of 7 years”. Were these annual post market reports provided to the TGA as required? What action did the TGA take when receiving these reports, particularly from 2008 onwards when the TGA became aware there were allegations of fraud by Medical Vision Australia relating to PIP breast implants?

Answer:

As explained in the 2012 Senate Inquiry into Poly Implant Prothese (PIP) breast implants, the Therapeutic Goods Administration (TGA) did not receive any annual reports regarding PIP breast implants. As a consequence of that enquiry, the TGA has implemented a process for following up on the submission of annual reports for all sponsors where this is a condition of entry on to the Australian Register of Therapeutic Goods.