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: E12-402

OUTCOME 1: Population Health

Topic: PIP Implants

Type of Question: Written Question on Notice

Number of pages: 1

Senator: Senator Xenophon

Question:

According to the Department's submission to the PIP inquiry, the first adverse event report received by the TGA in relation to the PIP Implants was in October 2002, when the device was available under the Special Access Scheme.

a) Who made this report?
b) What action was taken?
c) How many reports did the TGA receive before the device was approved for listing on the ARTG, and where did these come from? How many after it was recalled?

Answer:

a) The report was provided to the Therapeutic Goods Administration (TGA) by the French manufacturer Poly Implant Prothese (PIP).

b) The report was acknowledged and entered into TGA's database of medical device incidents.

c) Thirteen (13) reports of adverse events were received prior to inclusion on the Australian Register of Therapeutic Goods on 30 November 2004. The reports were made by the manufacturer (nine), surgeons (three) and patients (one). As of 4 July 2012 there have been 372 reports of all adverse events to the TGA since the recall on 6 April 2010.