Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2015-16, 1 - 2 June 2015

Ref No: SQ15-000649

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

Topic: ASR Implants

Type of Question: Hansard Page 62, 2 June 2015

Senator: Xenophon, Nick

Question:

1. Has the TGA learned from the lessons of the ASR and is the TGA more cautious about these devices?

Answer:

1. On 1 July 2012, the Therapeutic Goods Administration (TGA) reclassified all hip, knee and shoulder prostheses from Class IIb (medium risk) to Class III (high risk) medical devices. All new implants supplied after that date are required to supply evidence to meet the higher requirements. Also, all implants in the marketplace prior to 1 July 2012 have been required to undergo re-assessment to the Class III requirements.