

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2011-2012, 15 February 2012

Question: E12-307

OUTCOME 1: Population Health

Topic: MEDICAL DEVICE REGISTRIES

Written Question on Notice

Senator Fierravanti-Wells asked:

Following the Poly Implant Prosthese breast implant issue, is the Therapeutic Goods Administration considering mechanisms to involve key stakeholders such as clinicians, health consumers and industry in the governance of and contribution to medical device registries?

Answer:

The Government acknowledges the potential value of clinical registers of high risk medical devices, including breast implants.

Any future activity in this area would be guided by the Australian Commission on Safety and Quality in Health Care Operating Principles and Technical Standards for clinical registries which were endorsed by Health Ministers in November 2010. The overarching Strategic Principles identify key stakeholders and the Operating Principles cover a range of issues including formalised governance structures which ensure accountability.