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: E12-401

OUTCOME 1: Population Health

Topic: PIP Implants

Type of Question: Written Question on Notice

Number of pages: 1

Senator: Senator Xenophon

Question:

It's obviously better to make sure these devices are never implanted in the first place. What measures will go hand in hand with this to ensure that only the best devices enter the market in the first place?

Answer:

Under the *Therapeutic Goods Act 1989*, medical devices must be included on the Australian Register of Therapeutic Goods (ARTG) prior to supply in Australia. Under the Therapeutic Goods (Medical Devices) Regulations 2002, mammary implants are classified as Class III medical devices.

Class III medical devices are high risk devices, and subject to pre-market scrutiny to ensure they comply with criteria for quality, safety and performance. These higher risk devices must undergo more stringent conformity assessment procedures than lower classification devices and are subject to more detailed review.

The TGA also undertakes post-market monitoring of medical devices included in the ARTG to ensure ongoing compliance with the legislative requirements. Monitoring of medical devices is carried out to ensure that safety and performance of the medical devices continues after supply to the Australian market.

Increasing pre-market scrutiny for implantable medical devices is a key recommendation of *TGA Reforms: A blueprint for TGA's future* and remains a priority for the Government.