

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2013-14, 5/6 & 7 June 2013

Question: E13-005

OUTCOME: 1 - Population Health

Topic: Medical Device Sponsors

Type of Question: Written Question on Notice

Senator: Xenophon

Question:

- a) What role does the TGA play in monitoring the activities of medical device sponsors?
- b) If the TGA plays no role, who does?

Answer:

- a) The Therapeutic Goods Administration's (TGA) role in relation to sponsors of medical devices is set out in the *Therapeutic Goods Act 1989* (the Act) and related regulations such as the Therapeutic Goods (Medical Devices) Regulations 2002. Section 3 of the Act defines a sponsor as the person or company responsible for the importation of medical devices into Australia, and/or the supply of medical devices in Australia, and/or the export of medical devices from Australia. Under section 41FC of the Act, the sponsor is responsible for making the application to the TGA to have their device included in the Australian Register of Therapeutic Goods (ARTG), which is required before a device can be supplied for sale in Australia.

In broad terms the types of activities over which TGA can exercise controls over sponsors relate to applications for inclusion of medical devices in the ARTG and postmarket reporting obligations once the device is included in the ARTG.

Post-market activities relate to the monitoring of the continuing safety, quality and performance of medical devices once they are on the market.

The TGA has a strong post market monitoring and surveillance program, which involves the assessment of adverse events that are reported to the TGA by consumers, health professionals, the industry, international regulators or by the medical and scientific experts on TGA advisory committees.

Where a new risk is identified by TGA post-market activities, the best course of action is assessed. This may consist of adding a warning statement to the Product Information or recalling the product from the market.

- b) The TGA's role is described in the answer to part a).