Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

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

Question: E13-006

OUTCOME: 1 – Population Health

Topic: Medical Devices

Type of Question: Written Question on Notice

Senator: Xenophon

Question:

Clearly, the TGA's mandate relates to consumer protection through the control and regulation of medicines and medical devices. Under what circumstances does this extend to examining companies seeking to sponsor devices in Australia, particularly small or medium sized companies?

Answer:

The medical device regulatory system is intended to ensure a high level of protection of public health and safety. Public trust and confidence in medical devices and in the administrative systems by which they are regulated are based on the safety and performance of devices throughout their life cycle.

Before someone can supply a medical device for sale in Australia they are required to make an application to include the device in the Australian Register of Therapeutic Goods (ARTG). The sponsor is 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, as well as making application to the Therapeutic Goods Administration (TGA) to have their device included in the ARTG. The sponsor must be a resident of Australia or be an incorporated body in Australia and conducting business in Australia where the representative of the company is residing in Australia.

When a medical device is included in the ARTG the sponsor has a number of obligations, relating to the availability and provision of information on the medical device, reporting on performance issues, continuing compliance with regulatory requirements, and payment of appropriate fees and charges. There are criminal and civil penalties for making false statements, and monitoring the on-going safety and performance of medical devices is an important part of the TGA's role.

The regulatory framework is primarily focused on the safety and performance of the medical devices. The responsibilities and obligations of sponsors (and through them manufacturers) are a key mechanism for the TGA to ensure ongoing compliance with the regulatory framework. If concerns arise in respect of a sponsor that do not relate to the safety and performance of the medical device or the regulatory obligations of a sponsor, these may be referred to other appropriate agencies. These may include the Australian Competition and Consumer Commission, the Australian Securities and Investments Commission, or other Commonwealth, state or territory agencies such as Departments of health, fair trading authorities, or the police.