Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2011-2012, 30/31 May 2011

Question: E11-020

OUTCOME 1: Population Health

Topic: TESTING OF MEDICAL DEVICES IN AUSTRALIA

Written Question on Notice

Senator Xenophon asked:

Dr Hammett, in the Four Corners program, you stated that "There are about a million individual medical devices on the Australian market at the moment.. it's not possible to individually test a million medical devices.."

Does this mean that the TGA is approving more devices than it knows it can properly test?

Answer:

It is not possible for the TGA, or any other regulatory authority, to physically test every medical device prior to making them available on the market. To do so would prohibitively impact the cost and availability of medical devices.

Instead, the TGA administers a risk-based regulatory model that provides for different levels of pre-market assessment, based on the relative level of risk associated with the use of the medical device.

The Australian regulatory framework for medical devices set down by the Commonwealth Government in the *Therapeutic Goods Act 1989* is aligned with the model recommended by the Global Harmonization Task Force (GHTF) for medical devices.