

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Additional Estimates 2013 - 2014, 26 February 2014

Ref No: SQ14-000161

OUTCOME: 1 – Population Health

Topic: Generic Medical Devices

Type of Question: Written Question on Notice

Senator: Xenophon Nick

Question:

In the 2013-2014 Supplementary Budget Estimates in November last year, I asked about the TGA's position on generic medical devices. In response to my questions, the TGA informed me that 'medical device' is defined under the *Therapeutic Goods Act 1989* and Therapeutic Goods (Medical Devices) Regulations 2002 and the legislation does not refer to 'generic medical devices'. In developed countries healthcare systems are under financial pressure, resulting in healthcare providers exploring opportunities to increase efficiencies and reduce costs. Developing economies are also part of the emerging market for low cost or 'generic' medical devices. It has been put to me that in the near future it is likely we will see the manufacture of 'generic' medical devices in a similar way that we currently have generic drugs. Is the TGA aware of this emerging trend and has the TGA received any applications for approval of these types of devices?

Answer:

Every application to include a medical device on the Australian Register of Therapeutic Goods, whether or not it might be described as 'generic', is assessed on its own merits to ensure that the particular device is of acceptable quality, safety and performance.