

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Supplementary Budget Estimates 2013-14, 20 November 2013

Question: E13-003

OUTCOME: 1 – Population Health

Topic: Generic Medical Devices

Type of Question: Written Question on Notice

Senator: Xenophon

Question:

- a) What is the TGA's position on generic medical devices?
- b) Has the TGA received any applications for approval of generic devices?
- c) How would the TGA ensure that a generic device met the same manufacturing standards as a 'brand name' device?
- d) Does the TGA have protocols in place for approving or assessing generic devices?

Answer:

a) to d)

Medical device is a defined term under the Therapeutic Goods Act 1989 and Therapeutic Goods (Medical Devices) Regulations 2002. The legislation does not refer to 'generic medical devices'. Every application to approve a medical device for marketing in Australia is assessed on its own merits to ensure that the device is of acceptable quality, safety and performance.