Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Additional Estimates 2013 - 2014, 26 February 2014

Ref No: SQ14-000163

OUTCOME: 1 – Population Health

Topic: Medical Devices

Type of Question: Written Question on Notice

Senator: Xenophon Nick

Question:

Earlier this month, Fairfax media reported on a study by Australian researchers that brought the safety of acupuncture needles into question.
a) Are acupuncture needles treated as 'medical devices' by the TGA?
b) What testing and monitoring standards does the TGA have in place for these needles?
c) What action will the TGA be taking following this report?

Answer:

a) Acupuncture needles are included on the Australian Register of Therapeutic Goods (ARTG) as Class IIa medical devices.

b) To be included in the ARTG manufacturers of medical devices are required to hold and maintain appropriate conformity assessment certification. For a Class IIa medical device, such as acupuncture needles, this typically involves a Production Quality Assurance Procedure, under which the manufacturer must implement a quality management system for the production and final inspection of the medical device. This is audited and certified by an independent certification body.

c) The Therapeutic Goods Administration (TGA) is not undertaking any investigation of acupuncture needles at this time. Incident reporting arrangements are in place to notify the TGA of any specific incidents with medical devices, and allow identification of adverse events trends occurring in the Australian market place.