Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Supplementary Budget Estimates 2014-2015, 22 October 2014

Ref No: SQ14-001327

OUTCOME: 7 - Health Infrastructure, Regulation, Safety and Quality

Topic: Medical Device Reforms

Type of Question: Written Question on Notice

Senator: McLucas, Jan

Question:

When did the public consultation occur of accepting international standards assessment, as outlined by Prof. Skerritt during estimates hearings? Were consumer groups represented? If so who was consulted?

Answer:

Consultation on changes to premarket assessment requirements for medical devices was undertaken between January and March 2013 and again between May and June 2013. The *Regulation Impact Statement: Premarket assessment requirements for Australian manufactured medical devices* summarises the outcomes of these consultations as they related to the proposed change for Australian manufacturers, as well as listing earlier consultation on this issue.

These consultations were open for public comment, and submissions were received from the Consumers Health Forum, Cancer Voices Australia, and Friends of Science in Medicine. Submissions were also received from a range of health practitioners (both individuals and health sector representative organisations) and the medical devices industry (individual companies, consultants and sector representative organisations).

The Regulation Impact Statement is available on the Therapeutic Goods Administration website at: www.tga.gov.au/publication/regulation-impact-statement-premarket-assessment-requirements-australian-manufactured-medical-devices