

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2011-2012, 19 October 2011

Question: E11-295

OUTCOME 1: Population Health

Topic: Third Party Conformity Assessment Bodies in Australia

Written Question on Notice

Senator Fierravanti-Wells asked:

On the 19th December 2008 the TGA commenced consultation on third party conformity assessment bodies in Australia. The TGA then implemented the Health Technology Assessment (HTA) review which dealt with this issue. The TGA then released the “Reforms to the Medical Devices Regulatory Framework” which also dealt with this issue, the response to which says “more consultation is needed”.

How much more consultation do you need to take on this before you allow Third Party Conformity Assessment bodies in Australia?

Answer:

At this time, given concerns about the regulatory oversight of medical devices by third party bodies, there has not been acceptance of the use of third party conformity assessment bodies. This issue is also the subject of a recommendation in the recently released report on the Senate Inquiry into the regulatory standards for the approval of medical devices in Australia. The Government’s response to the Senate Inquiry recommendations will be made in due course.