

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Supplementary Budget Estimates 2014-2015, 22 October 2014

Ref No: SQ14-001331

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

Topic: Medical Device Reforms

Type of Question: Written Question on Notice

Senator: McLucas, Jan

Question:

What concerns have been raised during public consultations on changes to medical device assessments? How have these concerns been addressed?

Answer:

There were a number of rounds of consultation on the proposed changes for Australian manufacturers. The response from stakeholders in consultation on this proposal was generally consistent:

- Industry stakeholders were supportive of allowing third party conformity assessment for Australian medical device and IVD manufacturers; and
- Some concern was expressed from consumers and healthcare professionals that this change would affect public health and safety if the level of TGA oversight of Australian medical device and IVD manufacturers is reduced.

The change enacted means that devices of the same risk classification will be subject to the same level of assessment by the Therapeutic Goods Administration (TGA) irrespective of the location of the manufacturer and, therefore, the safeguards that are inherent in the current regulatory system, and which apply to devices manufactured overseas, will apply to those devices manufactured in Australia.

Specifically, where devices are of the highest risk (e.g those containing a medicine or animal material), irrespective of the location of the manufacturer, TGA will continue to undertake the conformity assessment for the quality, safety and performance of the device. For high risk devices, irrespective of the location of the manufacturer, TGA will continue to assess an application for the marketing approval of a device (i.e the step after a conformity assessment certificate is issued).