

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2010-11, 20 October 2010

Question: E10-047

OUTCOME 1: Population Health

Topic: REMANUFACTURED HEART CATHETERS

Written Question on Notice

Senator Xenophon asked:

In June, in response to comments from Canadian cardiologist Dr Larry Sterns expressing his concerns about the performance of remanufactured heart catheters, Dr Hammett said: "I am delighted that you have got those views in the Hansard, because those views are very similar to the views shared within the TGA."

- a) Is this still the TGA's view on remanufactured devices?
- b) How has the TGA's position changed, and why?

Answer:

- a) The TGA's view remains that remanufactured medical devices must meet the same requirements for safety and performance as a new device. Reprocessing of single use medical devices is considered to be "manufacture" in accordance with the definitions in the *Therapeutic Goods Act 1989*. Accordingly, the person undertaking the re-processing must demonstrate that the performance of the reprocessed device meets all the requirements for quality, safety and performance that are set out in the Conformity Assessment Procedures in the *Therapeutic Goods Act and Regulations*.
- b) The position has not changed.