

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2010-11, 23 February 2011

Question: E11-026

OUTCOME 1: Population Health

Topic: REPROCESSING AND REMANUFACTURING

Written Question on Notice

Senator Xenophon asked:

- a) How does the TGA differentiate between 'reprocessing' and 'remanufacturing'?
- b) What is the TGA's position on each?

Answer:

- a) For the TGA, the terms "reprocessing" and "remanufacturing" are interchangeable and there is no difference in their meaning.
- b) Both the original manufacturer and the remanufacturer must demonstrate that the process of manufacture/remanufacture ensures that the device complies with the essential principles for safety, quality and performance.