Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2010-11, 20 October 2010

Question: E10-048

OUTCOME 1: Population Health

Topic: SINGLE USE DEVICES

Written Question on Notice

Senator Xenophon asked:

The TGA's Guidelines on single use devices state that 'The TGA will include the device in the ARTG based on manufacturer's intended purpose. Therefore, the TGA does not conduct any pre-market assessments to determine if a device can be reused if the manufacturer states that the device is for single use or single patient use.'

a) Is this case for devices remanufactured overseas as well as in Australia?

b) When is the TGA planning to review these guidelines?

Answer:

a) The situation is the same for all kinds of devices on the ARTG, irrespective of where they are manufactured.

b) The TGA's current Australian Regulatory Guidelines for Medical Devices (Section 19: Single use devices and the reuse of Single use devices) states that a reprocessed device must meet the same standards of safety, quality and performance as a non-reprocessed device. The manufacturer and sponsor of any reprocessed devices must demonstrate that they meet these standards before the TGA would approve registration of such a device. The TGA has no plans to review these guidelines.