Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2010-11, 23 February 2011

Question: E11-027

OUTCOME 1: Population Health

Topic: CATHETERS

Written Question on Notice

Senator Siewert asked:

It is our understanding that a remanufacturer must go through 'conformity assessment' in order to supply remanufactured catheters in Australia. I understand that 'conformity assessment' requires the provision of a 'design dossier' of all 'remanufactured' devices.'

a) Can you explain how a remanufacturer can have access to design details that presumably could only be supplied by the original manufacturer?

b) If not, how can a remanufacturer provide the same level of design detail without access to the original manufacturer's design dossier?

c) Do remanufacturers only need to provide a lower level of information?

d) Presumably there will be multiple remanufacturing cycles for an individual catheter. What additional testing will be required by the remanufacturer to identify, for example, material fatigue or degradation which could put a patient at risk of injury or even death, especially when a catheter may be inside someone's heart for an extended period of several hours?

Answer:

a) In most cases, the remanufacturer cannot access that information, unless it is provided to them by the original manufacturer.

b) In the case of remanufacture, it is the design of the remanufactured device that is assessed. The remanufacturer is expected to provide information to demonstrate that the remanufacturing process does not adversely impact the design of the device. In order to do this, the remanufacturer must understand the design specification, investigate the construction of the product and then reconstruct the device to their particular specifications to create their own version of the product.

c) No. Remanufacturers need to provide different information. The information required to establish that the remanufacturing process does not adversely impact the design of the device is very extensive.

d) The remanufacturer would be expected to demonstrate that any device, having undergone the maximum number of allowable reprocessing cycles, is still able to meet the requirements for quality, safety and performance.

For example, a remanufacturer would be expected to perform fatigue testing on the device.