

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2010-11, 20 October 2010

Question: E10-247

OUTCOME 9: Private Health

Topic: ARTG

Written Question on Notice

Senator Fierravanti-Wells asked:

- a) Is the TGA aware of any devices that are or have been approved by the PDC that have not been listed on the Australian Register of Therapeutic Goods (ARTG)?
- b) If so, what was the nature of these products?
- c) How did PDC approve a listing without it being approved on the ARTG?
- d) How long have the products been on the prosthesis list?
- e) What action has been taken?

Answer:

- a) Yes.
- b) The Oncura RapidStrand Rx Brachytherapy kit.
- c) The PDC does not approve listings.
- d) Since July 2008.
- e) If it is alleged that a prosthesis does not meet the listing criteria, natural justice requires that the affected sponsor of the product is given an opportunity to respond and provide further information which must be taken into account in making any decision about whether the prosthesis should remain listed. This procedure is currently being followed for the Oncura RapidStrand Rx Brachytherapy kit.