**Senate Community Affairs Committee**

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

**Additional Estimates 13 & 15 February 2013**

**Question:** E13-214

**OUTCOME 1:** Population Health

**Topic:** Urogynaecological Mesh

**Type of Question:** Hansard Page 29, 13 February 2013

**Senator:** Senator Xenophon

**Question:**

Whether you consider that there is any consistency between the response given to my question and the statement given to the *7.30* program and, if so, whether there will be a correction issued.

**Answer:**

The answer provided to Question E12-028, from Supplementary Budget Estimates 2012-2013 of 17 & 19 October 2012, is consistent with the information provided to the *7.30 Report* program.

The answer to Question E12-028 explained that the Therapeutic Goods Administration (TGA) does not require 12 month clinical data for these products for approval for use. These products do not require 12 months of clinical data to support inclusion on the Australian Register of Therapeutic Goods (ARTG). The statement provided to the *7.30 Report* did not provide any information about the clinical evidence requirements for a urogynaecological mesh product to be included (sometimes referred to as "registered") on the ARTG and, therefore, available for sale and use in Australia.

The statement provided to the *7.30 Report* explained that the Urogenital Prostheses Clinical Advisory Group that assesses applications to list urogenital prostheses on the Prostheses List for private health insurance reimbursement requires sponsors applying to list new urogynaecological products to provide published and peer reviewed clinical evidence with at least 12 months of follow up data to support the application. This requirement was instituted as a result of the concerns raised by the Food and Drug Administration about complications arising from the implantation of urogynaecological mesh products.

Statement from the TGA in response to 7.30

- Since 2006, the TGA has received 63 adverse event reports for all urogynaecological surgical meshes. The majority of reports are from the sponsors and manufacturers of these devices. There have been many thousands of these mesh devices implanted in the same time period.

- At a recent meeting the TGA had with the Urogynaecological Society of Australia (UGSA) they reinforced their view that the issues were about the use of these meshes rather than the meshes themselves. The TGA has provided both the UGSA and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) with information on how to report adverse events.

- A detailed review of urogynaecological meshes was undertaken by TGA in 2010.

- The Clinical review found that the reported rate of complications was low. Further they found evidence that these rates do depend on the skill and training of the surgeon as well as patient factors. This outcome was endorsed by the then Medical Device Incident Review committee.

- TGA consulted the RANZCOG and the UGSA as part of its monitoring of these surgical meshes. Both RANZCOG and UGSA are aware of the matters raised by the FDA. The TGA ensured that the colleges were aware of the situation and that they had communicated this information to their surgeons who are closest to the consumer.

o In light of this RANZCOG and UGSA are advising that surgeons should have special training on performing these procedures and patient selection. Also that surgeons need to ensure patients understand the possibility of complications associated with this type of procedure. The UGSA has initiated a Pelvic Floor Surgical Database which started to collect data from operations prospectively in April 2012 which was modified from the UK equivalent to satisfy Australasian law.

o In late May 2012 Johnson and Johnson notified all regulators that they will be ceasing supply globally over the next three to nine months of their surgical mesh products used in the treatment of pelvic floor prolapse and urinary incontinence.

o The TGA has reviewed these devices since receiving the notification from Johnson and Johnson of the intent to remove their devices. Johnson and Johnson have confirmed that all of the above products were removed from supply in Australia on 15 August 2012, except for the Prosima which is being used by one surgeon in a surgeon driven clinical trial.

o TGA also contacted Private Healthcare Australia and other private health funds regarding any adverse event data they are willing to share.

o The FDA has also been contacted to determine if it has undertaken any regulatory or other action as a result of this notification. The FDA has indicated that it is not pursuing any regulatory action.

o The TGA continues to monitor the rate of complications with surgical mesh along with other regulatory bodies and discussions with the colleges.

- The urogynaecological meshes are either for Pelvic Organ Prolapse (POP) or Stress Urinary Incontinence (SUI) and are classified as either class IIb or class III devices. Those that are class III are biological meshes. The J&J meshes withdrawn from use are class IIb.

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- The ARTG entries for class IIb devices can cover several products. The Class III entries will cover only one product however.

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- There are currently 47 entries for Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI) devices for 16 sponsors

- The TGA urges any patients with mesh implants who are concerned to contact their surgeon.

o Note that mesh products are listed on the Prostheses List (PL) which means that private health insurers are required to pay a benefit on behalf of their member for the cost of the mesh. The mesh is purchased by the hospital from suppliers such as Johnson and Johnson. Currently there are 25 vaginal mesh products on the list. The relevant Clinical Advisory Group (UPCAG) are aware of the concerns around these products and any new sponsors seeking to list mesh products on the PL are being asked to provide published and peer reviewed clinical evidence with at least 12 months of follow up data to support their application.