Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2012-2013, 17 & 19 October 2012

Question: E12-029

OUTCOME 1: Population Health

Topic: UROGYNAECOLOGIC MESH

Type of Question: Written Question on Notice

Number of pages: 1

Senator: Senator Xenophon

Question:

The statement from Johnson & Johnson in relation to urogynaecologic mesh stated that the decision to discontinue these products was based on their commercial viability in light of changing market dynamics and is not related to safety or efficacy. Does the TGA agree that the device is safe and effective?

Answer:

The Therapeutic Goods Administration (TGA) has reviewed these devices since receiving the notification from Johnson and Johnson of the intent to remove their devices, and found evidence that suggested complication rates were low. When complications did occur the TGA found that this was closely linked to the skill and training of the surgeon as well as patient factors.

As at 5 December 2012, the TGA has received 71 adverse event reports for all urogynaecological surgical meshes used in Australia since 2006. 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.

The TGA continues to monitor the rate of complications with urogynaecological mesh. The advice from surgeons experienced in the use of these types of devices is that many of the observed complications arise not from the device but from the use in inappropriate patients and from a lack of training of the surgeon.