Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

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

Question: E12-028

OUTCOME 1: Population Health

Topic: UROGYNAECOLOGICAL MESHES

Type of Question: Written Question on Notice

Number of pages: 1

Senator: Senator Xenophon

Question:

In the TGA's response on the mesh story on the ABC 7.30 program, it stated:
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. During the hearing, it was established that there is not a one-to-one relationship between reimbursement and data collection, but it was not established whether the requirement for published and peer reviewed clinical evidence over 12 months applied to the mesh that is now in question. Was there a 12-month published process before it was approved for use or reimbursement?

Answer:

Regarding approval for use, the Therapeutic Goods Administration does not require 12 month clinical data for these products, but the clinical data is assessed on a case by case basis.

Regarding approval for reimbursement, the requirement for peer-reviewed clinical evidence over 12 months was not applied to the urogynaecological mesh products sponsored by Johnson & Johnson Medical Pty Ltd.

After becoming aware of this issue, the Urogenital Prostheses Clinical Advisory Group (UPCAG) implemented a requirement for published and peer-reviewed clinical evidence with at least 12 months follow up data on a reasonable sample of patients to support applications.