Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Supplementary Budget Estimates 2014-2015, 22 October 2014

Ref No: SQ14-001254

OUTCOME: 7 - Health Infrastructure, Regulation, Safety and Quality

Topic: Metal-on-Metal Joint Prostheses

Type of Question: Written Question on Notice

Senator: Xenophon, Nick

Question:

In the June 2013 Budget Estimates, I asked about research into the performance of metal-on-metal joint prostheses. I was advised the TGA was following the progress of research of ASR implants being conducted by the Massachusetts General Hospital in the US. I was also advised about an Australian study being developed to investigate the health effects in patients with MoM implants. Can you provide an update on this research and advise of any new research commissioned by the Department, or new overseas research being conducted overseas?

Answer:

The Therapeutic Goods Administration (TGA) constantly monitors the literature for any well controlled clinical study on whether there is an increased risk of systemic toxicity among people with MoM implants. To date there has been none. One such study was planned to commence in Massachussets, USA last year, using patients enrolled from around the world, including Australia. In May 2014, the TGA received this advice from the study coordinators:

> *The enrolment has been slower than expected. Not all surgeons are willing to join the study. Currently we have 850 patients enrolled in the study and we are still recruiting more sites and more patients. It is still too early to draw any conclusions from the data set that we have.*

In Australia, the TGA is aware of a study by the Centre for Research Excellence – Medicine and Device Surveillance, which used the Department of Veterans' Affairs Health Claims Database and the data from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) to determine if there is an association between metal-on-metal (MoM) prostheses and adverse systemic effects. The study looked at private hospital admissions for any reason among veterans who had received either:

- A metal on polyethylene (MOP) implant
- An ASR XL MoM implant
- Another (non ASR XL) metal on metal implant

The as yet unpublished study found a significantly increased risk of hospitalisation for heart failure with the ASR XL MoM implant. But the risk of hospitalisation for heart failure with other MoM implants is not different to the MOP group. In fact, if anything, MoM implants are a little lower. This suggests that the observed difference in the hospitalisation rates due to heart failure in the ASR XL group is not related to the fact that the implant is a MoM implant.