

**Senate Community Affairs Committee**

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

**Budget Estimates 2015-16, 1 - 2 June 2015**

**Ref No:** SQ15-000384

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

**Topic:** Australian Cardiac and Orthopaedic Device Registries

**Type of Question:** Written Question on Notice

**Senator:** Xenophon, Nick

**Question:**

When Australian cardiac and orthopaedic device registries reveal a device displays poorer clinical outcomes than comparable devices, what is the process for alerting clinicians of this finding so as to minimise their use?

**Answer:**

The Cardiac Device Registry is currently being established and has not produced results that can be used in this way. The following response applies only to the long established Australian Orthopaedics Association Joint Replacement Registry (AOANJRR).

Every orthopaedic surgeon in Australia has access to the AOANJRR data, including the list of implant combinations that are identified as having poorer outcomes and the outcomes of the implants that they themselves have implanted. Therefore, surgeons are informed directly by the AOANJRR in relation to implants that they are using that are having high rates of revision as well as access to information about the outcomes of their own procedures.

If, using the process described in our response to Question on Notice SQ15-000383, the Therapeutic Goods Administration (TGA) has determined that regulatory action is necessary, the TGA will require the Sponsors alert clinicians of the details of the regulatory action in accordance with the Uniform Recall Procedure of Therapeutic Goods – In most cases implanting surgeons will be notified by letter or e-mail directly, and Hospitals and State Health Departments will be notified by the TGA. The TGA will also publish details of the regulatory action on the TGA's website. The TGA also informs the Australian Orthopaedic Association about any regulatory action to be undertaken.

Outcomes of the Orthopaedic Sub Committee's meetings, where implants identified by AOANJRR as having higher than anticipated revision rates are discussed, are published on the TGA's website.