Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2015-16, 1 - 2 June 2015

Ref No: SQ15-000383

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 having poorly performing devices removed from sale?

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).

It is important to note orthopaedic implants are revised for a number of reasons and that only a few of them are related to the design or performance of the implant itself. It follows that not all implants that are identified as revision rate outliers in the annual report of the AOANJRR will require regulatory intervention, and removal from the market is one of a number of regulatory interventions available.

The Therapeutic Goods Administration's (TGA) review of the implants that were identified for the first time begins as soon as the Annual Report and the detailed implant revision analyses become available from the AOANJRR. This is usually on or around 1 October of each year.

1. The first step is to contact the Sponsor (supplier) of each implant asking them to provide additional detailed information collected in Australia and abroad about the performance of the implant, such as details of clinical studies and results from other registries.
2. The second step is to carry out an analysis of the data provided by the AOANJRR and the response from the Sponsor.
3. The third step is to refer the information from the AOANJRR, the response from the Sponsor and the TGA analysis generated in step 2 to the Orthopaedics Subcommittee (OSC) of the Advisory Committee on the Safety of Medical Devices for its consideration and advice.

4. OSC advice about each of the implant combinations that have been identified in the AOANJRR report generally falls into one of three categories:

   a. That further information is required before definitive advice can be provided. In this case the matter remains active until the information is obtained and referred to a future meeting of the OSC.

   b. That an implant can "Continue to be observed". In this case the matter is normally closed until further information becomes available or until the next edition of the Annual Report of the AOANJRR.

   c. That there is sufficient evidence that the revision rate of an implant is unacceptably high, and that there are no special features associated with the implant that may compensate for the additional risk of revision. In this case the TGA will normally initiate regulatory action to effect product cancellation, recall, alert, or changes to the Instructions for Use (such as contra-indications).

   In most cases implants listed in the annual report of the AOANJRR listed as being "Re-Identified and Still Used" are implants that that the OSC has considered in the past and advised that they should "Continue to be observed". The OSC meets in March or April of each year to re-consider the implants in this category.

   Removal from the market requires the TGA to write to the Sponsor:

   i. Proposing to cancel the entry of the device in the Australian Register of Therapeutic Goods (ARTG) in accordance with Section 41GN of the *Therapeutic Goods Act 1989* (the ACT), outlining the reasons why, and providing a reasonable opportunity for the Sponsor to provide a response to the proposal.

   ii. If a response is provided that fails to satisfy the TGA decision-maker that the implant should not be removed from supply, the TGA will write to the Sponsor again to notify them that the entry of the device has been cancelled and stating the reasons why. The TGA's decision to cancel a product from the ARTG is subject to appeal under Section 60 of the Act and – if the appeal is not successful - through the Administrative Appeals Tribunal.