Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2015-16, 2 June 2015

Ref No: SQ15-000385

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 data produced by Australian cardiac and orthopaedic device registries reveals poor clinical outcomes and this data is used to remove devices that produce poor clinical outcomes from sale in Australia, what is the average time in days from the date the data was produced to the date the item is 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).

As outlined in our response to Question on Notice SQ15-000383, not all implants that are identified by the AOANJRR as revision rate outliers require regulatory action. Regulatory action can range from cancellation or "removal from sale" to amending the Instructions for Use such as contra-indicating the device in particular circumstances or use with other components.

The AOANJRR annual report is released on or around 1 October each year. As outlined in our response to Question on Notice SQ15-000383, the Therapeutic Goods Administration (TGA) will seek the advice about implants of concern from the Orthopaedic Sub-committee (OSC) of the Advisory Committee on the Safety of Medical Devices before contemplating regulatory action. The OSC normally meets in late November or early December of every year. If the OSC advises the TGA that the revision rate appears to be unacceptable and that there are no mitigating circumstances or particular characteristics of the device where a higher rate of revision may be acceptable (such as specific clinical scenarios making surgery difficult), the TGA will then contact the Sponsor proposing to cancel the implant from the Australian Register of Therapeutic Goods and allowing the Sponsor to provide a justification as to why the device should not be removed from the market.

In some cases the Sponsor agrees voluntarily to the TGA's proposal to cancel the device and the product is removed from sale shortly after – (by about January or early February). In these circumstances a hazard alert is also published on the TGA website.

If the Sponsor does not agree with the proposal to cancel and provides a further submission in defence of their product, as is their legal right, then the process takes longer as the evidence must be reviewed and may be presented to the OSC once again at its March/ April meeting.

As outlined in our response to Question on Notice SQ15-000383, the OSC may ask for further information about the device's performance before they provide definitive advice. If this is the case then the regulatory action may be delayed.

In any case, regulatory action is usually completed within two to eight months from the time that the OSC has provided their final, definitive advice about the performance of the implant combination that was identified. Whether it is two or eight months depends on whether the Sponsor agrees with the TGA's initial proposal to cancel or makes further submissions to the TGA that must be considered.