Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

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

Question: E12-026

OUTCOME 1: Population Health

Topic: TGA

Type of Question: Written Question on Notice

Number of pages: 2

Senator: Senator Xenophon

Question:

During the hearing, officers of the TGA also stated that Australia had received recognition for its early action in relation to the ASR hip device. As covered in the Senate inquiry into medical devices, the ASR manufacturer implemented a training program for surgeons to reduce the complications occurring with the device. This training program was attributed by Dr Rohan Hammett to a reduction in use of the device; however NJRR data showed that the most significant decline in use was in 2007, before the training program was introduced. The committee report also notes minutes from the OEWG, which state that the manufacturer later approached the TGA when 'the revision rate [was] no longer acceptable'. The manufacturer then withdrew the device.

a) Does the TGA acknowledge the above information, as described and referenced in the committee report, is correct?

   Dr Kelly stated: "The actions that we took I think set a standard around the world for the use of the registries as a way of performing post-market decision-making for regulators." (Emphasis added)

b) Given that attempts to mitigate problems with the ASR, and its eventual withdrawal, can be attributed to the manufacturer, can the TGA clarify the use of 'we' in this instance? Does it refer to the TGA or to the Australian jurisdiction?

c) Does the TGA acknowledge that, in this instance, it is inappropriate for the TGA to claim that they were the ones to 'set a standard' when they did not in fact take any significant action?

d) If so, will the TGA acknowledge and correct their statement in the hearings?

Answer:

a) The Therapeutic Goods Administration (TGA) records show that the sponsor advised TGA in September 2007 that, effective immediately, it was implementing a training program for surgeons intending to use the Articular Surface Replacement (ASR). In May 2008, and in October 2009 the sponsor advised TGA of decreasing use of the ASR implants. This is supported by data from the National Joint Replacement Register which shows 2436 ASR implants (resurfacing head, conventional head, and resurfacing cup) were used in 2006, 2734 ASR implants were used in 2007, 2631 ASR implants were used in 2008, 1046 ASR implants were used in 2009. These data show the most significant fall off in use of the ASR implants took place during 2008-09.

b) to d)
The ASR hip implants were removed from the Australian Register of Therapeutic Goods by the sponsor in December 2009. On 2 October 2009 TGA had written to the sponsor seeking, amongst other things, an explanation for the higher than expected revision rates and how the perceived benefits of using the implants compensated for the increased risk of early revision. The sponsor was advised that the information provided would be used to determine further regulatory action. On 8 October 2009, TGA met with the sponsor to discuss TGA's letter. The sponsor advised that it would remove the ASR implants from the ARTG. The actions involving regulatory intervention based on registry data was significant in that the net result was that the ASR devices were removed from supply in Australia 10 months before the world wide recall.