

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2011-2012, 30/31 May 2011

Question: E11-017

OUTCOME: 1: Population Health

Topic: WITHDRAWAL OF THE DEPUY ASR HIP DEVICE

Written Question on Notice

Senator Xenophon asked:

The DePuy ASR hip device was eventually withdrawn from the market by DePuy. Dr Hammett, in an interview with Four Corners, you state that the device was withdrawn: “as a result of the TGA, and its expert clinical groups analysing data and presenting that to the company, making it quite clear that we regarded the performance of this device as no longer acceptable”.

- a) So the TGA did not require DePuy to remove the device from the market, it merely provided information and allowed the company to make that decision?
- b) Who are the “expert clinical groups”, and was their information also provided to the TGA?
- c) What “data” did the TGA analyse and provide to the company?

Answer:

- a) The TGA, through bringing the company to a point where it understood that the data was showing that there was a problem, achieved removal of this device from the Australian marketplace ten months before it had been removed anywhere else in the world.
- b) The expert clinical group consulted by the TGA in relation to the DePuy ASR hip device was the Orthopaedic Expert Working Group (OEWG) established in 2007. It plays a crucial role in advising the TGA on the regulation of orthopaedic devices. It is called upon to review available clinical data and other relevant information and provide advice to the TGA on whether an early revision (replacement) rate for orthopaedic devices is acceptable for the identified implant of concern.

The Working Group consists of eight members, seven of whom have expertise in orthopaedic surgery, including the Director of the National Joint Replacement Registry (NJRR).

The TGA uses the NJRR Annual Report to identify implants with a high revision rate, to seek detailed reports on performance issues, and to request further information from manufacturers. The TGA also uses the NJRR Annual Report to present information to the OEWG for consideration on the need for further action.

- c) The TGA analysed data from NJRR Annual Reports, together with information from the OEWG, and the sponsor.