

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2013-14, 5/6 & 7 June 2013

Question: E13-004

OUTCOME: 1 - Population Health

Topic: Metal-on-Metal Joint Prostheses

Type of Question: Written Question on Notice

Senator: Xenophon

Question:

- a) Has the TGA become aware of any issues with other metal-on-metal joint prostheses since the DePuy case?
- b) How many have been withdrawn from the market?
- c) When did this occur?
- d) Has the TGA commissioned any research or is it following any of the overseas research?
- e) What is the TGA's current position on metal-on-metal devices?

Answer:

a) to c)

The implants in the following table were experiencing higher than expected revision rates as reported by the National Joint Replacement Registry (NJRR). All of the implants in the table have been withdrawn from the market.

Implant	Date of Withdrawal
Bionik Acetabular Component and Modular Femoral Head (ESKA)	Nov 2011
Mitch TRH Modular Heads (Stryker)	Apr 2012
Co/Cr Metal Liners used in R3 Acetabular components (Smith and Nephew)	Jun 2012
Durom Acetabular Component (Zimmer)	Sep 2012
Birmingham Modular Femoral Head used in total conventional hip replacements (Smith and Nephew)	Sep 2012
Adept Modular Head and Acetabular component (Depuy)	Jan 2013

- d) See response to E13-003, part a).
- e) The Therapeutic Goods Administration (TGA) has sought the advice of the Australian Orthopedics Association (AOA) and the Orthopedics Expert Working Group (OEWG) that advises the TGA on these matters.

Both the AOA and the OEWG advised that metal on metal hip implants should not be condemned solely on the basis that they are of the metal on metal type, and that an implant-by-implant review of performance data generated by the National Joint Replacement Registry continues to be the most appropriate way to evaluate the relative performance of orthopedic implants, including those that are of the metal on metal type.

The TGA has accepted that advice.