

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Supplementary Budget Estimates 2014-2015, 22 October 2014

Ref No: SQ14-001251

OUTCOME: 7 - Health Infrastructure, Regulation, Safety and Quality

Topic: Metal-on-Metal Joint Prostheses

Type of Question: Written Question on Notice

Senator: Xenophon

Question:

In the June 2013 Budget Estimates hearings I put questions on notice about Metal-on-Metal Joint Prostheses. I have again recently been contacted by a number of women who have brought to my attention shocking stories of their experiences with MoM devices, in particular the Smith and Nephew Birmingham Hip Resurfacing devices (BHR). Have there been any changes in the TGA's approach to regulating MoM devices?

Answer:

Beginning in July 2012, all joint implants were required to be included in the ARTG as Class III medical devices. Existing implants have until 30 June 2015 to transition to the new classification. The transition process requires the TGA to re-assess safety data relating to the device including the AOANJRR performance data. The greater level of discrimination in the ARTG for Class III medical devices will enable the TGA to identify components that can be used in MoM implants.