

**Senate Community Affairs Committee**

**ANSWERS TO ESTIMATES QUESTIONS ON NOTICE**

**HEALTH PORTFOLIO**

**Additional Budget Estimates 2014/15, 25 February 2015**

**Ref No:** SQ15-000040

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

**Topic:** Smith & Nephew BHR

**Type of Question:** Hansard Page 96, 25 February 2015

**Senator:** Xenophon, Nick

**Question:**

Senator XENOPHON: The warning advises that these groups are at greater risk of requiring early revision surgery. My first question is: when did the TGA initially receive communication from Smith & Nephew that led to the issuing of the hazard alert? What was the turnaround time? a) When did the TGA initially receive communication from Smith & Nephew that led to the issuing to the hazard alert? b) What was the turnaround time? c) Does this mean there is a medium or high rate of revision for BHR amongst these groups have been referring to? That is, women, males, aged 65 or greater and a number of categories? Please give details about the extent of that increase. Senator XENOPHON: He does simply outstanding work. But there has been a problem in the past in terms of the work that the registry is done. There is no question of the quality of their work, but it is whether the TGA has acted appropriately in respect of that. Can you, on notice, assure us in respect of that action?

1. When did the TGA initially receive communication from Smith & Nephew that led to the issuing to the hazard alert?
2. What was the turnaround time?
3. Does this mean there is a medium or high rate of revision for BHR amongst these groups have been referring to? That is, women, males, aged 65 or greater and a number of categories? Please give details about the extent of that increase.

**Answer:**

1. The sponsor of Birmingham Hip Resurfacing (BHR) system, Smith & Nephew, initially notified the Therapeutic Goods Administration (TGA) about the proposal to undertake the hazard alert and updates to the instructions for use (IFU) for this product late Friday 23 January 2015 outside of normal office hours.
2. The TGA's review of the action proposed by Smith & Nephew commenced on the next working day, 27 January. TGA reviewed the information submitted by Smith & Nephew and agreed to the hazard alert and updates to the IFU on 4 February. This information included statistical analysis data from various joint registries around the

world, including the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). Consistent with TGA procedures for hazard alerts, a statement regarding the BHR issues was published on the TGA's website on 6 February.

3. The higher rates of revision among people over 65 years of age and for implants with a small femoral head are a feature of all Total Resurfacing hip replacements. All of the following information, drawn from the text, tables and figures in the 2014 Annual Report of the AOANJRR (pages 117-125), relates to all Total Hip Resurfacing implants, including BHR.

People over 65 years of age at the time of the primary procedure are most at risk of having their Total Resurfacing Hip Replacement revised in the initial 6 months after the procedure. People over 65 are approximately 3 times more likely to need a revision during this 6 month period than people who are less than 65. The risk of revision for people over 65 decreases significantly after this initial 6 month period and is in fact lower than the risk of revision for people who less than 65.

Overall, women are approximately 3 times more likely to have their Total Resurfacing Hip Replacement revised than men. The difference is lower in the first 12 months from the time of implantation.

This knowledge has emerged slowly but has changed surgical practice in Australia. In 2013 (a year before the BHR alert) only four procedures were undertaken in females (1 per cent) and the proportion of patients aged 65 or older has declined from 11.1 per cent to 4.8 per cent. These reductions are superimposed onto an overall reduction in the use of Total Resurfacing Hip Replacements in Australia, from 1,547 in 2003 to 392 in 2013.