

25 October 2011

Dr Ian Holland
Committee Secretary
Community Affairs References Committee
Parliament House
CANBERRA ACT 2600

Dear Dr Holland,

Inquiry into the Regulatory Standards for the Approval of Medical Devices

Thank you for your letter dated 21 October 2011 seeking a response to the evidence presented by Dr Hammett of the Therapeutic Goods Administration (TGA). The information sought is in relation to the timeliness of the Therapeutic Goods Administration in responding to information from the National Joint Replacement Registry about higher than usual revision rates for the Depuy ASR and hip resurfacing device.

Please refer to the attached table showing the date data was provided by the AOANJRR to the TGA. A second table lists when that data was reviewed by the TGA Orthopaedic Expert Working Group (OEWG).

Dr Hammett also made a comment about the impact of retraining surgeons in the operative procedure for the use of the ASR Resurfacing hip prosthesis and linked this training to a reduction in the use of the prosthesis.

Compared to the ASR Conventional hip, the ASR Resurfacing hip was used in smaller numbers and a decline in use was evident prior to the company initiated focus on training, which did not commence until early 2008. The most significant decline in the use of the ASR Resurfacing hip occurred in 2007. The AOANJRR had first raised concerns regarding the ASR Resurfacing hip in the 2006 Annual Report. The OEWG considered the 2007 ASR Resurfacing Hip data for the first time in May 2008. This was well after the major reduction in the use of the prosthesis.

If further information is required please do not hesitate to contact me.

Yours sincerely,

STEPHEN GRAVES
DIRECTOR AOANJRR

PROVISION OF DATA BY AOANJRR TO TGA

SEPTEMBER 2007 – SEPTEMBER 2009

DATE DATA SENT	TGA RECIPIENT	REPORTS SENT
20 September 2007		1. 2007 Annual Report
		2. Updated analysis of prostheses previously identified in the 2006 Annual Report
		3. Detailed analysis of prostheses being identified for the first time in the 2007 Annual Report. This included the ASR Resurfacing Hip Prosthesis. This was the first notification of the ASR Resurfacing Hip Prostheses being identified as a prosthesis with a higher than anticipated rate of revision.
26 February 2008		Request received that reports sent on 20 September 2007 be resent. The three reports listed above were resent.
18 September 2008		1. 2008 Annual Report
		2. Updated analysis of prostheses previously identified in 2007 Annual Report. This included the ASR Resurfacing Hip Prosthesis which was identified for the second time.
		3. Detailed analysis of prostheses being identified for the first time in the 2008 Annual Report. This included the ASR Conventional Hip Prosthesis in combination with the Corail Stem. This was the first notification of ASR Conventional Hip Prostheses being identified as a prosthesis with a higher than anticipated rate of revision.
23 September 2009		4. 2009 Annual Report
		5. Updated analysis of prostheses previously identified in 2008 Annual Report. This included the ASR Resurfacing Hip Prosthesis which was identified for the third time.
		6. Detailed analysis of prostheses being identified for the first time in the 2009 Annual Report. This included the ASR Conventional Hip Prosthesis being identified for the first time in combination with any stem, however this was the second time the ASR Acetabular Component was identified.

Note: The NJRR has continued to provide subsequent Annual Reports and detailed analyses of prostheses identified in the report to the TGA. The most recent reports were provided on 21 September 2011.

Copies of any of the above reports can be provided on request.

ORTHOPAEDIC EXPERT WORKING GROUP (OEWG) MEETINGS UP TO DECEMBER 2009

DATE OF MEETING	DATA REVIEWED
8 August 2007	This was the first time the OEWG was convened. Data from the 2006 Annual Report was reviewed.
21 February 2008	This meeting did not review data from the 2007 Annual Report. The TGA was seeking general advice about assessment of prostheses
21 May 2008	Hip data from the 2007 Annual Report was reviewed including the ASR Resurfacing Prosthesis for the first time.
18 June 2008	Knee data from 2007 Annual Report was reviewed.
9 December 2009	<p>This was the first time data from the 2008 Annual Report was reviewed along with data from the 2009 Annual Report. This included review of both the ASR Resurfacing and ASR Conventional Hip Prostheses.</p> <p>The 2008 data for the ASR Conventional Hip Replacement was considered for the first time. Both ASR Resurfacing and Conventional were withdrawn from the Australian market in December 2009</p>

Note: In an out of session document from the TGA to the OEWG dated 18 September 2009, the TGA explained that it had initiated an internal review of the process for dealing with implants identified in the NJRR reports. During the review the process of reviewing these implants was suspended.

The review dates for specific prostheses are documented in the minutes of the relevant OEWG Meeting. These minutes would be available from the TGA.