AUSTRALIAN ORTHOPAEDIC ASSOCIATION

6 September 2011

Mr Stephen Palethorpe
Inquiry Secretary
Standing Committee on Community Affairs
House of Representatives
Parliament House
CANBERRA ACT 2600

By email: ec.sen@aph.gov.au

Dear Mr Palethorpe

Response to Adverse Comments received by the Inquiry into the Regulatory Standards for the Approval of Medical Devices

Thank you for the opportunity to respond to adverse comments pertaining to the Australian Orthopaedic Association (AOA) and the National Joint Replacement Registry (NJRR) that the Inquiry has received within a submission.

AOA is the peak professional body for orthopaedic surgeons in Australia. AOA provides high quality specialist education, training and continuing professional development. AOA is committed to ensuring the highest possible standard of orthopaedic care and is the leading authority in the provision of orthopaedic information to the community.

AOA representatives would like the opportunity to appear before the Standing Committee to provide more in depth information to assist the Committee with its deliberations.

Please find AOA's response attached.

Yours sincerely,

Adrian Cosenza
Chief Executive Officer

AOA RESPONSE

Re: Adverse Comments Received

Inquiry into the Regulatory Standards for the Approval of Medical Devices

6 September 2011

AOA
AUSTRALIAN
ORTHOPAEDIC
ASSOCIATION

The Australian Orthopaedic Association (AOA) welcomes the opportunity to provide a written response regarding adverse comments received about AOA by the Inquiry into The Regulatory Standards for the Approval of Medical Devices.

This response is on behalf of AOA which includes the AOA National Joint Replacement Registry (NJRR).

The submission from Mr Robert Lugton does make many valid points but there appears to be a misunderstanding about the role and purpose of the AOA NJRR.

The NJRR was established to reduce the revision rate for joint replacement surgery in Australia. It does this by identifying differences in patient outcomes by assessing revision rates. It must be kept in mind that the requirement for joint replacement revision surgery can be multifactorial and include patient, surgical or prosthesis factors.

The role of the NJRR is to provide information. The information provided by the NJRR is widely disseminated to surgeons, hospitals, government, regulatory bodies, the medical device industry and the public. The provision of data to the NJRR by orthopaedic surgeons is voluntary and currently there is 100% compliance with data provision. It would be difficult to achieve and maintain this level of compliance if the NJRR had the roles of data collection, analysis and reporting as well as policing.

The regulation of prostheses is undertaken by the regulatory body which utilises data from many sources, the NJRR being one of those sources. In regards to joint replacement prostheses, the NJRR is able to provide quality post market surveillance data for the regulatory body to assess.

The Therapeutic Goods Administration (TGA) has established a process by which those prostheses identified as having a higher than anticipated rate of revision by the NJRR are subsequently reviewed and assessed. TGA also seeks the advice of the Orthopaedic Expert Working Group. This group was established by TGA some time ago and comprises experienced orthopaedic surgeons. The group provides expert advice on devices identified by the NJRR.

It should be noted that not all prostheses that are identified by the NJRR as having a higher than anticipated rate of revision have factors that are specific to that prosthesis. The revision rate may be due to factors other than the prosthesis.

It is correct that the NJRR first identified the ASR as an issue. The resurfacing ASR was first identified as having a statistically higher rate of revision in September 2007, although concern about this device was mentioned in the 2006 Annual Report. The resurfacing device has been identified in subsequent annual reports.

The conventional ASR hip replacement was first identified in September 2008 and has been identified in subsequent annual reports. This data was also presented at major orthopaedic meetings and in specific reports undertaken for the company. The identification of these prostheses by the NJRR was associated with a significant reduction in their use. Both the ASR conventional and the ASR resurfacing devices were withdrawn from the Australian and New Zealand markets in December 2009. This was nine months earlier than withdrawal from other countries which occurred in August 2010.

The AOA has made submission to the TGA that joint replacement prostheses should be reclassified to Class 3. However, reclassification of joint replacement prostheses to Class 3 is only part of the issue. It is also necessary to define more precisely the standards required for pre-market testing; in particular pre-clinical and clinical pre-market testing. The Prostheses Listing Advisory Committee has had a policy of requiring two years clinical data for new joint replacement prostheses to successfully apply for reimbursement via listing on the Private Health Insurance Prostheses List.

The current approach used by the NJRR has been very effective at reducing revision rates in Australia and identifying prostheses that have a higher than anticipated rate of revision. Many of these devices are no longer available on the Australian market.

AOA representatives are happy to be involved in the provision of further comment or discussions with the Inquiry.