AOA SUBMISSION

Inquiry into the Regulatory Standards for the Approval of Medical Devices

29 July 2011

AOA
AUSTRALIAN ORTHOPAEDIC ASSOCIATION

The Australian Orthopaedic Association (AOA) welcomes the opportunity to provide a written submission to the Inquiry into The Regulatory Standards for the Approval of Medical Devices.

The Australian Orthopaedic Association 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 members provide advice to Australian Government by way of membership on many health technology related committees and working groups both within the Department of Health and Ageing and the Therapeutic Goods Administration.

AOA members participate in the various government regulatory bodies governing the pre-market assessment, introduction and post market surveillance of orthopaedic devices in Australia. These groups include Medical Device Evaluation Committee (MDEC), Prostheses Listing Advisory Committee (PLAC), Orthopaedic Expert Working Group (OEWG), Clinical Advisory Groups (CAGs), Panel of Clinical Experts (PoCE) and Medical Services Advisory Committee (MSAC) and the AOA National Joint Replacement Registry (AOANJRR) Consultative Committee. AOA members also participate in a number of ad hoc committees/working groups and working parties as set up by government from time to time.

Of note are AOA's previous submission to and participation in the Health Technology Assessment (HTA) Review process and AOA's submission to the Therapeutic Goods Administration (TGA) on reclassification of prostheses from Class IIb to Class III (May 09), AOA continues to exchange with TGA, updates on usage of Metal on Metal prostheses and has established Web links with TGA for early notification of Hazard alerts and mechanisms for prompt and early conveyance of recalls to all members of AOA.

AOA NJRR continues to report on a regular basis to TGA the prostheses with a higher than anticipated revision rate. AOA believes that this multifaceted participation by members places AOA in a unique position to comment on the regulatory standards related to Orthopaedic devices in use within Australia.

Terms of Reference for the Inquiry

The regulatory standards for the approval of medical devices in Australia, with particular attention to devices with high revision rates, and in undertaking the inquiry the committee consider:

(a) The role of the Therapeutic Goods Administration in regulating the quality of devices available in Australia;
AOA has previously expressed concern at the number of 'gate-keepers' regulating prostheses and medical devices introduction into the Australian market. Prior to the HTA Review, there was in effect, three 'gatekeepers'. Despite the HTA Review recommendations these three gatekeepers remain. The gatekeepers are TGA, the Prostheses Listing Advisory Committee (PLAC - formerly the Prostheses and Devices Committee (PDC)) and MSAC.
The reason all three gatekeepers remain is that no single gatekeeper undertakes a total assessment of new prostheses and despite apparent overlap, serious and clinically unacceptable gaps remain in the assessment process. For instance, TGA

will assess the biomechanical safety (for issuing the Australian Register of Therapeutic Goods-ARTG number), but will not look at efficacy, PLAC can comment on clinical safety, but only advise TGA and MSAC. The HTA review agreed the CAGs could raise concerns related to safety but those concerns had to be referred to the TGA who was the sole decision maker on safety. There is however considerable overlap between safety and efficacy and while both should be assessed separately the process would be streamlined if it was done all at once because in many circumstances it is the same information is used to assess both.

AOA believes there should be simultaneous allocation of ARTG numbers, Private Health Insurance prostheses listing, and allocation of billing codes, catalogue numbers and CMBS item numbers for each device and/or technology.

The review remains cumbersome, repetitive, time consuming and expensive. It also involves the same small pool of clinical experts providing input to many HTA processes at different points and for different agencies.

As above, AOA has supported TGA to reclassify hip and knee prostheses in particular from Class IIB to Class III. Orthopaedic CAGs have adopted a minimum two year independent clinical data requirement for all new joint replacement prostheses being considered for listing. Private Health Insurance (PHI) Prostheses listing arrangements remains for the Private sector only with less impact on Public Hospital usage which tends to rely on State Government procurement arrangements with individual prostheses suppliers. Unfortunately the way HTA processes are currently structured and more importantly currently work, many prostheses that are rejected from listing for clinical reasons on the PHI Prostheses List remain available for use in the public sector thus creating a two tier health system.

Movement to Class III does not necessarily mean that there will be increased or defined clinical requirements in that assessment process so what is required is movement to class III and standardized clinical assessment using internationally agreed criteria.

The recent ASR Hip recall, highlights urgency for the change in device classification, its inherent requirements and appropriate supportive legislation. The Australian registry was the first to identify that the ASR was a prostheses that was associated with a higher than anticipated revision rate and this lead to the prostheses being withdrawn in Australia in 2009 almost a year earlier than the worldwide withdrawal.

AOA NJRR has proven to be a world benchmark in the establishment and maintenance of rigorous post market surveillance. It is pro-active, centrally driven, government funded, conflict free with professional ownership of the data and protected under Quality Assurance legislation for compliance.

Currently AOA NJRR reports regularly to TGA and to other government bodies regarding demographics, trends in prostheses usage and prostheses with a higher than anticipated revision rate. It has also provided TGA with secure internet access to its database that enables the TGA to obtain preliminary outcomes data on any joint replacement prostheses being used within the country. This data is up dated daily and reflects the national situation as of six weeks earlier. The AOA NJRR also provides the TGA with ad hoc reports on request. These are sometimes requested if TGA have received adverse event notifications and want more in depth information on a particular prosthesis.

AOA NJRR has been very successful in significantly changing the clinical behaviour of orthopaedic surgeons. This is demonstrated by the proportion of revision hip replacements declining from 13% in 2003 to 11.2% in 2009, equating to 600 less hip revisions in 2009 and 2,352 less since 2003. This is not only a significant cost saving to the health care sector; it is a significant increase in patient surgical outcomes. In the 2010 Annual Report, the proportion of revision knee procedures has declined from a peak of 8.8% in 2004 to 7.9% in 2009. This equates to 378 fewer revisions procedures in 2009 compared to what would have been the case if the proportion of revision procedures had not declined from 8.8%

Due to the success of the AOA NJRR, AOA would advocate for the establishment of additional registries for things such as Anterior Cruciate Ligament (ACL) reconstructions, hip fractures, cardiac/cardio/thoracic devices and trauma registries. AOA believes these registries should be established, funded and supported by similar professionally independent mechanisms as the AOA NJRR.

(b) The cost effectiveness of subsidised devices;
It is not as clear as it used to be. In the past there was a much cheaper price in the public system but this is dissipated somewhat with the advent of States rather than hospitals negotiating procurement arrangements.

It is commonly believed that Australia has relatively high prostheses prices and that relativity of prostheses prices between countries should be reviewed.

Another factor with costing is that the current system does not allow a decline in price as Australian dollar increases in value.

(c) The effectiveness and accuracy of the billing code and prostheses list;
As previously indicated, a single entry point for each device or technology would improve the efficiency, effectiveness and accuracy of billing codes, catalogue numbers and prostheses list.

AOA through AOA NJRR has long canvassed for linking of billing codes and catalogue numbers in particular, as any one billing code can cover a multitude of catalogue numbers with inherent capacity for new technologies to be introduced into the billing code without scrutiny. In the past there have been numerous examples of this practice occurring. These examples have been brought to the attention of the Department of Health & Ageing via the relevant Clinical Advisory Groups (CAGs) which were subcommittees of the Prostheses and Devices Committee (PDC) the forerunner to the Prostheses Listing Advisory Committee (PLAC).

This linkage would not only enable more accurate auditing of devices and technology, but would enable device and technology companies to more accurately access their data through independent bodies such as registries. It would also bring a level of transparency to billing practices.

There are some residual issues with the accuracy of Prostheses Listing descriptors and the linkage would enhance the capacity for ensuring that the prostheses are correctly grouped. CAGs are still identifying products that have been incorrectly listed in higher paying groups which companies rarely volunteer is an issue.

There are no penalties to ensure effective compliance and from the evidence it would seem that companies are not good at self-regulation.

(d) The processes in place to ensure that approved products continue to meet Australian standards;
Post market surveillance through registries established, funded and governed as indicated above, would ensure that approved products continue to meet Australian standards. Reactive post market surveillance driven by reports of adverse outcomes from sponsors has inherent conflict of interest and generates considerable danger to Australian patients.
Whilst registries can report data, there needs to be robust independent, clinician driven, interpretation of data. This process needs to be supported by regulatory rigour in liaison with sponsors.

Cross referencing of registry data bases has the opportunity to provide substantial insight into multi-modal management of medical conditions.
There is a notification system were problems with devices are reported to the TGA. There is an overseeing committee but it appears to have a limited capacity to identify problems.

(e) The safety standards and approval processes for devices that are remanufactured for multiple use;
This category of devices does not apply to orthopaedic devices but there is an issue related is the over use of single use device classification. There are many items that could be safely used more than once that are now disposed of as they are labelled 'single use'.

(f) The processes in place to notify the relevant authorities and the general public of high revision rates or possible faulty devices;

AOA NJRR continues to demonstrate world's best practice on regular reporting of prostheses with a higher than anticipated rate of revision to the Australian Regulator- the TGA. Whilst the data is statistically analysed for acceptable variants in any analysis ie infection, low numbers, complexity of surgery, there is provision for early notification of catastrophic failure should the need arise.

Most notifications have occurred following review of the data by an independent committee who review the report and decide what devices data is significant enough to report.
AOA has recently, through discussions with TGA, established web based linkages for early notification of ' hazard alerts' with respect to particular products to enable early and rapid dissemination of information to AOA surgeons. This expediency precludes further devices being implanted during any 'lag' period of notification. Note this is distinguished from the web based access the registry gives the TGA. Various 'hazard alert' levels have previously delayed circulation of information due to perceived less 'urgency' of any notification in some cases.

The web based link also bypasses sponsor contact of 'user surgeon' only with the inherent risk that a 'non user' surgeon is not contacted and is unaware a particular device has been notified as a 'hazard' .

There seems little doubt that the ideal method of dissemination of information to patients and the consumers, is through the surgeons who implant the devices and informed medical practitioners. To do otherwise, promotes patient, media and legal mischief and misinformation. It would appear to AOA that there is there a role for TGA to advise the public directly.

This process does rely, however, on robust codes of conduct of various practitioner groups, reaction to disregard of and governance of those codes and protection of the Australian community.

(g) The effectiveness of the current regimes in place to ensure prostheses with high revision rates are identified and the action taken once these devices are identified;
See (f)above

(h) The effectiveness of the implemented recommendations of the Health Technology Assessment; and
It does not appear that the implementation of the recommendations of the HTA review has created significant differences in the processes.

(i) Any other related matter.

1. Funding of TGA – The current funding for TGA is insufficient particularly if an increase in clinical assessment requirements is implemented. The cost recovery process whereby the funding for the TGA budget is directly levied on the medical device industry raises issues of accountability and transparency. AOA questions whether this is the best method to recover costs.
2. Insufficient clinical evidence requirements before the devices are put on the market - AOA has previously recommended that the clinical requirements pre-release be defined. AOA recommend that two years pre-release clinical testing for joint replacement devices and that RSA studies be undertaken in conjunction with continued post market surveillance. AOA recommends that International collaboration on this issue is required AOA are ideally placed to influence things through International Committee of Orthopaedic Registries.
3. TGA Issues: AOA considers that the development of a publically available list of approved devices on the ARTG is vital. Currently no such list exists making it difficult for anyone to ascertain what is approved. Currently the TGA publishes limited information about medical devices included on the ARTG. The information can be viewed through the publicly accessible version of the ARTG, published on the E-Business TGA website. AOA is supportive of the proposal to increase the information available to the general public via the TGA Website. Specifically:

- The types or classes of devices which should be included in such a scheme:

  - Only higher risk classification devices such as Class III and AIMD;

  - All medical devices including lower risk classification devices;

  - All higher risk medical devices, and ‘more interesting’ lower risk devices where the technology is new or innovative for example;

- The information which should be included when published, including the depth of that information;

- Responsibility for authorship of the information (i.e. the manufacturer or the TGA);

- Responsibility for ensuring information is up to date;

- Whether to publish, or not, information relating to rejected applications:

- Should all rejections be published, including lower risk classifications such as Class I and IIa;

- The information which should be released if the application is rejected;

- The reasons for rejection.

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