AOA
AUSTRALIAN ORTHOPAEDIC ASSOCIATION

17 December 2010

Office of Device Authorisation
Therapeutic Goods Administration
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By email: devices@tga.gov.au

Discussion Paper on Reforms in the Medical Devices Regulatory Framework

The Australian Orthopaedic Association (AOA) welcomes the opportunity to provide a response to the consultation paper from the Therapeutic Goods Administration on the Discussion Paper – Reforms in the Medical Devices Regulatory Framework.

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.

In particular, AOA's National Joint Replacement Registry (NJRR) provides excellent post market surveillance on joint replacement procedures carried out across Australia to ensure ongoing safety and efficacy of the medical devices implanted. NJRR data is used to inform surgeons, other health care professionals, governments, orthopaedic device companies and the community.

Although the NJRR has only been in existence and fully operational for a relatively short time, the information provided by the NJRR is already influencing joint replacement usage and associated technologies in a beneficial manner.

AOA members have long provided a significant contribution to the Commonwealth regulatory processes that relate to hip, knee and shoulder arthroplasty devices. Our members have provided expert orthopaedic input on these devices through Therapeutic Goods Administration (MDEC and the Expert Orthopaedic Working Group) the Prostheses and Devices Committee and its various Clinical Advisory Groups and Panels and the Medical Services Advisory Committee. AOA is well placed to provide feedback as to the effectiveness of current methods of reviewing both pre and post market prosthetic performance and offer valuable input to the issues to be considered in this public consultative process.

AOA notes the confidence and high regard that the Therapeutic Goods Administration (TGA) hold in data emanating from the AOA National Joint Replacement Registry.

Please find AOA's submission attached.

Yours sincerely,

Adrian Cosenza
Chief Executive Officer

AOA Submission

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Proposal 1: Reclassification of joint implants

A new classification rule is added to Schedule 2 of the medical device Regulations to reclassify all hip, knee and shoulder joint replacement implants from Class11b to Class 111 medical devices.

Currently there are no standards that define what is required for pre-market assessment of hip and knee replacement prostheses and the approach to the assessment by both manufacturers and regulators is ad hoc. It is likely that the type and amount of information that is required to undertake a pre-market assessment needs to be re-evaluated and clarified. Regulators must develop more stringent approaches to both product approval and post market surveillance. Finally it is also clear that orthopaedic surgeons need to be more discriminatory and evidence based in their approach to prostheses choice.

AOA agrees with the proposal as outlined in the discussion document. However, AOA believes that re-classifying total and partial hip, knee and shoulder implants from Class IIb to Class III, will bring with it a requirement for an increased assessment process of clinical evidence. AOA recommends that for this assessment to be appropriate and rigorous, an overarching committee must be formed to review these prosthetic applications in a timely manner. AOA recognises the importance of balancing timely access to innovative therapies with regulatory oversight and would recommend that such a committee be chaired by a suitably qualified clinician with nationally recognised clinical and managerial skills and qualifications. The committee should also comprise of a range of representatives from key stakeholder groups, including government, the clinical colleges, medical device and technology groups and health actuaries.

AOA notes the confidence and high regard that the Therapeutic Goods Administration (TGA) hold in data emanating from the AOA National Joint Replacement Registry (AOANJRR)and agrees with the decision to include partial joint replacement replacements in Class 111.

Transition Period

Although AOA supports the TGA proposal to amend the Regulations by re-classifying total and partial hip, knee and shoulder implants from Class IIb to Class III medical devices, AOA is, however, concerned re the proposed transition period of two years.

AOA's concern is that there is the potential for implants which are unacceptable to overseas regulators being legally available in Australia. AOA is concerned this will occur once a change is flagged. For these reasons, AOA would prefer a transition time of six to twelve months. AOA is aware that this may incur practical and financial challenges to orthopaedic implant providers. AOA is also cognizant that Europe has already moved to Class 111 so sponsors are already dealing with the new regulatory requirements and it is important to be consistent particularly in view of global harmonization.

AOA agrees with the general concept of management of applications within any transitional timeframe apart from:-

a. The two year transition period. AOA would recommend a reduction in the transition period from two years to six to twelve months.

b. AOA recommends a clinical review of all applications, once the date of change is announced to avoid supply of joint implants into Australia that are unacceptable in other countries and Europe.

Proposal 2: Third Party Assessment Bodies and Supporting Reforms

This proposal involves a package of reforms aimed at addressing the outcome of the third party confonmity assessment consultation, while at the same time addressing concerns raised during the Department's HTA review regarding the appropriate level of pre-market scrutiny for higher risk medical devices.

AOA submits the following comments:

According to a study undertaken in2008, over 75% of new hip and knee prostheses introduced to the Australian market were not used in large numbers. The reason for this almost certainly relates to a lack of clinical or theoretical advantage which can be attributed to the individual prosthesis. It is likely that clear evidence that prosthesis provides a significant advantage in a particular clinical situation may be necessary to ensure substantial use.

This however is not always the case as most new prostheses do not have any supportive clinical data specific to that device. Despite this lack of clinical evidence almost 25% of new prostheses were used in over 100 procedures. None of these prostheses had a better outcome when compared to the best performing prostheses within the same class. Most (72.1%) performed equally as well however the remainder (27.9%) had a significantly higher rate of revision. The percentage that did not perform as well was similar for both new hip (27.3%) and new knee prostheses (28.6%).

It could be argued that if no new hip and knee prostheses were approved for use during the study period then the overall outcome for both hip and knee replacement surgery may have been better. Not only has the introduction of this new technology been potentially detrimental to patient care but the current approach may also be an important driver for increased health care costs. Not only is there the potential for increased revision rates but also because new technology usually has an increased cost compared to existing technology. The current approach to the introduction of new hip and knee replacement prostheses does not appear to be either clinically or cost effective.

1. **Class III Equivalents**
   A prosthesis issued with an EC-certificate or equivalent from an overseas regulatory body will require confirmation of the data provided, by a Clinical Advisory Body (CAB) amongst the other technical requirements for release into the market for use.

2. **Prostheses in Transitional Timeframe**
   AOA agrees with the general concept of management of applications within any transitional timeframe apart from:-
   c. a reduction in the transition period as previously stated from two years to six to twelve months.

d. CAB review of all applications, once the date of change is announced to avoid supply of joint implants into Australia that are unacceptable in other countries and Europe.

3. **'Look Alike' or New Applications**

AOA NJRR has experience with minor changes to prostheses causing 'catastrophic failure' of that implant. With the patents of some commonly used prostheses expiring, 'look alike' prostheses are being introduced to the Australian market and require rigorous review of their comparability to the original prosthetic design and performance.

Variation must initiate New Application status.

AOA is concerned that with the introduction of Class III classification of partial and total hip, knee and shoulder implants, innovative prosthetic research will be inhibited by the regulatory requirements on new and 'modified' prostheses. AOA believes that several Scientific Institutions within Australia have the capacity to assist sponsors with the construction, implementation and critical review trials of new prostheses, to satisfy clinical requirements, once the regulatory documentation requirements and CAB assessment have been completed.

Institutes with radiostereometric capability, for instance, are able to accurately predict wear and migration characteristics of prostheses within a two year period.

AOA would prefer such clinical assessments were offered within Australia, where possible, to nurture continuing research and development and provide more timely review, rather than being sourced overseas.
Such reviews will be mandated by this re-classification.

AOA recommends the following guidelines for such a research process

1. Capable Institutes to register their bona fides with the regulatory body
2. All research studies to adhere to NH&MRC guidelines
3. Sponsors to contract with Institutions for appropriate studies
4. A temporary 'registration' certificate is allocated to the specific prosthesis to enable rebate for its use during the limited and specific trial period, whilst the sponsor funds the recruitment, review and documentation/assessment and outcomes of the study (*to not do so would significantly disadvantage smaller device companies)*
5. A designated time frame is critical for the completion of process for expediency in the introduction of new technologies.

Proposal 3: Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices

At present, medical devices, with the exception of Class 111 and Active Implantable Medical Devices (AIMDs), and Class 4 IVDs and Class $ in-house IVDs, are included as a group on the ARTG under a single entry if they have the same:

- *Sponsor;*
- *Manufacturer;*
- *Risk classification; and*
- *GMDN code and term.*

AOA agrees with the approach and proposed changes outlined within this proposal.

Post market surveillance through Registries such as AOA NJRR does highlight prostheses with a greater than expected rate of revision, which then requires due diligence to ensure confounding factors are removed from any assessment. As AOANJRR data is based on description and catalogue numbers for each individual component thus making identification of poor performing prostheses a relatively simple process.

Proposal 4 – Publication of device product information on the TGA Website

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; and

- Any other information useful and relevant to the clinical user and consumers.