



**MTAA Response to the Proposal from the TGA  
to Reclassify Implanted Hip, Knee and Shoulder Joints**

4 December 2009

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**Introduction**

The Therapeutic Goods Administration (TGA), through the release of the consultation paper considering the reclassification of implanted hip, knee and shoulder joints, is seeking views relating to this and a number of related issues.

MTAA has consistently proposed that the classification of medical devices should be consistent with the recommendations of the Global Harmonisation Task Force (GHTF), but as far as the application of a classification scheme applies in Australia, it should also be closely aligned with the regulatory system in the European Union (EU). The Australian regulatory framework has been based on the principles established by the GHTF with legislation guided by the Medical and Active Medical Device Directives developed by the EU. As more than 95% of the medical technology used in this country is imported, close alignment leads to minimising the administration, application and costs of regulatory compliance for companies supplying products in Australia. This applies equally to companies based in Australia or overseas. Domestic companies benefit as the jurisdictional similarities support their efforts in expanding their markets into the EU. Overseas companies supplying into the EU and Australia benefit from more broadly acceptable conformity assessment procedures and certification requirements. Perhaps more importantly, the Australian population benefits from the supply of healthcare technology which may have been precluded from supply when the size of the Australian market, and the returns on investment after regulatory compliance costs and long reimbursement time frames, were factored in.

MTAA therefore supports the proposal to reclassify implanted hip, knee and shoulder joints to the extent that it aligns with the classification of those implants in the EU and no further. Complications inherent in the systems used by the TGA to characterise and process applications to supply medical technology and the differentiation of Class III products in the Australian Register of Therapeutic Goods (ARTG), have to be eliminated before the reclassification program is introduced.

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## **Streamlining the Process: Issues to be Resolved before Reclassification**

### **1. Definitions of Unique Product Identifier and Associated Variants**

There are a number of inter-related factors that are different between the reclassification of implanted hip, knee and shoulder joints in Australia and that which occurred in the EU. These factors all centre on the use of the ARTG in Australia, particularly the requirements to identify Class III products in the ARTG. At the Class III classification level an extra identification criterion is imposed which has been problematic since it was introduced. The selection of a Unique Product Identifier (UPI) and associated variants, while, according to the legislation, is assigned by the device manufacturer, is often reassigned by the TGA. A manufacturer develops an application to the TGA based on its decision on the UPI and associated variants, and budgets accordingly. Any change imposed by the TGA results in additional work, costs and delays.

MTAA has consistently advocated that if this additional degree of specificity is necessary in the ARTG at the Class III level, a more clearly defined and transparent categorisation has to be developed before the reclassification proposal is implemented.

### **2. Preparation of Applications, Technical Files and Design Dossiers**

Since 2002, when the revised regulatory system for medical technology was adopted in Australia, the TGA has often commented on the poor quality of submissions it receives in support of applications. It has now been 7 years since the introduction of the revised regulatory system and with the reclassification proposal requiring the development of further submissions, it would be more than appropriate for the TGA to develop and run training programs and produce guidance material to assist the industry improve the quality of submissions. In turn it could be expected that higher quality submissions would make the work load more manageable for the TGA and improve the success rate of applications for the industry through a better understanding of the documentation requirements.

MTAA also recommends that the TGA offer a similar service to that used by a number of Notified Bodies during the same reclassification program in the EU. The TGA should instigate a program in which companies could arrange a submission schedule for applications once issues such as appropriate UPIs, variants and GMDN codes were agreed to. This project management approach would not only allow companies to better plan, budget and resource the development of their submissions, it would also benefit the TGA in being better able to plan, resource and train their application assessment sections.

### **3. Alignment of the GMDN System used in Australia with that of the GMDN Agency**

MTAA supports the use of the Global Medical Device Nomenclature (GMDN) system as it was originally intended to be used; a system to identify medical devices in post market vigilance programs. The divergence of the GMDN coding system used by the TGA from that developed and used by the GMDN Agency by the TGA adapting the GMDN system to differentiate entries in the ARTG detracts from the usefulness of the GMDN system. There are now many examples where the GMDN codes assigned to entries in the ARTG are different from the codes assigned by overseas medical device manufacturers

supplying the same devices in other jurisdictions.

MTAA advocates that if a GMDN code is necessary to discriminate between entries in the ARTG, the TGA codes and descriptions should be identical and be updated at the same time as updated by the GMDN Agency. This issue should be resolved before the reclassification of implanted hip, knee and shoulder joints is implemented in Australia.

#### **4. Clear Definition of an Accessory to an Implanted Joint**

The current reclassification proposal refers to accessories of implanted orthopaedic joints without proposing a clear definition of the term ‘accessory’. The definition should be completely consistent with what has been understood through the EU reclassification program. This will assist companies to understand what needs to be reclassified in Australia and what does not, thereby avoiding unnecessary confusion and reliance on TGA advice.

MTAA recommends that the TGA and the industry jointly develop a definition of an accessory to an implanted orthopaedic joint before the reclassification program is implemented.

#### **5. Introduction of a Reimbursement Code to Support Revision Procedures**

The TGA has suggested that the Special Access Scheme (SAS) could be used by companies supplying components of implanted joints for surgical revisions requiring implants which are no longer supplied at the Class III level after the transition period. Because of the peculiarities of the Australian reimbursement system for privately insured patients where reimbursement for medical technology is linked to ARTG entries, this issue was not a factor in the EU reclassification program.

The SAS option will limit the availability of products for revision procedures unless reimbursement is provided for ‘spare parts’. The SAS has been provided to supply therapeutic products that, for a number of reasons are not entered in the ARTG to patients because there is a clinical need to do so. The SAS is not appropriate for the more broadly-based revision surgery requirement. An appropriate reimbursement position will need to be negotiated with the private health insurers.

#### **6. Details of the Proposed Notification Scheme**

It is difficult for MTAA to comment on the notion of a notification period when so little detail has been provided in the consultation paper. If the intention of the notification scheme is to assist TGA with its work flow planning then MTAA sees merit in the scheme but would like to understand it more.

#### **7. Assessment of Applications to Reclassify Implants**

At the time of preparing this paper MTAA understands that, based on GMDN descriptors, there are approximately 500 Class IIB entries in the ARTG that are likely to be affected by the current reclassification proposal. Given the current fees for Class III applications, annual charges and application audits, a conservative estimate of the additional revenue the TGA could expect during the transition period, allowing for, say, 20% of those entries not being reclassified, could be of the order of \$2.5 million. MTAA

would anticipate that the additional work demands on TGA would be appropriately provisioned for out of this increased income, to ensure a smooth transition, unlike the previous transition in October 2007.

## **8. Guidance on the Development of Clinical Evidence**

Despite the fact that the TGA has required higher levels of clinical evidence than many Notified Bodies since late 2002, in a number of cases, companies have been uncertain of the TGA's specific requirements until applications are being assessed or application audits are conducted. To ensure that companies provide the required evidence, TGA should specify its preferred approach to the development of clinical evidence for products which have been supplied for many years and which takes into account the clinical performance during that time. Current guidance documents developed as part of the recent Australian Regulatory Guidelines for Medical Devices (ARGMD) project should be reviewed by the TGA, in consultation with the industry, with the reclassification proposal in mind.

### **Questions raised by the Consultation Paper**

A number of statements have been included in the consultation paper which the MTAA considers need to be clarified by the TGA.

1. The paper alludes to enhancements to the TGA's post market controls that could be made through the implementation of this reclassification proposal and yet provides no details.

MTAA would appreciate learning what enhancements would flow that cannot already be implemented by the TGA.

2. In one section of the consultation paper it is suggested that Class IIB implants can continue to be supplied while remaining in the ARTG during the time reclassification applications are being assessed and yet in another section of the paper, supply will be terminated at the end of the transition period even though an application could still be in the process of being assessed. This anomaly needs to be better explained and clarified.
3. The paper refers to "a review of the manufacturer's application of a relevant conformity assessment procedure" without providing any details as to what it would entail?

In addition to the comments and views presented in this paper, MTAA provides the following in response to the five questions posed on page 10 of the consultation paper:

**Question 1** The intention to increase the degree of pre-market review considered appropriate to ensure orthopaedic joint replacement implants approved for marketing in Australia are in compliance with the essential principles (of safety and performance) and have adequate clinical evidence to substantiate claims made by the manufacturer for device performance.

MTAA considers that reclassifying implanted hip, knee and shoulder joints from Class IIB to Class III would be appropriate given the reclassification of the same joints in the EU.

**Question 2** The intention to include partial implants in the re-classification of orthopaedic joint implants.

The TGA has not presented any evidence that would justify any changes to the classification of partial hip, knee or shoulder implants. This was not done as part of the reclassification of implanted hip, knee and shoulder joints in the EU.

MTAA does not support this part of the proposed reclassification changes, given the divergence from the EU reclassification process.

**Question 3** Any alternative options to that proposed in order to address issues identified in the paper.

While not necessarily suggesting alternative proposals but rather initiatives which will assist the TGA introducing the same classification system for implanted hip, knee and shoulder joints as in the EU, MTAA encourages the TGA:

- to work with the industry to overcome the problems with the assignment of Unique Product Identifiers, their associated Variants and GMDN codes assigned to entries in the ARTG;
- to adopt a project management approach to receive and process applications by working with companies to develop submission schedules for the “transitioning” applications;
- to work with the industry to define an accessory to implanted hip, knee and shoulder joints;
- to assist with the development of appropriate reimbursement for orthopaedic products used for revision procedures; and
- clarifying the clinical evidence requirements for products which have been supplied for many years.

**Question 4** Any likely impact on devices currently supplied, or planned for supply to the Australian market.

MTAA considers that this broad question cannot be answered satisfactorily unless and until a survey designed in association with the industry is developed, circulated and analysed, and with the results being made publically available.

**Question 5** The proposed transition arrangements.

MTAA considers that the proposed transition timeframe may not be adequate for a number of reasons:

- Based on advice from companies which participated in the reclassification program in the EU, even though the necessary files to submit to Notified Bodies were developed in compliance with agreed schedules, the size of the workload overwhelmed the resources of some Notified Bodies and jeopardised timely evaluation of submissions.
- As discussed earlier in this paper, unless and until appropriate and clearer definitions of the Class III Unique Product Identifier and their associated variants are agreed to and introduced, the development of submissions at the Class III level will be compromised.
- The volume of work to develop the necessary submissions may mean that it is unlikely to be completed in time, even if the questions of the UPIs, GMND codes, and clear guidance on appropriate clinical evidence are resolved.
- A longer transition period will allow more time for orthopaedic companies to consult with surgeons to better phase in any replacement implants and organise any necessary training and familiarisation initiatives.

MTAA considers a four year transition period during which the TGA would accept submissions would be more appropriate than the proposed two year period.