INFORMATION FOR SPONSORS WHO MAY BE AFFECTED

Dear Sir/Madam

Subject: How reclassifying hip, knee and shoulder joint implants will affect you

From 1 July 2012 hip, knee and shoulder joint implants have been reclassified from Class IIb to become Class III medical devices under the Therapeutic Goods (Medical Devices) Regulations 2002. A device intended by the manufacturer to be a total or partial hip, knee or shoulder joint replacement is now classified as Class III (see Schedule 2, Part 3, paragraph 3.4 (4)(f) of the Therapeutic Goods (Medical Devices) Regulations 2002).

The Therapeutic Goods Administration (TGA) has identified from the Australian Register of Therapeutic Goods (ARTG) that companies MAY be affected by this initiative if companies use any of the following Global Medical Device Nomenclature (GMDN) codes for their ARTG entries. The following GMDN codes have been identified as MAY be affected by the reclassification implementation:

35256, 35267, 35642, 35659, 35691, 38154, 40752, 41122, 44052, 44053, 44055, 45038, 45041, 46647, 46648, 46649

Please note that while the TGA has identified ARTG entries for your review this list may not be complete, and it remains the responsibility of all sponsors to consider all your current ARTG medical device entries to identify whether they are affected by the changes and need to be reclassified. To assist you with undertaking this review the details of this initiative are provided in a question and answer format at Attachment A.

The reclassification initiative will have a two year transition period from 1 July 2012 until 30 June 2014. If your company identifies ARTG entries that need to be reclassified, you must apply to reclassify these no later than 30 June 2014 so that your company can continue to supply the hip, knee and shoulder joint implants in Australia. After that date affected Class IIb entries in the ARTG for these devices for which there is not an application for reclassification pending will be cancelled.

If you do not have any items which need to be reclassified then you will not need to take any action. If you do have items which need to transition by 30 June 2014 the information provided below is relevant to you.

When do you need to take action?

Some fees and charges are being waived to encourage sponsors to transition earlier rather than later. These include:

- For the first year of the transition period (1 July 2012 to 30 June 2013) sponsors lodging transition applications for Class III medical devices will have their application fee of $1,150 (2012-13 rate) waived for each application.
• Mandatory application audits will not be undertaken for transitioning devices during the two year transition period which means that sponsors will not be charged the mandatory audit fee of $6,170 (2012-13 rate).

• Finally as annual charges are payable for a product included on the ARTG for any part of a financial year, the Class III annual charges of $1,150 (2012-2013 rate) will be waived until 30 June 2014 for those devices required to transition. Class IIb annual charges of $890 (2012-13 rate) will continue to be applied while there is a Class IIb entry on the ARTG, even if a product is has been successfully reclassified as a Class III. These measures will prevent charging twice for the same device within the same year.

See Attachment B for more information on the fees and charges.

**What action do you need to take?**

To reclassify your affected Class IIb device entries you will need to fill out the hip, knee and shoulder joint implant reclassification application form available through TGA eBusiness Services (eBS) portal. It is expected that a single Class IIb entry may result in several transition applications, as Class III medical devices are included on the ARTG as individual devices.

It is important that you use the hip, knee and shoulder joint implant reclassification application form to ensure that you receive the correct fee and charge waivers.

To support your transition applications, you will need to attach documentation to each application as a Class III medical device. As transitioning devices are already in operation in Australia, the TGA will look at post market information in assessing these applications, as information normally required for Class III applications. See Attachment C for a detailed list of requirements.

This reclassification initiative is in line with changes already completed in the European Union (EU) for hip, knee and shoulder joint implants. Therefore, the documentation already used to support supply to EU markets should be sufficient in completing transition applications to supply the Australian market except where your company is the Australian manufacturer.

**What about new applications for hip, knee or shoulder joint implants?**

New total or partial hip, knee or shoulder joint implant applications (ie those that were not already included in the ARTG as Class IIb devices) will need to go through the normal conformity assessment and application audit processes for a Class III medical device. This will include payment of Class III application fees and undergoing mandatory audit including payment of associated audit fees. If the Class III device is included on the ARTG, Class III annual charges will apply.

**What are the details of the reclassification change?**

In summary, total and partial implantable hip, knee and shoulder joint replacements, intended to replace a natural articulating surface of a hip, knee or shoulder joint require reclassification from Class IIb “kinds of medical devices” to Class III medical devices. The focus of this letter is to clearly outline what action your company needs to take to comply with this change. Details of this change are provided in a question and answer format at Attachment A.

**What if you need help or more information?**

Information on this initiative is available from the TGA website at [www.tga.gov.au](http://www.tga.gov.au).
Direct email communication is planned to alert companies that may be affected to the approach of future key milestones over the two year transition period.

Finally, you can email questions to devices@tga.gov.au or phone 1800 141 144 (freecall within Australia) and press 1 for enquiries about transition applications for medical devices.

**Suggested next steps for you**

- Consider the information in this letter and attached documents so that you understand the actions your company needs to take.

- If you consider that the attached material does not cover implementation issues particular to your company then you can email your queries to devices@tga.gov.au for a TGA response. Note that additional guidance information will be provided as it is developed.

- Plan your company's implementation strategy for this change, including a thorough review of your ARTG medical device entries and identify all entries that will need to be made compliant by 30 June 2014.

- Review the attached explanatory materials to ensure you understand the application requirements, especially Attachment C, which provides a checklist of the documentation to be provided with transition applications.

- Determine as soon as possible whether this initiative affects your company and if so, commence action on reclassification sooner rather than later to take advantage of the fee and charge waivers but also in recognition that it will take time to prepare and provide the necessary documents and for the transition applications to be processed by the TGA.

Yours faithfully

Andrea Kunca
Office Head
Office of Devices Authorisation

1 August 2012

Attachments:

A: Information Sheet – Hip, knee and shoulder joint implant reclassification initiative

B: Reclassification initiative fees and charges diagrams

C: Documentation checklist for hip, knee and shoulder joint implant reclassification