TGA Reforms in the Medical Device Regulatory Framework 2010
Comments from: Zimmer, Inc.

Proposal No.	Comments / Impact
1. Reclassification of Joint Replacement Implants (2 years transition)	The classification of medical devices should be consistent with the recommendations of the Global Harmonisation Task Force (GHTF). As far as the application of a classification scheme applies in Australia, we propose that it should also be closely aligned with the regulatory system in the European Union (EU). Close alignment to GHTF principles and the EU regulatory system would minimize the regulatory burden. TGA specifically includes Partial joints as Class III, whereas the revisions to EU MDD for reclassification specifically apply to Total Joint Prostheses and can be interpreted to allow IIb classification for partial joint prostheses. This may mean that some devices classified IIb in Europe will now be Class III in Australia and subject to higher review requirements in Australia. In keeping with alignment with the EU approach, we recommend that "partial" joint implants be removed from the scope of this proposal. Also in keeping with alignment with the EU approach, we propose that TGA accept Design Examination Certificates from European Notified Bodies as evidence of safety and performance of Total Joint Replacement Implants with no additional requirements. Reclassification in EU had a five-year phase in period, ending in Sep 2010. TGA's proposed transition plan of two years for transitioning products to be lodged with TGA is deemed insufficient, considering that manufacturers must collate evidentiary data to demonstrate safety, quality and performance of the affected implants. We propose the same transition time of five years. Whilst most of the documentation could be available in our company, the grouping of products required by TGA will not be the same as those submitted in the EU. Additional effort and time is required to collate these information and data. We propose that TGA consider using a risk management approach to the review and granting of marketing approval to transitioning implants. For affected implants which have been in the Australian market for more than 10 years, TGA should consider reducing clinical evidence to be submitted. For affected products in the market for less than 10 years, TGA can subject the manufacturers to provide all evidentiary data required to lodge a Class III application. Concerning the use of the Special Access Scheme for partial revisions, we recommend that TGA resolve all reimbursement issues with the Australian Health Insurance Association and advise of this prior to any implementation of this reform. In reviewing lessons learned from the re-classification of total joint implants in the EU, we recommend that a guidance document be developed with input from all stakeholders prior to implementation of the proposed re-classification of joint replacement implants in Australia Given the significant burden that the proposed Re-classification of Joint Replacement Implants will place on TGA resources to review the large number of applications transitioned products, there is concern about the negative impact of this up-classification on the reviews for new product submissions. We suggest that TGA take this into consideration in its budget and strategic plans.

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2. 2A. Use of Third Party Assessment Bodies for Australian Manufacturers	We support this move. The requirements for Australian manufacturers to be subjected to separate Australian TGA assessment, even if they also hold CE mark, has been a long standing source of frustration. These proposed reforms make two changes which will result in completely equal treatment for Australian manufacturers.
2B Increasing Pre-Market Scrutiny for Implantable Medical Devices (4 year transition period)	This reform requires 'renewal' of existing ARTG entries. TGA has proposed a four year transition period and applications lodged with TGA within the transition period are allowed to be supplied while TGA's reviews are on-going. However, for new applications, marketing is prohibited until (successful) reviews by the TGA are completed. There is potential for new applications to be delayed by this 'renewal' process which causes market access delays.
(i) Devices requiring a TGA Conformity Assessment Certificate to be Issued	The requirement for direct TGA review of Class III implants and AIMDs plus a new requirement for a TGA application audit (a desktop review of key Technical File Data) for Class IIb will see an increased level of scrutiny of implantable devices. We propose that TGA consider a risk management approach and review only higher risk and novel/innovative products. Another proposal is for TGA to consider having two evaluation routes, namely Abridged Conformity Assessment Route and Full Conformity Assessment Route. Singapore has demonstrated much success when it implemented the two evaluation routes as it reduced the burden on industry. TGA needs to clearly identify the rules for abridged conformity assessment and the fees involved. For more details, please refer to page 18 of GN-15: Guidance on Medical Device Product Registration, published by the Health Sciences Authority (HSA). In addition, The HSA has published the exact fee structures for its abridged and full evaluation routes. Please refer to page 1 of the Fees and Charges document attached.
(ii) Applications to be Selected for Auditing	For existing devices currently on the ARTG, we propose that TGA accept the EU Notified Bodies' Design Examination Certificates. For new applications submitted after the implementation date, we accept TGA's review as an application audit.

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2C Recognition of Third Party Assessment Bodies (i) Confidence for EU Notified Bodies Designated under the MRA (ii) Recognizing Australian Third Party Assessment Bodies	Given the concerns about the differences in capabilities of Notified Bodies, it would be ideal to implement an accreditation and monitoring program for third party assessors. To develop and implement a model of third party assessment, it is prudent that TGA shares the following with the industry: • How third party assessment bodies would be accredited • How third party assessment bodies would be monitored • The role of third party assessment bodies in reviewing and assessing all classes of medical devices. With third party assessment bodies being made available to Australian manufacturers, TGA could play the role of a designating body and the body which makes the regulatory decision. However, if TGA wishes to remain a Conformity Assessment Body, there is a conflict of interest if it is a Designating Body which designates and recognizes third party assessment bodies.

Proposal No.	Comments / Impact
3. Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices (i) Amend the way in which a kind of device is included on ARTG (iii) Enhance the ability to identify the devices that have been approved by TGA for supply in Australia (within 12 months from legislation)	We fully support this proposal. However, for Class III devices that have Design Examination Certificates issued by accepted Notified Bodies, we propose the TGA accept the identification for those devices as mentioned on the Design Examination Certificates. For new Class III applications that do not have Design Examination Certificates, the sponsor should make the identification in the application. For Class IIb, the sponsor should make the identification for both existing and new applications. However, TGA must provide specific guidelines to advise industry on the level of information which is required to be submitted for models to be captured in the ARTG. As this is part of enhancement of information to the public, fees should not apply. What is the fee structure to include models? TGA needs to better clarify how models can be grouped or split. How does TGA define "Model"? The proposed transition timeline of one year to update existing records is too short. In terms of regulatory costs, manufacturers would be impacted. During this one year transition timeline, it is a 'no charge transition' for industry to update existing records. However, during post transition time, fees will be charged to vary an inclusion to an existing ARTG entry.
4. Publication of Device Product on TGA Website	We propose that TGA only publishes device product information for consumer products such as contact lenses and contact lens solutions. The information provided should only be targeted at consumers because safety and device information creates value-add to consumers. TGA could look into the following information to be published without divulging proprietary information: 1 Device and Application Information 2 Intended use 3 Indications 4 Instruction for use (IFU) 5 Warnings and precautions 6 Contraindications 7 Care of the product (e.g. For contact lens solutions, consumers are not supposed to decant solutions and use them again) We propose that information about rejected applications should not be made public. Withdrawing a file does not mean that the manufacturer has abandoned the device or technology. In addition, there is no public health benefit to making that information public.

Additional Comments

A. Proposal for Timelines

- For up classification, we propose a five year transition period.
- For Class IIb implantable devices currently included on the ARTG that are not subjected to up classification, we propose a two year transition period to identify models.
- For ARTG number to be applied on the device, we propose a two year transition period.

B. General Comments

- Impact Assessment – We propose that TGA be transparent and publish a regulatory impact assessment process for the proposals. This impact assessment should be made public for the industry to have an opportunity to provide inputs and to see the results.
- Process – We propose to TGA to provide the industry the process for finalizing the proposals and implementation plans. This information needs to be made public early so that we can plan ahead and ensure compliance to the new laws.
- EU Notified Body Certifications – To avoid duplication, we should confirm that the TGA will accept the Design Examination Certificates issued by Notified Bodies per the EU up-classification, with no additional clinical data requirements.
- Guidance documentation – We propose that TGA publishes good and clear guidance documentation on the implementation of the proposals once it is finalized.
- TGA Resources – We should insist on assurances from TGA that its reviews for new products submitted during the up-classification transition phase will not be adversely impacted. In other words, TGA should demonstrate how it plans to continue its normal workload for unaffected products at the same pace during up-class transition.
- Using Special Access Scheme for partial revisions – TGA must resolve and advise this prior to any implementation of the entire process of up-classification.

C. Annual Fees and Conformity Assessment Recertification

- As the number of ARTG entries will increase dramatically based on the number of UPI's currently under one ARTG, annual re-registration fees should only be effective after the end of the transition period for device affected by up-classification. This will not disadvantage those that submit early notifications to include products as Class III device in the ARTG and TGA approving them early.
- Any Conformity Assessment Certificates issued by TGA under these reforms should expire 5 years from the end of the transition period. This will not disadvantage those that submit early notifications to include products as Class III device in the ARTG.