Reforms in the Medical Devices Regulatory Framework Discussion Paper
Stryker Australia's Response

Background rationale for the TGA Reforms

Although the TGA does have a robust assessment system, there is indeed a chink in the armour of control and visibility of medical devices supplied. In context to long term implantable medical devices Australian Sponsors currently supply a large number of different systems with the same core characteristics as identified in section 41BE of the Therapeutic Goods Act 1989, under the one ARTG entry, thus concealing the identity, and the TGA awareness, of these individual systems. This is most apparent for Orthopaedic implants such as hips and knees, which are separately tracked in the Australian National Joint Replacement Registry and are thus overt to the Orthopaedic community but are otherwise invisible to the TGA.

As a result the proposals identified by the TGA all follow a central theme of increasing the TGA oversight of medical devices. As the designated body responsible for the safety and efficacy of medical devices, in general this is not an outcome that Stryker would or should disagree with. It is the method that the TGA employs to establish this increased oversight that needs to be carefully evaluated to ensure that unnecessary burden and impractical requirements not be evoked to achieve this goal. As the majority of medical devices supplied in Australia are sourced from overseas, validation of these products has typically already undergone rigorous review by other approved regulatory bodies, and thus their safety and efficacy has already been established. In other words, the TGA's ability to establish their own oversight of these products adds no further safety or efficacy per se.

The TGA's suggestion to establish revalidation threatens a regime of redundancy as well as resource, cost and time blowouts. Strategically there needs to be a position that allows the extra oversight without a major workload/bottleneck emerging that contributes little to the bottom line of safety and efficacy.

General Comments

The following comments are made on the premise that the proposals as outlined by TGA will go ahead without alternative solutions. They will be used as argument against the proposals and for suggested alternative solutions to be outlined.

- Understanding how the TGA resources these proposals will be crucial to their success as the current recommendations will result in a high numbers of applications for conformity assessment certification, applications for entries in the ARTG, and the potential high numbers of application audits required for transitioning products, The TGA will also need to ensure these transition efforts will not adversely affect processing of routine applications.
- Implementation dates will need to be clearly specified to allow companies to plan for the production of applications, additional resources including additional staff, as well as assessing the budgetary impacts for the changes.

Proposal 1 - Reclassification of Implantable Hip, Knee and Shoulder Joints from Class IIB to Class III

As mentioned above, there is a need for these implants to be reclassified to Class III, not just to emulate the European MDD but to respond to the discrepancy between TGA's knowledge of the separate systems in each ARTG versus that published by the NJRR. This is inherent in the way Class IIb devices need to be represented under the ARTG listing requirements, and will be solved by reclassification where individual systems are separately called out and assessed. The remainder of implants will be addressed by proposal 3 which is addressed later.

Stryker recommends that the following issues are addressed before the implementation of proposal 1, reclassification:

1. The current method in which Variants and Unique Product Identifiers (UPI) are used by the TGA impose an unnecessary burden on the registration process for Class III medical devices, that not only increases the cost by increasing the number of ARTG's that are required to be submitted, but also increases the resources required to complete the submission and perform an assessment.

Recommendation: The TGA to consult with industry to add additional variants to the current approved variant list and provide greater flexibility in the selection of UPI's. This change will allow for the same level of visibility and reduce the number of applications assessed by the TGA reducing the cost and allocated resources for both the TGA and industry.

2. The proposed Australian classification excludes the reference to total joint replacement thus including partial joints to the requirements for reclassification. Although only total joints have been referenced in the European system, there are some who believe that the inclusion of partial components is inherent within the scope, but this has not been verified. It is apparent from the NJRR results that to avoid including partial joints, especially in light of the safety issues delineated, would be difficult to justify. Unlike implants that fall under the total joint some partial joint implant manufacturers may not have all the documentation available in a format that is required for a class III assessment.

Recommendation: The TGA to offer an extend transition period for partial joint replacement implants, to allow manufacturers to work with the notified body and obtain the necessary documents.

3. As medical devices are frequently upgraded under the proposed scheme Australian sponsors will move to discontinue an ARTG and the associated products to avoid the burden and cost of registration. Should one component of the discontinued system require revision, no longer could the surgeon offer a minor revision to replace a bearing surface, a more complex operation of higher risk would be undertaken, a total joint replacement. It has been recommended that the Special Access Scheme (SAS) would able to support the supply of discontinued systems however the current model is cumbersome and would struggle if demand was dramatically increased.

Recommendation: To redesign the SAS, expand the current model of approval of specific patient procedures, to a notification based modal similar to that which has been introduced for custom made implants.

Proposal 2 – Third Party Assessment Bodies and Supporting Information

1. An appropriately validated third party assessor is a practical solution that is essential should the TGA mandate the requirements in proposal 1. Third party bodies would need to be reviewed and approved by the TGA and an appropriate structure would need to be introduced. This would provide the necessary oversight without requiring the TGA to review each and every device themselves.

Recommendation: The TGA would play a similar role to a European Competent Authority, however would be a single arbiter over all approved Notified Bodies.

Proposal 2A – The use of third party assessment bodies for Australian manufacturers

1. Stryker is in support of this proposal.

Proposal 2B(i) – Devices requiring a TGA Conformity Assessment Certificate to be issued

1. The majority of class IIb implantable joints supplied in Australia are approved on the basis of CE certification. For the TGA to impose that all new and old devices undergo a separate additional Conformity Assessment so that the TGA can issue independent certification is difficult to justify, especially when the additional costs, resources and timeframes are considered.

Recommendation: Request additional information during the application assessment

2. During the Transition period the TGA will experience a dramatic increase in workload for the assessment of existing joint replacement implants that are currently supplied and endorsed by the TGA as class IIb medical device and the ongoing workload for the assessment of any new class III device. If there is no change in the to the current environment the average time taken by the TGA to approve a device may increase which will result in unnecessary delays for new products being introduced into the market.

Recommendation: Not to implement the need to obtain a Conformity Assessment certificate for any joint replacements reclassified as a class III under proposal 1 implants, to instead undergo a Level 2 application audit and a review of their summary technical file (according to GHTF guidelines).

Proposal 2B(ii) – Applications to be selected for auditing

1. Stryker understands the perceived need to subject implantable Class IIb products to a Level 2 application audit.

Proposal 2C(i) – Confidence building for EU Notified Bodies

1. The MRA continues to have value for companies manufacturing in the EU and supplying medical products in Australia. The EU MRA provides an effective mechanism to reduce the level of TGA assessment as the notified body undertakes a review of the differences between the Australian legislation and the EU legislation and applies these to their Conformity Assessment of the device. With the reclassification of joint replacement

implants the percentage use of the MRA certificate will increase and the MRA will manufactures/ sponosrs with an express approval option once the MRA certificate has been issued.

Recommend: Maintain the current EU MRA process.

2. The confidence building period has been established since 2002 and it is unclear as to the confidence level the TGA's has with notified bodies.

Recommendation: TGA to provide a clear objective that defines how the TGA intends to build confidence, the associated result should be made public. For the TGA to increase the confidence level of a Notified Body the TGA need to introduce an accreditation process, with sufficient training available to improve the notified bodies understanding.

Proposal 2C(ii) – Recognising Australian third party assessment bodies

1. Stryker supports the TGA in further consultation on this proprosal and would recommend that the TGA expand this to allow the third party assessment bodies to assess, audit, and certify conformity assessment bodies based in Australia or overseas without providing conformity assessment certification services itself.

Recommendation to facilitate this process it is recommended that the TGA take on the role of accrediting notified bodies to issue a certificate of conformity for the Australian Market.

Proposal 3(i) – Amending the way in which a kind of medical device is included in the ARTG

1. This is another cornerstone of this reform, and is necessary for the TGA to be able to claim oversight of all medical devices. However, this proposal will increase the ongoing administrative costs of registration if additional assessment is added. This process could easily be facilitated through self declaration.

Recommendation: The most practical approach to implement this project is a fee free notification process managed online via the eBusiness system. This would allow a smooth transition of existing products and allow similar products of the same family that are all ready approved internationally able to be supplied without delay..

Proposal 3(ii) – Enhancing the ability to identify devices that have been approved by the TGA for supply in Australia

1. The implications of implementing this proposal have been greatly underestimated. The current requirement is to include the sponsors name and address this process is simplified as the detail required to be added is generic, however the complexity of the proposal is compounded as the ARTG is specifically assigned to a single product or group of products the logic and process that need to be implemented to ensure that the correct label is applied is similar to that which is implemented by a manufacturer. The average Australian sponsor is not a manufacture and would not have the technology/ system to support this process. Implementation of such a system would increase the regulatory burden and cost of support the device in the Australian Market place.

Recommendation: With the implementation of proposal 1 and 3i the TGA will have greater visibility as to what devices are covered by what ARTG this information should be built into a public search engine to allow the user to identify the ARTG or alternatively the user can contact the Australian Sponsor as per the details supplied under 10.2 of the Therapeutic Good (Medical Device) regulations.

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

1. This suggestion is a continuation of outcries from consumer groups who believe there is not enough information available via TGA for approved medical devices. However sufficient information is usually available on company websites, which typically are aimed directly at the patient level. Providing more technical/scientific information intended for the user on the TGA website by copying the IFU is not likely to provide anything more than confusion, and the effort to paraphrase IFUs would be a vast undertaking and not provide anything more than what the company website already provides. The additional information supplied by the US is a result the FDA providing the original application documentation.

Recommendation: If the TGA intend to supply additional information similar to the FDA the TGA should examine what information is captured during the medical device application and review and what data is made available on the public summary for each ARTG.