Reforms in the Medical Devices Regulatory Framework

Submission in Response to the TGA Discussion Paper of 25 October 2010

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CONTENTS

1 EXECUTIVE SUMMARY

The Therapeutic Goods Administration (TGA) have proposed reforms to the Medical Device Regulatory Frame work and requested input from industry, regarding the proposal. The main elements of the TGA proposal include:

- Reclassification of orthopaedic joints including; total and partial hips, knees and shoulders from Class IIb to Class III medical devices.
- Removal of the requirement for Australian medical device manufacturers to hold TGA conformity assessment certificates.
- Increased pre-market scrutiny by adding:
    - A requirement for all Class III and Active Implantable Medical Devices (AIMD) to obtain TGA issued Conformity Assessment certificates.
    - An application audit to **all** Class IIb implantable and long-term surgically invasive medical devices
- Introduction of a confidence building program with designated Notified Bodies, to include sharing of medical device manufacturer audits and product assessments
- Consideration of Australian based assessment bodies to issue conformity assessment certificates to Australian manufacturers
- Amending the description of medical devices included in the Australian Register of Therapeutic Goods (ARTG)
- Improved availability of information to the public about medical devices via publication on the TGA website and labelling of ARTG numbers on goods.

Johnson & Johnson Medical (JJM) welcome the opportunity to comment on the proposed changes. Whilst supporting many of the proposals we have concerns regarding an increased regulatory burden, additional associated costs and transition periods. Of particular concern is the expectation that currently available, higher risk devices that have been performing well will require TGA conformity assessment. We believe this is an unnecessary additional regulatory hurdle with no clear patient safety benefit. If approved, the costs should not be met by industry, who have complied with current requirements in good faith.

In summary JJM has responded as follows:

- We support the re-classification of orthopaedic implants to Class III but request that the proposed two year transition period be increased to a minimum of four years.
- JJM supports the proposal that Conformity Assessment Certificates from authorised international notified bodies should be recognised for Australian Manufacturers
- JJM agrees that increased scrutiny of Class IIb, Class III and AIMD devices is appropriate. However, this should not require the introduction of Level 2 application audits, and TGA issuance of conformity assessment certificates. Increased oversight of international agencies and acceptance of certification from those demonstrating high standards would serve the same purpose.

- JJM support the requirement to list 'grouped' medical devices on the ARTG, provided the system can be electronically updated by the manufacturer at no cost.
- JJM believes the administrative burden of supplying the ARTG number with the device will introduce additional risk associated with over-labelling and will also be a costly and unnecessary duplication of information available on the public ARTG.
- Suggestions on the level and type of product information that should be published on the TGA website have been provided.

2 INTRODUCTION

Johnson & Johnson Medical (JJM) welcomes and appreciates this opportunity to comment on the TGA's proposed reforms to Australian medical device regulation. The proposals result from evolving medical device regulation both in Australia and overseas and are in the context of a number of recent independent reviews of Australian regulation.

While JJM supports initiatives to increase the safety and efficacy of medical devices, we believe it is of fundamental importance that such amendments do not introduce unnecessary regulatory burden or excessive cost.

In addition to providing direct comment on the specific proposals, we have also offered suggestions for alternate approaches which may address the concerns raised by the TGA in their discussion paper.

It should be noted that JJM has contributed to and broadly supports the submission made by the Medical Technology Association of Australia (MTAA) but wish to provide further recommendations in this submission.

3 THE TGA PROPOSALS

The TGA proposals fall into three broad areas:

- Reclassification of Orthopaedic Prostheses
- Substantial increases in the number of devices which will require direct conformity assessment or an application audit prior to inclusion on the Australian Register of Therapeutic Goods (ARTG)
- Changes to methods of identification of devices in the ARTG and on product labelling

The following comments are provided in response to each of the specific proposals.

Proposal 1 Reclassification of joint replacement 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 Class IIb to Class III medical devices.

JJM response

JJM is a sponsor of a broad range of orthopaedic devices including hip, knee and shoulder joint implants. As the TGA's proposal to re-classify these particular devices from Class IIb to Class III would be of significant impact to our company, we welcome the opportunity to collaborate with the TGA on this proposed Regulation amendment.

JJM understands the TGA's position to align Australia's regulatory system with equivalent international regulations such as the European Union (EU) Medical Device Directive 93/42/EEC (MDD) and supports the re-classification of hip, knee and shoulder implants.

a) Additional requirements associated with ARTG inclusion and UPIs

In aligning with the EU regulatory system it is important to recognise that, while both systems have similar frameworks for applying conformity assessment, Australia has the additional requirement to include medical devices on the ARTG before supply. In particular, the ARTG introduces an additional level of complexity with regards to Class III devices and the requirement to include devices at the Unique Product Identifier (UPI) level. The restriction of allowable 'variants' within each UPI is a further limitation of the ARTG .

The TGA's definition of a UPI is currently an area of uncertainty within industry and the re-classification of orthopaedic implants will require manufacturers to list affected devices on the ARTG at the UPI level for the first time. While JJM supports the TGA's intent to increase visibility and traceability of high risk Class III devices, we have concerns regarding the TGA's interpretation and ruling on acceptable UPIs which we would submit has, at times, been inconsistently applied. JJM recommends that the TGA work with industry to clarify the UPI requirements for orthopaedic implants before introduction of the amended Regulations. This will allow for flexibility of grouping a broader range of devices within a product family or UPI as determined by the manufacturer.

b) The proposed transition arrangements

Based on experience from the transition to the current Regulations, JJM believes a two year transition period for the scale of proposed changes is not feasible. The previous transition highlighted the significant increase in resources required for these types of Regulation amendments. The additional regulatory burden associated with the proposed re-classification will require significant additional resource and risk delaying access for Australian patients to new medical device technology.

While it is understood that the necessary documentation to support Class III device applications is more readily available due to the recent classification change in the EU, it will still be a significant additional effort for the Australian sponsor to enter the devices on the ARTG: For existing Class III devices, the sponsor will need time to receive all required documentation from the manufacturer, prepare the device application and then compile and submit the supporting documentation. In our experience, this pre-submission process can take up to 6 months. Furthermore, JJM estimates that we would need to submit approximately 200 device applications as part of the re-classification transition process. This would not be feasible within the proposed two year timeframe.

Another important consideration when determining an appropriate transition period is the TGA's intention to include partial implants as part of this proposal. The proposed Australian classification rule will differ from the equivalent MDD classification rule which only applies to components of total joint replacements. The TGA must therefore recognise the considerable additional time and cost required to register devices which have a lower classification in Europe. Manufacturers currently experience this additional regulatory burden when registering devices affected by the difference in definition of the central circulatory system between Australia and Europe. For example, peripheral vascular stents used in the common iliac are currently Class IIb in Europe and Class III in Australia. After the transition to the current Therapeutic Goods (Medical Devices) Regulations in October 2007, some manufacturers were unable to continue supply of these devices due to the additional conformity assessment required for inclusion on the ARTG. This difference in classification

has also been an ongoing issue when manufacturers consider the feasibility of supplying such devices in the relatively small size Australian market at such increased effort.

When a device is a lower classification in Europe, the manufacturer is required to either apply for design examination to upclassify the device in Europe or to apply for TGA conformity assessment. Experience from the previous transition to the current Therapeutic Goods (Medical Devices) Regulations in October 2007 indicates that the five year transition period provided for transferring such devices was insufficient.

Overall, it is difficult to comment on a suitable transition time without a clear understanding of the requirements for entering hip, knee and shoulder implants on the ARTG as Class III devices. JJM request further consultation on this particular element of the proposal pending the outcome of Proposal 2B (i) which will determine whether orthopaedic implants will be subject to an application audit based on EC certification or require TGA conformity assessment as part of the transition.

Proposal 2A — Use of third party assessment bodies for Australian manufacturers

That Subregulation 4.1(1) is removed from the medical device Regulations, so as to no longer require Australian medical device manufacturers to hold TGA conformity assessment certification.

JJM response

The proposal to accept third party conformity assessment for all classes of medical devices manufactured in Australia builds upon the strengths of the TGA's current regulatory structure and experience with accepting conformity assessment certificates from overseas Conformity Assessment Bodies (CABs).

JJM welcome and fully support Proposal 2A.

Proposal 2B	**Increasing pre-market scrutiny for implantable medical devices**
(i)	**Devices requiring a TGA Conformity Assessment Certificate to be issued** *Subregulation 4.1(2) of the medical device Regulations be amended to require a TGA conformity assessment certificate to also be issued for all Class III and AIMD implantable medical devices.*
(ii)	**Applications to be selected for auditing** *Regulation 5.3 of the medical device Regulations be amended to require applications for all Class IIb implantable devices to also be selected for an application audit prior to inclusion in the ARTG.*

a) Current regulatory framework

In 2002 TGA introduced a new regulatory framework which was based on the guidelines published by the Global Harmonisation Task Force (GHTF) and closely aligned with the regulatory systems of the EU and of Canada. The aims of these reforms were to introduce a regulatory system which was consistent with contemporary international best practices and by alignment with overseas systems, to minimise regulatory burden on industry through elimination of differences in regulatory requirements or duplication of assessments.

Recognition of third party conformity assessment certificates is particularly important. Australia imports a very large proportion of devices, and exports a large proportion of devices that are locally manufactured. Based on figures provided to the Productivity Commission *Annual Review of Regulatory Burdens on Business* (Productivity Commission) – August 2008[1] TGA currently accepts evidence of EU assessment as the basis for approximately 97% of premarket reviews. Of the devices included on the ARTG:

- 58% are Class I and not subject to premarket assessment;
- 32% are entered onto the register solely on the basis of European (CE) certification;
- 8% are subject to an application audit in addition to review of CE certification; and
- 2% are directly assessed by TGA[2].

The TGA has effectively implemented third party conformity assessment for 98% of medical devices since the introduction of the new regulatory framework in 2002. As detailed above, almost one third of all devices requiring premarket assessment, have been entered onto the register based solely on presentation of CE certification. Only 8% have been subject to further review by the TGA via an application audit, with only 2% of device approvals based on direct TGA assessment.

[1] *Annual Review of Regulatory Burdens on Business* (Productivity Commission) – August 2008
[2] *Ibid.* Table 4.1.

b) JJM response

In response to Proposal 2B (i), JJM believe that the TGA should continue to accept evidence of EU assessment for Class III implantable medical devices and AIMDs in order to minimise the additional and repetitive regulatory burden on suppliers and facilitate timely availability to Australian patients of compliant medical devices. Only in cases with well-founded safety concerns should additional or alternate requirements apply.

In response to Proposal 2B (ii), JJM accepts that Class IIb implantables require appropriately rigorous regulatory oversight to ensure the long term safety and performance of these devices. However JJM does not believe that subjecting these devices to an application audit prior to inclusion in the ARTG is the most appropriate model.

An alternate approach to both Proposals 2B (i) and (ii) is provided below in section g) Alternate approach.

c) Re-registration of currently approved devices

The proposed requirement to re-register affected devices currently included on the ARTG on the basis of European Notified Body certification is of particular concern. JJM believe that resubmitting applications which have already undergone rigorous review by a recognised regulatory body and subsequently included on the ARTG imposes a significant and unnecessary regulatory burden.

Re-registration of the affected devices would result in an unreasonable and unjustified additional cost to industry. Therefore JJM would like to recommend that TGA waive all application fees for transitioning devices.

d) Resource Increase

The TGA currently only conduct direct conformity assessment for 2% of devices entered on the ARTG, and a proportion of these are Australian manufacturers. JJM are concerned about the increase in resources required by both industry and the TGA if this proposal to significantly increase the number of devices requiring TGA conformity assessment is implemented.

The implications in the area of total joint prostheses are particularly concerning. For affected devices currently entered on the ARTG on the basis of CE certification, the proposed changes contained in Proposals 1 and 2B will involve an extreme shift to a requirement for direct conformity assessment by means of design dossier review. With the re-classification of orthopaedic implants to Class III, it is estimated that an additional 200 design dossier evaluations will be required for JJM supplied implants. This represents a significant increase in resources required by the TGA to manage during the proposed transition. In addition to the increase in design dossier evaluations, JJM have further concerns regarding the resources required by the TGA to conduct the necessary quality system audits of overseas manufacturers.

e) Fee Increase

The reforms in Proposal 2B have the potential to lead to significant increases in total assessment fees to industry. Class III and AIMDs are currently included on the ARTG after

undergoing a Level 2 application audit at a cost of $5,650. For these devices to undergo TGA conformity assessment as proposed, the current fees are $23,800 for a full quality management system audit with the addition of $46,900 for the design dossier evaluation (total of $70,700). TGA audits of overseas manufacturers also attract additional costs relating to travel estimated at $15,000. For Class III and AIMD implants this represents a significant increase in fees per individual device (and presumably equivalent increase in resource requirements for assessment of these devices). Similarly for Class IIb implants, there will be a new requirement for an additional $5,650 fee not previously levied.

f) EU –Australia Mutual Recognition Agreement (MRA) and Canada-Australia Memorandum of Understanding (MOU)

Current and revised MRA and MOU arrangements operate in parallel to TGA conformity assessment of medical devices, whether that is by direct assessment or by acceptance of CE certification in lieu of a TGA conformity assessment certification.

The TGA proposals do not include any statements of intent to limit the scope of MRA/MOU arrangements and so it is anticipated that ARTG inclusion for Class III implants by means of MRA certification from a Notified Body would still be available to European manufacturers, although paradoxically, presentation of CE certification from the same Notified Body, which is obtained by assessment against identical criteria and uses equivalent conformity assessment methods would no longer be acceptable under the current proposals.

g) Alternate Approach

JJM acknowledge the TGA's concerns about the adequacy of review of higher risk devices. However we do not believe that the proposed increase in pre-market scrutiny is the most appropriate model for ensuring the quality, safety and performance of medical devices supplied in Australia. The nature of complex medical technology is that some unexpected outcomes of device use only manifest with extensive post approval clinical use and post-market surveillance is essential to identify these.

The current regulatory framework is based on a risk management approach designed to ensure public health and safety with review directed toward higher risk devices but also complemented with a robust post-market surveillance system.

JJM support this risk management approach and believe we should continue to build upon the strengths of the current regulatory system. It is recommended that TGA reduce their level of involvement in direct assessment and concentrate resources on TGA's role as the Australian Competent Authority, with particular focus on supervision of Notified Bodies and on post-market regulatory supervision.

The TGA have had approximately eight years of experience with the current regulatory system and assessment of medical devices based on CE certification, including application audits of supporting design dossier/technical file documents. As a result, the TGA are already in a strong position to form judgments on which Notified Bodies are acceptable for the purposes of assessment of devices to be supplied in Australia.

JJM therefore wish to propose an alternative approach which we believe may address the concerns raised by the TGA and others, and will improve both public health outcomes and public confidence in TGA and the Australian regulatory framework.

TGA should:

- Adopt the role of a designating authority for international and domestic Conformity Assessment Bodies (CABs) which can demonstrate competence to evaluate all medical devices requiring pre-market assessment for supply in Australia.
- Extend the confidence building measures in Proposal 2(c)(i) to include a subset of Notified Bodies from which CE certification in lieu of TGA conformity assessment certification can be accepted without further review.
- Continue to emphasise and maintain a robust post-market surveillance system for medical devices in Australia.
- Proceed to full acceptance of third party conformity assessment as the basis for ARTG inclusion.
    - This could be achieved rapidly by immediate selection of the current MRA accredited Notified Bodies plus any others the TGA considers acceptable based on its eight years of experience of application audit review of products with CE certification.
    - As an added safeguard for high risk devices, the current practice of Level 2 application audit of these devices prior to ARTG inclusion could be continued. However consideration should be given to phase out such audits as confidence continues to grow.

Proposal 2C	**Recognition of third party assessment bodies**
(i)	Confidence building for EU Notified Bodies designated under the MRA *That the TGA commence discussions with the EC over a program of confidence building with the designated Notified Bodies under the MRA, which might include sharing of product assessments and observed audits of medical device manufacturers.*

a) JJM Response

Rigorous supervision of Notified Bodies is critical to ensuring the competence of the assessment bodies so that regulatory controls are adequate to ensure acceptable safety and performance.

JJM strongly supports the intent of this proposal and believes that the role of the TGA in assessing and assuring confidence in EU Notified Bodies should be extended beyond the MRA to include confidence building for those Notified Bodies from which CE certifications are accepted in lieu of TGA conformity assessment certification.

The discussion paper identifies specific concerns with the variability of EU Notified Bodies and in particular the capacity of some of the smaller Notified Bodies to deliver adequate standards of assessment.

JJM shares these concerns and notes that the presence in the regulatory system of assessors which may not meet adequate standards would not only undermine the regulatory system but would also permit unfair competition. Some manufacturers and suppliers may deliberately seek easier assessments in order to compete unfairly with the large majority of ethical manufacturers who willingly submit to rigorous assessment by properly supervised and reputable Notified Bodies.

JJM recommend TGA identify a subset of Notified Bodies which meet acceptable standards for assessment of manufacturers of devices to be supplied in Australia. A suitable starting point would be those already accepted into MRA arrangements. This list could be supplemented based on acceptable designation arrangements made by either the TGA directly or by specified European Competent Authorities.

b) European Reform

The European Commission is currently proposing further improvements in the MDD arrangements. These are centred on the same concerns that have been expressed in Australia, namely inconsistencies in supervision and competence of Notified Bodies. The current draft proposals are directed towards:

- Strengthening and harmonising the oversight of Notified Bodies in terms of demonstration of competence, impartiality and transparency.
- Simplifying and streamlining the conformity assessment procedures; and

- Ensuring uniform high standards and criteria for conformity assessment review by Notified Bodies, in particular regards to the assessment of the manufacturer's clinical evaluation and in the field of new technologies.

It is likely that this process will result in a reduction in the number of Notified Bodies, with those of unacceptable standard withdrawing or being removed from designation.

External commentators have reinforced the view that the European system of regulation is effective:

A study on the FDA impact on US medical technology innovation by Dr Josh Makower[3] found that:

> *"no information is currently available to suggest that patient safety in Europe has been compromised" by the lower hurdles in the EU.*

John Wilkinson, chief executive of the EU medtech industry association, Eucomed commented on the current Recast proposals[4]:

> *"With regards to the recast of the European Medical Device Directive, we expect to take a step further forward that will strengthen the system's safety elements, reduce redundant regulatory processes while sustaining the industry's drive for research and innovation."*

In summary the GHTF regulatory framework as implemented in Australia, Canada and Europe is self evidently working well. There is no evidence of systemic regulatory failure or of proliferation of unsafe or substandard medical devices or of significant public health concern associated with medical devices in these jurisdictions. Current European reforms are directed to further strengthening the system by eliminating specific deficiencies in supervisory arrangements rather than any deficiency in the regulatory framework itself.

[3] Makeower J., Meer A., Denend L. (2010) *FDA impact on U.S. Medical Technology Innovation*, http://www.eucomed.be, Date Accessed: 13/12/10

[4] *European patients have access to new medical technology sooner than American patients*, http://www.eambes.org, Date Accessed: 13/12/10

(ii)	**Recognising Australian third party assessment bodies** *That further consultation be undertaken to investigate the development of a system whereby Australian based assessment bodies can be designated to issue conformity assessment certificates to Australian manufacturers.*

JJM Response

JJM supports this proposal in principle, although we would question whether there is sufficient volume of work to sustain an Australian third party conformity assessment body (CAB).

Although the possibility of designating an Australian based CAB merits discussion, we do not believe that CABs should now be required to have a physical or legal presence in Australia. This is not required currently for CAB's certifying Class I and II products or for Class III products certified through the MRA.

Where a CAB has been designated by an acceptable overseas Competent Authority such as the MHRA in the UK, we would submit that this should be accepted by the TGA as meeting Australian requirements for designation once each country's requirements are clearly articulated and understood. Duplication of the designation process should be avoided.

However we would have concerns regarding TGA's acceptance of third party conformity assessment certification for Australian manufacturers while Proposal 2B (i) requires overseas manufacturer's to hold TGA conformity assessment certification.

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

(i) Amending the way in which a kind of device is included on the ARTG;

The following comments are provided with input also from Johnson & Johnson Pacific Pty Ltd (JJP), part of the Johnson & Johnson family of companies. JJP are a sponsor of medical devices typically supplied direct to consumers which are affected by Proposals 3 and 4. Comments on behalf of JJP have been included accordingly.

Response

JJM supports the TGA's intent to increase visibility of individual devices supplied under an ARTG entry. However, the process for maintaining this level of information should minimise the administrative burden and costs.

As discussed in the response to Proposal 2B, JJM does not support the TGA's proposals for increased or direct assessment of each new model of devices which are Class IIb or above prior to their inclusion on the ARTG. The process for adding new products should not delay market access and be consistent with the current rules for grouping as a "same kind of medical device".

JJM recommend that the addition of new products should be via a notification only process using the current eBusiness System. A suitable upgrade to this system should allow sponsors to add new products and maintain information with built in validation negating the need for TGA review and associated fees. JJM also recommend that this notification only process be supported by the post-market audit system currently used for Class 1 non-sterile devices which are entered on the ARTG without premarket assessment.

In addition, both JJP and JJM would like to request further clarity of the definition of what constitutes an individual device and on the process of how products will be added to existing ARTG entries. Careful consideration of this definition is required to avoid creating an unmanageable list which is difficult for healthcare professionals, consumers, TGA and sponsors to navigate. We request flexibility on how this is approached.

JJM currently has over 1,300 inclusions in the ARTG across all classes of devices so we do not believe that the proposed transition period of one year will allow sufficient time to update each of these entries. However, without a clear understanding of the process for updating existing ARTG entries and the level of detail required, it is difficult to comment on a suitable transition period. JJM would like to request further consultation on the transition period pending clarification of this information.

(ii)	**Enhancing the ability to identify devices that have been approved by the TGA for supply in Australia.**

JJM does not support the proposal to publish the ARTG number on the information that accompanies a medical device.

Implementation of this proposal may require Australian sponsors to over-label individual products locally. The process of over-labelling device packaging is a manufacturing step requiring appropriate facilities, systems and competently trained staff. The process introduces additional risk in that incorrect labels may be applied and vital product information may be obscured without clear patient benefit.

If Proposal 3 (i) is implemented, public access to the ARTG will enable users to search the increased level of product information available to cross-reference and determine the applicable ARTG number. The administrative burden of supplying the ARTG number with the device will be a costly and unnecessary duplication of information.

Proposal 4 Publication of device product information on the TGA Website

JJM acknowledges that the TGA currently publishes limited information about medical devices on the ARTG and supports the TGA's interests in improving the transparency and accountability in their decision making processes.

JJM also support the patient's right to such information with the intent of facilitating better informed consent however the level of information should be appropriate to the type of medical device and intended audience.

The discussion paper references the public information made available by the FDA for approved devices and the information published by the TGA for medicines in Australia with the proposal to develop a similar program for medical devices in Australia. JJM do not believe that the level and type of information provided in these existing programs should be published on the TGA's website for devices which are supplied directly to and used by a health care professional. For example, the scientific and technical detail provided in the Instructions for Use (IFU) and patient instructions is not typically appropriate for the general public and is intended for the appropriately educated health care professional only. The information contained in these documents can however be used by the health care professional in their consultation with patients to better educate them about the medical device. Furthermore, it is noted that advertising controls are different according to the intended recipient of the information (patient or health care professional) so the provision of such documents on a public website may contravene relevant advertising restrictions.

In considering the fundamental differences between the product information which should be published for medicines when compared to medical devices, JJM wish to comment on the specific issues raised by the TGA in the discussion paper:

a) The types or classes of devices which should be included in such a scheme

JJM believe the scheme should only be applicable to devices of a higher risk classification i.e. Class III implantables and AIMDs to be consistent with Proposal 2B (i) and to devices where the end user is a patient e.g. devices supplied directly to consumers.

b) The information which should be included when published, including the depth of that information

JJM currently provide device and surgical procedure information aimed at educating patients via booklets and company websites. JJM therefore welcome this opportunity to further enhance accessibility of this information to our patients and recommend that this be done through collaboration with industry associations such as the Medical Technology Association of Australia (MTAA). JJM believe industry should work with the MTAA to develop publications on general surgical procedural information which is appropriately targeted at a patience audience.

JJM do not support the publication of any information which is intended solely for the user of the device (health care professional) and which may contain competitive information that is commercial-in-confidence.

c) Responsibility for authorship of the information (i.e. the manufacturer or the TGA)

JJM believe the responsibility of authorship should rest with the manufacturer and MTAA as suggested above to ensure accuracy and currency of the information published.

d) Responsibility for ensuring information is up to date

As above, responsibility should rest with the manufacturer and MTAA however this would still be dependent on the TGA publishing updated information on their website in a timely manner.

e) Whether to publish, or not, information relating to rejected applications

JJM do not support the TGA's proposal to publish information relating to rejected applications on their website. This information should remain commercial-in-confidence. As an alternative, JJM recommend that publishing a percentage of applications rejected versus those approved would be a more appropriate measure of effectiveness.

In conclusion, JJM wish to thank the TGA for this opportunity to comment on the proposed changes to the medical devices regulatory framework. JJM trust that they are of assistance and look forward to further collaboration to develop a mutually agreeable program of regulatory reform.