3M Australia Pty Limited
A.C.N. 000 100 096
A.B.N. 90 000 100 096

950 Pacific Hwy
PO Box 99 PYMBLE
NSW Australia 2073

9th December 2010

The Coordinator
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
Woden ACT 2060

Re: Comment on TGA Reforms of Medical Devices Regulatory Framework
Discussion Paper 25 October 2010

Dear Sir/Madam,

Please find below 3M Australia Pty Ltd comments on TGA Reforms of Medical Devices Regulatory Framework:

PROPOSAL 1:

Reclassification of joint replacement implants
This proposal has no effect on our business and therefore we have no comments

PROPOSAL 2:

Proposal 2A: Use of third party assessment bodies for Australian manufacturers
This proposal has no effect on our business however 3M Australia supports this proposal

Proposal 2B:
Increase pre market scrutiny for implantable medical devices:

2B (i) Devices requiring a TGA Conformity Assessment Certificates to be issued
This proposal does not have any impact on our business therefore we can not comment.

2B (ii) Class IIB implantable devices are to be selected for an application audit prior to inclusion in the ARTG
We suggest that the TGA need to further revise their internal evaluation process for class IIb applications rather than applying application audit. The reasons being are:

1. The current requirements for level 2 application audit require compliance with Essential Principles Schedule 1 (Risk Management) and Essential Principles 14, Schedule 1, Part 8 (Clinical Evaluation). Submissions made by sponsors for class IIb must comply with the Essential Principles rules and thus all the required documentation for application audit, would be already part of the submission and therefore there is no need to apply application audit for class IIb implantable.

2. The proposal will significantly increase the cost for every same kind of device to be included. The current cost for class IIb application is $810. If TGA applies application audit the cost will be $5,650.
3. We are also aware of TGA's proposal 3 – where the TGA is proposing to amend the way in which a medical device is included in the ARTG and enhance identification of approved devices. The proposal indicates that every new device will undergo an application audit and this will significantly increase the cost as discussed above.
4. The proposal will increase the market authorisation period.

Proposal 2C:
Recognition of third party assessment bodies:

2C (i) Confidence building for EU Notified bodies designated under the MRA and
We support this proposal

2C (ii) Recognising Australian Third party assessment bodies
This proposal has no impact on our business therefore we have no comments

PROPOSAL 3:

Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices via:

3 (i) amend the way in which a kind of device is included on the ARTG, and
We do not support this proposal due to the following:

1. Itemising various models will not enhance the consumer's or patient's ability to identify registered products as many products are used as part of a service that a dentist/ nurse/ doctor provides to patients and these consumable products or brands often aren't visible to patients.
2. For dental and orthodontic products, maintenance of products by item number is a huge undertaking (several hundreds items per same kind of device) and again the benefit is questionable as the patient would not be able to visualize those products.
3. If the intent of the proposal is to enable patients or consumers to be able to identify which products are registered then we suggest the listing of brand names as alternative, as we currently do for prescription and OTC. Consumers are more likely to identify Brand names.
4. The proposed transition is too short and can not be met. We recommend to extend the transition period.
5. This will result in a significant ongoing cost and TGA must verify the process and cost adequately (instead of paying for one group application, the sponsor would be paying for grouping each new item added?).

3 (ii) enhance the ability to identify devices that have been approved the TGA for supply in Australia.
The proposal will cause significant problems for devices manufactured overseas as it is likely to require special production lines for product intended for marketing in Australia. This would result in additional cost and the proposed transitioning period would be too short to be met. The TGA must also realise that some devices are imported in small volumes for certain consumers and the cost associated with applying this proposal maybe significant enough to discontinue supply.
PROPOSAL 4:

Publication of device product information on the TGA website
3M Australia supports publications of higher risk devices such as Class III and AIMD, however there is no necessity for publishing information for lower classes.

3M Australia does not support publication of information relating to rejected applications. This process does not apply to prescription or OTC medicines. In addition this would be considered to be corporate confidential information and it has no benefit to consumers.

Yours Sincerely

Juliana William
Medical Regulatory Affairs
3M Australia Pty Ltd
Tel: +61 2 9498 9120
Fax: 1800 500 155
Email: jwilliam@mmm.com