MAQUET
GETINGE GROUP

Office of Device Authorisation
Therapeutic Goods Administration
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devices@tga.gov.au

19 Nov 2010

**Re: Reforms in the Medical Devices Regulatory Framework**

Dear Sir/Madam

Thank you for this opportunity to present a response to the above proposed reforms, on behalf of MAQUET Australia Pty Ltd. We are both a sponsor of medical devices manufactured in Europe, USA and China, and an Australian manufacturer of medical devices ranging from Class I to Class IIa.

I would like to make the observation that specific aims of the recommendations coming out of the HTA Review is "*to reduce unnecessary regulatory burdens on the sector while providing timely access to new and improved technologies and treatment modalities*". In the case of MAQUET Australia, all proposed changes without exception actually increase the regulatory burden. The *necessity* of each element of increased burden is also questionable. Secondly, it is not clear how the proposed changes will make it more efficient for MAQUET Australia to bring new and improved technologies into the marketplace.

**Proposal 1 – Reclassification of Joint Replacement Implants**

Whilst this change does not currently affect MAQUET Australia, I wish to make the general comment that relates to this change and most of the other proposed changes. The majority of sponsors will have agreements with both the public and private sector to supply at contractually agreed pricing for in some cases up to five (5) years. Significant increases in the regulatory burden in terms of both TGA fees and regulatory resources in this situation cannot be passed on to the customer, and therefore represents a direct reduction in margin and profitability for the sponsor. Proposal 1 clearly represents a significant increase in fees and regulatory resources for this segment. The current fee for Level 2 Application Audits is $5650, which multiplied by the number of IIb implantable joint inclusions most sponsors in this segment have currently, represents a huge increase in fees. The justification for this increased burden needs to be better communicated, and the various proponents (consumer groups, healthcare providers etc) for this change need to be prepared to pay more for a given device.

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**Proposal 2A – Use of Third Party Assessment Bodies for Australian manufacturers**

Whilst in principle this proposed change appears to reduce the regulatory burden, it will have no impact on MAQUET Australia as we have no intention to utilize CE certification in support of our current inclusions.

**Proposal 2B(i) – Devices requiring a TGA Conformity Assessment Certificate**

Comments against Proposal 1 apply, to an even greater degree.

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

Depending on the level of associated fees, this change could drastically limit new products coming onto the market, so I would urge the TGA to consider limiting fees to well below to current Level 2 application audit fee of $5650.

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

One of the possible options given for ways to give greater weight to CE certificates issued by a MRA Notified Body is:

- Only accepting CE certificates from MRA Notified Bodies as manufacturer evidence

Depending on how inclusive the MRA Notified Bodies list is, this could be yet another example of significantly higher barriers than anywhere else in the world, for 2% of the medical device market.

**Proposal 3(i) – Amending the way a kind of device is included on the ARTG**

The declarations made by an appropriately authorized person at the point of application for inclusion of a medical device continue to apply while that particular inclusion is still current. So when a new model of a particular kind of device arrives, the sponsor is obliged to ensure these declarations are still current – i.e.

> (e) I:
> (i) have available sufficient information to substantiate that compliance with the essential principles; or
> (ii) have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
> (f) an appropriate conformity assessment procedure has been applied to devices of that kind

At any point in time the regulator can (and does) ask for demonstration of compliance in relation to a specific model of device.

The alternative to this increase in workload for sponsor RA teams both initially and on an ongoing basis, could be greater application of the penalties already available to the TGA when non-compliance is identified.

Should this consultation process result in the suggested amendment, in order to maximize compliance a fee to vary the inclusion should not be charged (as proposed) especially if the sponsor is performing the effort in updating the list of products under each entry.

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**Proposal 3(ii) – Enhancing the identification of approved devices**

Whilst the intention is good, and the advantages of this in relation to medicines are clear, this is not practical for medical devices. In contrast to a medical device, generally speaking a given medicinal product will:

Have a much shorter useful life
Typically be retained within its packaging for the duration of its useful life
Generally be restricted to a single user/patient
Manufactured in much higher volumes

The logistics associated with making and maintaining this change are very significant. The discussion paper states:

> *"This change should not adversely impact on regulatory costs as sponsors are already required to publish their contact details on the information that accompanies a medical device"*

This statement demonstrates a lack of real world practicalities. Requesting overseas manufacturers to add a label/revise an insert for 2% of the market is a big ask, and in our situation would not be at all feasible.

To add this information locally before shipment to the customer, is very different to adding sponsor contact details to a product. This contact information is a standard piece of information common to all products, and therefore very simple for logistics staff to include. For a sponsor of for example fifty (50) inclusions, this would represent a huge task and in order to be accurate would need to be automated somehow. Maintaining such a system as products are introduced/obseleted would require effort also.

The practical benefit from all this effort will be negligible. It would be very safe to assume that most sponsors would add the ARTG number to either the inner packaging, the outer packaging or have a separate insert. Adding a label to the device itself is an unlikely scenario. Given this, as soon as the product is actually used, in all likelihood the ARTG number will no longer be attached to the device.

Currently healthcare providers can and do request this information of the sponsor at any point in time, often prior to purchase. This method can continue to be the primary way that healthcare providers gain confidence that a given item has been approved for supply. Enhancements to the ARTG site itself would be welcome, including general user-friendliness and the ability to search by overseas manufacturer (not just sponsor).

**Proposal 4 – Publication of device product information on the TGA Website**

Patient instructions, IFU's, User Guides, references to Clinical Papers are typically available on the manufacturer's website. As with any website initiative, one of the most important considerations is the effort involved in maintaining currency. For example, User Guides are often revised so ensuring the latest version is on the TGA site at all times would require significant commitment.

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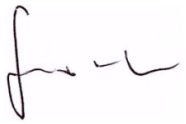
A final general comment is that we should be cautious about implementing higher regulatory barriers as a response to complaints or concerns of a minority. In many respects, the Australian market already has a reputation for being particularly difficult to enter from a Regulatory standpoint. Whilst this may be something to be proud of and give the patients and clinicians in this country a level of confidence, care needs to be taken to make certain we do not over-regulate to the detriment of the industry. Ensuring medical device safety and effectiveness will always require a Risk based approach, and my concern is that continuing to increase the rigour of the Australian system will inevitably result in a narrower range of healthcare solutions at a higher price to the individual.

Once again, I thank you for the opportunity to present MAQUET Australia's perspective and trust this will assist in your formulation of a strategy that is an improvement for all stakeholders.

Yours sincerely



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