BIOTRONIK
excellence for life

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Office of Device Authorisation
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

17 December 2010

Submission to "Reforms in the Medical Devices Regulatory Framework – Discussion Paper" dated 25 October 2010

Dear Sir or Madam,

BIOTRONIK is a leading European company in the field of biomedical technology. We focus on devices for vascular intervention and electrotherapy of the heart. Our products (including implantable pacemakers, defibrillators, stents, balloon catheters and guide wires) help physicians to save lives and to improve their patients' quality of life.

BIOTRONIK operates a global network. About 5100 employees research, develop, produce and sell BIOTRONIK products, and support our customers on every continent.

BIOTRONIK Australia was established in 1999 and has since enjoyed an ever growing reputation as a reliable partner to the Australian physicians, the TGA and health care providers.

We appreciate the opportunity to submit our views on the above mentioned discussion paper. In our submission, we will quote the relevant section from the discussion paper first followed by our response to the respective proposal.

Best regards

Falko Thiele
Director Clinical and Regulatory Affairs

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## Proposal 2B – Increasing pre-market scrutiny for implantable medical devices

This proposal is designed to focus on those invasive medical devices that are also subject to other Government HTA review processes for the purposes of reimbursement.

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

Sub regulation 4.1(2) currently requires a TGA conformity assessment certificate to be issued for specific kinds of high risk medical devices. In particular, devices containing:

- Tissues of animal origin;
- Substances of microbial or recombinant origin;
- Stable derivatives of human blood or plasma; or
- Medicines.

In addition to these high risk products, the TGA proposes that Sub regulation 4.1(2) of the Therapeutic Goods (Medical Devices) Regulations 2002 be amended to require a TGA conformity assessment certificate to also be issued for all Class III/AIMD implantable medical devices intended for long-term use.

This would require the reference in sub regulation 4.1(2) to medical devices manufactured outside Australia be removed to subject Australian manufacturers to the same regulatory requirements or processes as overseas manufacturers (See proposal 2A).

Medical devices covered by current classification rules 3.4, 5.2, 5.7 and 5.9 would be subject to this proposal. Typical examples of these types of Class III/AIMD medical devices are:

- Joint replacements reclassified as Class III under Proposal 1;
- Implantable pacemakers and defibrillators;
- Implantable accessories to Class AIMD medical devices, such as pacemaker leads;
- Ventricular assist devices, heart pumps and total artificial hearts;
- Prosthetic heart valves;
- Implantable contraceptive devices, such as IUDs;
- Implantable radionuclide sources, such as radioactive seeds used for brachytherapy; and
- Breast implants.

### Transition Period

This proposal has direct implications for affected products currently included in the ARTG on the basis of European Notified Body certification.

As such, it will be necessary to provide a transition period for affected manufacturers to have a TGA conformity assessment certificate issued for their medical devices.

The TGA proposes a four year transition period for this purpose.

For affected devices included in the ARTG at the time of implementation of the new regulations, if an application is submitted to the TGA for conformity assessment certification within the four year transition period, the products can continue to be supplied until the assessment is finalised.



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If a conformity assessment application is not received by the end of the four year transition period, the affected devices will be cancelled from the ARTG, and will not be able to be supplied until a TGA conformity assessment certificate has been issued, and the devices are included in the Register.

For new products intended for introduction to the market after commencement of the transition period, manufacturers will need to submit a new TGA conformity assessment application. As with any new application, these products will not be able to be supplied until such assessment has been completed and the device is Included in the ARTG.

Periodic review

It is proposed that Sub regulation 4.1(2) be reviewed regularly, to ensure that the list of devices subject to conformity assessment remains aligned with public health concerns and that provision is made for adequate regulation of evolving technology. These reviews may add, or delete, from the list.

Any future additions to Sub regulation 4.1(2) would be subject to separate consultation before any amendments to the Regulations were made.

## Proposal 2B (i) Response

Proposal 2B (i) in its current form constitutes a significant departure from the principles of global harmonisation, which had been actively advocated for the past 8 years by the TGA and the Australian government. The majority of medical devices sold in Australia are imported. Manufacturers typically operate globally with Australia representing a minor share of their global market. Efforts to harmonise regulation of medical devices globally therefore constitute an important initiative in managing the increasing complexity and cost of providing health care also in Australia. A continued movement to align local regulations within a globally (or – as it is – at least European) harmonised regulatory environment would reduce time to market and thus make these important products available to the Australian patient earlier. It would reduce costs to the manufacturer thus reducing prices of these devices. Most importantly it does not need to lead to potentially unsafe devices if Notified Bodies adhere to the respective regulations and are being monitored accordingly.

Proposal 2B (i) represents a break away from a recognition of European Notified Bodies as being capable to assess the compliance with the Essential Principles for medical devices. It would introduce an anti-competitive clause, effectively closing out all European Notified Bodies, regardless of reputation and/or capability for assessing class III implantable devices and AIMDs. Proposal 2B (i) seems to counteract the initiatives in Proposal 2C which would open the assessment of medical devices to competition rather than place further restrictions on the industry.

Proposal 2B (i) suggests that there is not one Notified Body which is capable of fulfilling the duties for conformity assessment responsibly. BIOTRONIK recognises that there is a wide spectrum of European Notified Bodies which unfortunately also includes Notified Bodies of a lower quality. However, rather than shielding the Australian market from any European Notified Body assessing class III products or AIMDs, a prudent response would be to restrict reliance on assessments by those low-quality Notified Bodies. If the TGA were to reject



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conformity assessments by certain low-quality Notified Bodies manufacturers would be prompted to avoid those in favour of high-quality Notified Bodies. This would in turn prevent the Australian market from being accessible to potentially unsafe medical devices.

Between 2005 and 2007 we unfortunately had to witness some of recalls of implantable defibrillators and defibrillator leads by our competitors worldwide. These products had undergone rigorous regulatory assessment in several countries including conformity assessment by the TGA in case at least of the defibrillator leads. Analysing the reasons for those recalls we come to the conclusion that the proposed mandatory TGA conformity assessment would not have been able to avoid any of those recalls. We therefore question the logic that a repeated conformity assessment – this time by TGA prior to Australian market entry – would increase the reliability of those medical devices.

Two of the HTA Review objectives are to support better health care and to reduce unnecessary regulatory burden. We are sceptical that either of those objectives will be achieved by implementing Proposal 2B (i). The regulatory burden would increase because the repetition of the conformity assessment in Australia for an international manufacturer would result in delays to market entry and higher cost. The changes proposed in Proposal 2B (i) would lead to approximately 3.5 million dollars in extra cost to BIOTRONIK given that the majority of BIOTRONIK's devices are class III and AIMDs. This would most likely result in increased prices and thus an additional burden to the healthcare system. Moreover, tested and proven innovation would only be available to Australian patients with a delay of up to one year compared with European patients. With new product cycles of 18 months, this would be a significant disadvantage to Australian patients.

In 2007, with the ending of the transitional period for the Therapeutic Goods (Medical Device) Regulations (2002), the TGA experienced a backlog of conformity assessment applications, and medical device applications which extended significantly past October 2007. We are concerned with the huge workload and resulting backlog that TGA will experience with the introduction of this Proposal 2B (i) at the end of the transition period. Even if TGA's strategy was to counter this increased workload with an increase in staff, we question whether qualified medical device assessors would be available in Australia in sufficient numbers given the ongoing skills shortage in our country.

We completely agree with the necessity to provide the Australian patients with safe and effective medical devices of a continuously high quality. As a matter of fact, we pride ourselves on the high quality of our products. We cannot, however, see how Proposal 2B (i) in its current form would effectively improve safety of medical devices. Instead it would increase the burden on the healthcare system and significantly delay access to innovations for Australian patients.

We therefore propose to amend Proposal 2B (i) as follows:

"Sub regulation 4.1(2) of the Therapeutic Goods (Medical Devices) Regulations 2002 to be amended to require a TGA conformity assessment certificate to also be issued for all Class III/AIMD implantable medical devices intended for long-term use unless their conformity has been assessed by a Notified Body which has been approved for the purpose of the European Community Mutual Recognition Agreement."



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Remark: Since confidence building as proposed in Proposal 2C would have to take place prior to the full implementation of Proposal 2B (i), we suggest to apply the transition period of four years also to new products intended for introduction to the market after commencement of the new regulations.



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Proposal 2B – Increasing pre-market scrutiny for implantable medical devices

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

Regulation 5.3 currently requires applications for the following types of medical devices to be selected to undergo an application audit prior to being included in the ARTG:

- Barrier contraceptives other than condoms;
- Implantable contraceptive devices;
- Implantable breast prostheses, other than water/saline filled implants;
- Class IIb devices intended to disinfect other medical devices;
- Class AIMD devices;
- Prosthetic heart valves;
- Implantable intra-ocular lenses;
- Intra-ocular visco-elastic fluids; and
- Class III devices not assessed under the European MRA.

In addition to these products, the TGA proposes that Regulation 5.3 of the *Therapeutic Goods (Medical Devices) Regulations 2002* be amended to require applications for all Class IIb implantable medical devices to also be selected for an application audit prior to inclusion in the ARTG.

Medical devices covered by classification rule 3.4 would be subject to this proposal. Typical examples of these types of Class IIb medical devices are:

- Spinal fixation devices;
- Orthopaedic fixation devices;
- Bone screws, plates, pins and wires;
- Finger, wrist and ankle joint prostheses;
- Artificial bone matrix implants;
- Non-absorbable implants such as sutures, staples and anchors;
- Surgical mesh, such as hernia repair devices;
- Long-term invasive vascular access devices, such as implantable ports;
- Maxillofacial implants;
- Peripheral vascular stents, biliary stents etc.; and
- Systems and procedure packs containing any of the above devices.

Periodic review

The TGA also intends to regularly review the list of devices required to undergo an application audit prior to entry in the Register; with a view to adding specific types of devices to the list if safety or performance issues arise due to new or novel technologies.

Any future additions to Regulation 5.3 would be subject to separate consultation before amendments to the Regulations were made.

Transition Period

No transition period is required for this part of the proposal. Any application received for these kinds of medical devices after the regulations come into effect will be selected for an



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application audit. An assessment fee will apply to these application audits and this will be explored in the cost recovery impact statement yet to be developed.

## Proposal 2B (ii) Response

We generally support this proposal. However, our concern with this proposal relates to the additional workload that TGA is going to experience and the extra cost imposed on the manufacturers. Therefore, the success of this proposal will depend on TGA being able to increase relevant resources to cope with the increased demand of class IIB audits within the prescribed time frames.



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*Proposal 2C (i) – Confidence building for EU Notified Bodies designated under the MRA*

Australia has a Mutual Recognition Agreement (MRA) with the European Commission (EC) for conformity assessment processes. The MRA is currently in revision and will allow for confidence building to occur so that both parties can be assured of the quality of the assessing body. The TGA and the EC have yet to undertake any confidence building arrangements.

To date, although the MRA has been generally beneficial to Australian manufacturers, there has been little uptake of the option by European based manufacturers as currently some high risk devices are excluded subject to confidence building, and European manufacturers of lower risk devices do not need to use the MRA provisions in order to have their products included in the Register. If the TGA proceeds with the other proposed reforms, there may be more uptake of the MRA option by European manufacturers.

The TGA proposes to 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.
After the MRA confidence building has been completed, it is anticipated that the TGA would give greater weight to CE certificates issued by a Notified Body that has undergone confidence building, compared to certificates issued by other non-MRA Notified Bodies.
Possible options for achieving this might include:
Only accepting CE certificates from MRA Notified Bodies as Manufacturer's Evidence; and
Requiring all applications supported by non-MRA Notified Bodies to undergo a mandatory application audit.

This part of the proposal may also require the review of the definition of TGA Conformity Assessment in the future.

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

Currently only the TGA is able to issue manufacturers with conformity assessment certificates under the Australian medical devices legislation.
To promote competition and enable further choice for Australian manufacturers, it is proposed that further consultation be undertaken to investigate the designation of Australian based assessment bodies to issue Australian conformity assessment certificates.
It is anticipated that such a system would work in a similar manner to the European Notified Body system, where a single Australian competent authority would be able to designate an Australian third party to undertake assessments of a manufacturer's quality system to Australian requirements. The resulting certification would then be able to be used to support applications for medical devices to be included in the Register before being supplied in Australia.

Further consultation will be required to discuss options for a system to designate Australian third party assessment bodies, where a key topic will be who should be responsible for designating the assessment bodies. This is particularly important given that the TGA may continue to operate as an assessment body in competition with any designated parties.



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## Proposal 2C Response

BIOTRONIK fully supports Proposal 2C. As a matter of fact, the confidence building for high-risk devices was supposed to have taken place within 18 months after commencement of the MRA with the European Community on 1 January 1999. We therefore suggest that the process of confidence building with the designated Notified Bodies under the MRA commences immediately and takes place concurrently with the MRA revision.
It is our hope that after a successful confidence building, Proposal 2B (i) can be amended as per our suggestion thus increasing the uptake of the MRA option by European manufacturers.



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

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

The TGA is proposing to require sponsors to itemise the devices and/or various models that are supplied under the same ARTG entry. Sponsors will be required to identify the different models in the application form, to be assessed by the TGA prior to making a decision to include the devices on the ARTG. If approved, this list of devices identified by model number or trade name will appear as a list of devices under the ARTG entry.
It is proposed that this list of devices will be accessible to healthcare providers and consumers in the public view of the ARTG.
As new models become available, sponsors will be required to submit an application to vary the existing ARTG record to add a new model of that kind of device. This new model would undergo assessment if the kind of device is Class IIb or above, and if it meets the requirements for supply, will be added to the ARTG.
This amendment will lead to more detail about what devices are being supplied in Australia and:

- Will enhance the regulator's ability to monitor the safety and performance of all devices of that kind supplied in Australia;
- Will ensure that the device being supplied under a particular inclusion is the same kind of device; and enable healthcare providers and consumers to search the ARTG to find the device model.

Cost Implications

The assessment of the subsequent variations of devices will result in increased regulatory costs for pre-market assessment but will not impact on the annual charges paid by sponsors.
It is proposed to have a transition period with no fees however a fee to vary the inclusion will be charged after this transition period.

Proposed Transition Times

Sponsors will be required to provide this information for all models at the time of entering a new inclusion. Entries currently included at the time of legislative change will have to be updated within a time frame of 1 year from the legislative changes.

Legislative Changes

Amendments to the Act will be necessary to require sponsors to notify the TGA of changes and to include a list of all models or products under the one entry as a condition of inclusion. Entries can be suspended or cancelled from the register if the sponsor fails to comply.

IT Requirements

Changes to the IT system will need to occur so that sponsors can enter/change/add to the list of products under each entry.

3(ii) – Enhancing the identification of approved devices



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The TGA is also proposing to amend the legislation to require sponsors of medical devices to publish the ARTG number on the information that accompanies a medical device (e.g. the product labels, instructions for use or packaging of the device).

This is expected to increase visibility of the ARTG number for medical devices to enable healthcare providers and consumers to easily identify medical devices approved for supply, and assist in cross referencing the device with the ARTG record. This change will also greatly enhance the TGA's ability to identify, and better manage those medical devices that have been supplied to the Australian market without first gaining approval by the TGA.

This amendment is in line with medicines regulations which require the AUSTR or AUSTL number on the label.

Cost Implications

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 amendment would only require sponsors to add the ARTG number to their contact details.

Proposed Transition Times

The TGA proposes to implement this proposal 12 months following the amendment of the regulations.

Sponsors will be required to label all devices with the ARTG number in accordance with Regulation 10.2 (amended) and essential principle 13.2 Information to be provided with medical devices – location.

Legislative Changes
Amendments to the regulations will be necessary to require sponsors to include the ARTG number on the label.

## Proposal 3 Response

BIOTRONIK recognises that this measure would aid the TGA in post-market surveillance. Since BIOTRONIK has and continues to fully support TGA in their post-market vigilance programs, we understand and support this proposal.

It is understood that the requirements for the addition of the ARTG number would be no different to the legislation for regulation 10.2 were the placement of the sponsor's name and address should take into consideration the user of the device:

**10.2 Information about sponsor**

(1) The sponsor of a medical device must ensure that the sponsor's name and address are:

(a) provided with the device in such a way that a user of the device can readily identify the sponsor; and

(b) located in accordance with clause 13.2 in Schedule 1.

However, we would reject any proposal to place the ARTG number on the label of the product itself because this would require country-specific labeling which is not feasible.



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