BOSCO
MEDICAL AUSTRALIA

13 December 2010

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

Re: Discussion paper dated 25 Oct 2010 response

To whom it may concern,

Our response to the discussion paper released by The Therapeutic Goods Administration (TGA) on the 25th October 2010 is as follows:

1. Publication of device information on the TGA website

- We do not see the requirement for more information on each product listed with the TGA to be placed on the TGA website as this information is freely available from the sponsor. Detailed information can be placed on the sponsor's website so that it can be accessed by the end user in a controlled manner. We would need to control who is accessing the information on every product that is currently listed with TGA.

- Also who would bear the cost of uploading a substantial amount of information onto the TGA website? If the sponsor is to bear the cost then it is another cost burden that in the end would have to be passed onto the end user. If we were to upload the information onto our website this can be completed in house and at minimal cost.

2. Requirement to add the product name to the registration

- If this is passed as a requirement then a transition period would need to take place and no fees charged for the variance as for us to add product names to every listed device would be a substantial cost. If each addition is seen as a variance with a cost of $350.00 for each variance.

- Your discussion document is suggesting all existing "inclusions" are to have detailed product descriptions by the sponsor added (over a period of time). We believe this is effectively back dating legislation. Backdated legislation is frowned upon by most democracies and has been said to be bad legislation. This type of change should only be enforced for new listings if at all.

- The transition period would be required to be at least 24 months due to the sheer volume of variations that would be required.

3. Requirement to have ARTG Inclusion Number printed on packaging supplied with the product

- We are very concerned over this requirement, if passed, as it would have an extremely large detrimental impact on our supply chain and overall business, Australia's 24 million population is a very small part of this world when it comes to the manufacturing process. Overseas manufacturers will not see the need to place Australia's ARTG Inclusion Number on product that they manufacture for the rest of the worlds 2 billion population. The impacts it would cause are as follows:

    - Disruption to the manufacturing process due to having to stop the normal production processes and change printing formats for one small order and then change it back after the run has been completed. This would see a significant delay in the delivery time line of the product and also a very significant cost to the manufacturer and in the end to us and that would need to be passed on to the end user. A lot of manufacturers simply will not bother to

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complete this requirement. Inevitably this would lead to Australian sponsors having to place stickers on the product in Australia. Under your current TGA legislation, if a sponsor over stickers the labels of any product they automatically become a manufacturer. This would then lead to all the registration problems that this entails.

- The manufacturer would also need time to implement the changes that may be required by TGA and after some discussions with our main suppliers they have indicated that this would not be able to be implemented at all. If this is the case then we would not be able to supply the product into Australia thus causing a detrimental impact to our business and potentially closing the doors.

- This would affect the smaller qty orders from suppliers and would require for us to place significantly larger orders to have special print runs completed and thus increasing our stock levels to unmanageable levels and also a higher turnover in out of date stock.

- What level of packaging would require having the ARTG Inclusion Number printed on it? As for the Custom Procedure Packers buy their product in bulk unsterile packages so each product would not be able to carry the ARTG Inclusion Number and who would be deemed as the manufacturer in this instance? The supplier of the product or the CPP Manufacturer that is repacking it into a procedure pack?

- Most of the Medical devices that are sold in Australia carry the manufacturer's details as per Regulation 10.2 and Essential Principle 13.2; this is done by the manufacturer at the time of production and is required by most regulatory bodies around the world. As per my previous point to add the ARTG Inclusion Number would mean a complete manufacturing run for Australian product and this cannot be done. Most Australian suppliers supply their invoices with the goods and this can have the ARTG inclusion Number added to it for the information of the hospital.

- Page 23 states that it would increase the visibility of the ARTG Inclusion Number for the end user and to identify if the product is approved for supply. We currently complete this with the purchasing officer in each of the facilities and also with each state supply board before the product is supplied for use.

- In our opinion there is no risk level to public health that will be alleviated by placing the ARTG Inclusion Number on the packaging what so ever. We are not aware of any other regulatory authority worldwide requesting such oppressive and nonsensical labelling.

- BMA's suggestion on this point is to include all relevant TGA information on the company's website; and this can be completed in house with and causes no disruption to the manufacturer or supply chain. This could also be completed in a the shorterest time frame of with 2 – 3 months. The following would be the suggestion for the information contained on the website portal:

  - Product Name and SKU - ARTG Inclusion Number - Inclusion Certificate – Product Information

  This would be beneficial to all parties as follows:

  - TGA is not burdened with updating the information or ensuring it's accuracy but at the same time have access to complete a surveillance report on the information

  - The end user will have access to download information as required

  - Significantly less disruption to the supply chain and cost implication for BMA

  - This suggestion would also comply with the discussion points raised in the discussion paper

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Thank you for your time and if you have any questions or comments please contact me.

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