Friday, December 17, 2010

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

To Whom It May Concern:

Please find on the following pages the Multigate response to the consultation paper ”Reforms in the Medical Devices Regulatory Framework” – October 2010.

We have commented on the Proposals which directly impact on our company. We appreciate the opportunity to contribute our point of view during the consultation process

Yours sincerely

Dr Stephen Firmer

Scientific Affairs Manager

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

We believe that this proposal will impose an inappropriate administrative burden on both our company and the TGA. In addition we believe that this proposal will lead to increased costs which are disproportionate to the perceived community benefit.

An example of the difficulty in the current proposal for us would be custom procedure packs. It is usual for different hospitals to require slight variations which in effect customise the pack to the particular requirements of a surgeon and hospital. Under the existing system, these can be grouped under a limited number of ARTG inclusions. If the new system is implemented this will impose on us the need to include every slight variant which has unique identification for inventory control purposes under the relevant ARTG. We estimate this could increase our administrative burden to the amount of up to 100 applications for variation to the ARTG each year. In addition we can foresee a very long list of items under each ARTG.

We do not believe this extra administrative burden will enhance the regulator's ability to monitor safety and performance for custom pack type of product, nor will it enable the regulator to ensure that all the devices in the list are the same type of device.

Proposal 3(ii) Enhancing the identification of approved devices

We believe that aim of this proposal may be better achieved through the use of GTIN numbers. It would be easy for relevant health professionals to determine the ARTG number for a device with reference to the GTIN number as this cross reference information is already available in the NPC database. For many devices (especially if only used by medical professionals in a hospital environment), the ARTG number is of little interest for consumers.

We also believe that a 12 month transition will impose undue cost on manufacturers if they have to retrospectively mark existing stock which may have a shelf life of up to 5 years.

Proposal Publication of device product information on the TGA website

We believe that this proposal should be restricted to devices of a higher classification – such as Class III and AIMD as the public benefit of having this information available for lower risk devices does not warrant the cost and administrative resources to keep such information up to date.