William Green
www.williamgreen.info
SUPPORTING DENTISTRY

15th December 2010

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

Dear Sir/Madam

Re: Reforms in the Medical Devices Regulatory Framework 25 October 2010

Thank you for providing William Green Pty Ltd an opportunity to comment on the proposed Reforms in the Medical Devices Regulatory Framework dated 25 October 2010.

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

The proposed changes indicate a requirement for itemisation of devises and/or various "models" and the continued requirement of listing "new models" as they become available; in our view it is unclear in the proposed reforms what constitutes a "model" and a "new model". We share the following example for the TGA to consider. A device today which carries a single ARTG could be identified by a "product ref number" determining very minor factors as, the colour, shape, orientation, paint finish, footprint size, etc., etc. All of which have no impact on the functionality of the product in its use or patient outcomes. The same could also be said for new "product ref numbers" becoming available and changes could occur which has no impact on the functionality of the product in its use or patient outcomes thus we recommend that the TGA include the requirement for a model name (but not the model number) and the TGA only receiving notification and significant changes take place. We recommend that the TGA consults with the industry to determine what constitutes a significant change. The proposed transition time of 1 year is too short and would not be met therefore we request that the transition time of 3 years be provided. In its current form the TGA proposed reforms substantially alters the existing regulatory arrangements for business and will result in a very large initial one-off cost to business and significant ongoing costs to our business eventually escalating the cost of healthcare in Australia.

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Proposal 3(ii) enhancing the identification of approved devices

It's our view that the proposed reforms do not clearly stipulate or define what the requirements are of a sponsor, is the TGA asking for labelling to occur on each of the examples shown in the discussion paper "e.g. the product labels, instructions for use or packaging of the device" or just one of the three examples provided by the TGA, or is the TGA requesting that the device itself be labelled with the ARTG number. This proposal is of concern to our company with devices manufactured locally and overseas having a requirement for special production runs for product for the relatively small Australian Market. The proposed transition time of 1 year is too short and would not be met therefore we request that the transition time of 3 years be provided. In its current form the TGA proposed reforms substantially alters the existing regulatory arrangements for business and will result in a very large initial one-off cost to business and significant ongoing costs to our eventually escalating the cost of healthcare in Australia.

Proposal 4 Publication of device product information on the TGA Website

We support improving transparency but consideration needs to be given to the benefit it will bring vs. the cost to the industry and the consumer. The proposal in its current form will result in a very large initial one-off cost to business and significant ongoing costs to our business eventually escalating the cost of healthcare in Australia. We feel that high risk devices in Classes III and AIMD is reasonable as they are high risk however what benefit will be provided to industry and consumers in publication of low risk devices. There is no public interest in publicising rejected applications.

Again we thank you for the opportunity to comment and trust that our suggestions will be taken into consideration. If you have any questions regarding the above please do not hesitate to contact us.

Yours sincerely

Evette Kellie

Regulatory Coordinator

William Green Pty Ltd