29 November 2010

Therapeutic Goods Administration
PO Box 100
Wooden, ACT, 2602
Att: Office of Devices Authorisation

Re: Reforms to the Medical Device Regulatory Framework

Dear Sir/Madam,
Following the information meeting, 23 November, 2010, we wish to draw you attention to a number of concerns associated with the reform proposal.

1) The area of harmonisation relating to of FDA 510(k) is an area that requires review. Both the FDA and TGA are founding members of the GHTF and the TGA proposal states that there are many common characteristics exist between FDA and TGA. The current situation sees an imbalance in the conformity assessment process. Sponsors of FDA products face an additional financial burden in order to meet EU conformity which has a direct impact on the cost of healthcare to consumers/patients.
2) Proposal 3. The claim that theses changes are being made following consumer driven concerns needs to be transparent, with support evidence being supplied to industry for review and comment. Practical Consideration: Take a typical visit to a dentist, unless the dentist is regulated and required to provide the consumer/patient will a complete list of products used including ARTG No.s, what is the consumer/patient benefit of this proposal. Consideration must also be given to reusable devices (autoclavable items), as they are routinely used as part of common healthcare appointments. How does this new framework address this application?
3) Proposal 3. For the labelling of products to be accurate, it is essential that this application forms part of the manufacturing process. In order for a manufacturer to consider such additions valid justification will be required; assessment will be required to review existing processes and hardware, even before costs can be considered. With many products being visually similar, and some products ranges incorporating thousands of items, the thought that labels can be manually applied to each product is an oversimplification of the process and would be highly error prone. This manually intensive process would also place significant additional costs on sponsors; these costs would be passed onto consumer/patient which intern increases the cost of fundamental healthcare.

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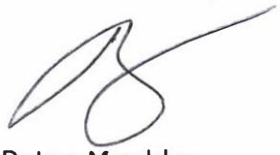
4) Direct importation of products not registered on the ARTG. With the internet and a global community, healthcare providers can readily purchase products direct from manufacturers and grey market profiteers. This is a perfect opportunity for the TGA to develop a co-operative approach with industry which tackles exposed loop holes creating even greater consumers/patients confidence.
5) A fundamental reality is that increased consumer/patient costs for healthcare will place greater pressure on the public system. More and more individuals will be forced to move away from private healthcare stretching an already oversubscribed system with lengthy waiting periods.

We wish to state that we are supportive of a practical reform program however we object to the proposal in its current form. We encourage the TGA to review the scope of these reforms and invite industry to take on a more significant role within this process.

Yours sincerely



Peter Mackley
Director