Worldwide Regulatory Affairs & Quality Assurance
Pfizer Australia Pty Ltd
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38 - 42 Wharf Road
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Australia

20 December 2010

The Coordinator
Re: Comment on Reforms in the Medical Devices Regulatory Framework
Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir/Madam,

Re: Comment on Reforms in the Medical Devices Regulatory Framework

Thank you for providing the opportunity to comment on the '*Reforms in the Medical Devices Regulatory Framework*'. Pfizer's comments are outlined below.

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

Definition of Assessment/Approval by TGA – the discussion paper mentions assessment of new applications for Class IIb devices. Pfizer would recommend further clarification be provided on what basis such applications will be 'assessed' and 'approved', and whether significant/technical data would need to be submitted?

Pfizer would also like to seek clarification regarding lower class devices (i.e. below Class IIb). If lower class devices will not undergo an assessment, then what is the nature of the application to be submitted for lower class devices and on what basis could such applications be rejected?

This proposal will potentially have a significant impact on the cost of medical devices, especially lower class devices. Perhaps a notification system could be considered for lower class devices instead, which would not attract fees.

Submission of applications for new models – devices tend to be different to medicines in terms of the volume of models/types of instruments and implants. In some cases there can be several hundred device codes per inclusion. It would be good to learn if there may be a potentially detrimental impact to the ARTG (e.g. decreased speed of website) as a result of including possibly thousands of extra line items. Itemisation of devices is already detailed on the Australian Declarations of Conformity. As an alternative, this could be supplied to the TGA via notification, without a new application being required.

Cost implications – the added fees to maintain multiple ARTG entries where previously there was one will be significant for many sponsors. While it is acknowledged that the annual charges are apparently not going to be affected, the requirement to submit multiple variations for a single change across several devices has not been addressed. The rules associated with the administration of these fees needs to be considered further.

Proposal 3(ii) Enhancing the identification of approved devices

While we acknowledge that the proposed change should not adversely impact on regulatory costs for sponsors that are already required to publish their contact details on the information that accompanies a medical device, we note that not all devices have an Instruction for Use (IFU) and/or label e.g. they are not required for low class devices with obvious use. Therefore, it would be useful to have further clarity on how the proposed change will be applied to these types of devices (e.g. would additional leaflets be required specifically for Australia), as it could lead to additional regulatory costs.

Proposal 4 – Publication of device product information on the TGA website

Publication of a document similar to an AUSPAR – we deem this to be appropriate only for Class III and AIMD devices, and perhaps only for those that have undergone Conformity Assessment by the TGA. The TGA should be responsible for authorship only if the documents relate to the decision-making process. We also believe that rejections should not be published as they can easily be taken out of context.

Provision of Product Information – device technology is constantly changing and evolving, at a much quicker rate compared to medicines. The maintenance of substantial Product Information-type documents is onerous, especially for the smaller Australian-based manufacturers. We consider that the responsibility for the provision of information should rest with the manufacturer, the stakeholder responsible for conducting the risk analysis.

Of note is the fact that the lower risk medicines (i.e. those available without a prescription) do not require a PI or CMI. If a PI is considered necessary by stakeholders, it should be for the higher-risk medical devices. Medical devices are largely used by doctors or healthcare workers and not self-administered. This also needs to be taken into account when PI and CMI for devices are being considered. We suggest that the legislation for the provision of device information could be amended to allow companies to supply IFUs to health care professionals and/or consumers via company websites, instead of requiring pack inserts or TGA website postings.

If there are any questions regarding these comments, please do not hesitate to contact me at 02 9850 3328 or by email at AustraliaTGA@pfizer.com.

Yours sincerely,