Johnson & Johnson Pacific

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

16 December 2010

Dear Sir/Madam,

RE: Comment on Reforms in the Medical Devices Regulatory Framework

Johnson & Johnson Pacific (JJP) and VisionCare Australia wish to provide comments on the proposed changes to the Medical Devices Regulatory Framework.

Proposal 3i - amend the way in which a kind of device is included on the ARTG

JJP supports the change to have all trade names to be listed under the ARTG entry. There are some points however that need to be considered before implementing the change. Clarity of the definition of what constitutes as an individual device will be required. For example devices such as contact lens and wound dressings may have the same technology but may come in different shape, sizes and design. If each variation of a device is required to be listed, the ARTG entry will contain a long list of products making it difficult for healthcare professionals, consumers, TGA and sponsors to navigate.

Clarity on the process of how products will be included on the ARTG entries will be required. JJP proposes the same system which is currently used for 'Other Therapeutic Goods' eg Tampons, could be followed. One point for consideration would be whether the eBS system will allow one ARTG entry to be used when formulated Medical device share the same GMDN and manufacturer but have different formulations.

JJP proposes the addition of products into an existing ARTG entry should be listed via a fee-free notification system rather than a variation. This system will reduce additional workload for TGA and sponsors as well as speeding up the time for products to be included on the ARTG. If a fee is required for the listing, the fee should only account for the administrative work involved.

Proposal 3ii – enhancing the identification of approved devices

JJP do not agree with TGA's proposal of including ARTG numbers of on medical device or the product labels. If **Proposal 3i** is implemented and all trade names appear on the eBS under each ARTG entry, the TGA search function will allow healthcare suppliers, consumers and TGA, to easily search for trade names on the eBS and identify the devices that approved for supply.

In addition, the following issues would arise if ARTG numbers are required to be on the medical device or product labels:

- Sponsors may have various manufacturing sites and to have new artwork developed to include the ARTG numbers for a large range of products is not logistically feasible and would create a large amount of work for sponsors. This

change would also be very costly as new print plates will need to be installed and existing artwork may need to be destroyed due to the short 12month transition time proposed by TGA.

- In the case of medical devices that are imported from overseas markets (shared artwork), we may be put into a position where we are required to over-label the products to introduce the ARTG numbers as other countries may not agree with the change to artwork. This in effect will create additional workload and costs. It should be noted that the over-labelling costs would not just be a one off cost but ongoing.
- The TGA expects the visibility of ARTG numbers will enable healthcare providers and consumers to have an easier identification of products with reference to the ARTG records. However, there may be various products with same ARTG numbers which could create further confusion.
- Confusion could arise when the same medical device is manufactured in two different sites which will create two different ARTG numbers.

JJP believes the introduction of ARTG numbers on product labels on the medical device will only create extra costs and workload for sponsors for questionable benefits for consumers, healthcare suppliers and TGA.

Proposal 4: publication of device product information on the TGA Website.

CMI's and PI's are currently only required for certain medicines. The suggestion of establishing similar publications for medical devices should only be included for higher risk classification devices such as some Class III devices (used in healthcare professional environments only) and AIMD's. We believe there is no value for lower risk classification devices to have published information on the TGA website because there is sufficient information supplied with medical devices, which is a requirement of complying with the Essential Principles.

It should be noted that CMI's and PI's for medicines are approved by the TGA before they are published. Since lower risk devices are not assessed by the TGA prior to marketing, the information that would be published on the TGA website for the devices would not have been validated.

JJP suggests the information presented for higher risk classification devices should target healthcare professionals only as the information may not be appropriate for consumers. Information could include product name, intended purpose, GMDN and classification code, sponsor/manufacturer details, safety data, instructions for use, dosage if applicable and date of approval.

Should you have any questions in relation to the issues and comments raised, please do not hesitate in contacting the undersigned.

[Contact details removed at request of the undersigned.]