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**Re: Submission comments on proposed Regulatory Reform Framework**
**Proposal 3 and Proposal 4**

Dear Shelley,

We wish to provide some feedback on the proposed reforms to the Medical Devices Regulatory Framework.

## Background

Draeger Medical Australia is a subsidiary of overseas manufacturer Dräger Medical GmbH Germany and a Sponsor/Importer and direct supplier of Class 1 to Class llb critical care medical equipment and associated accessories to public and private hospitals in Australia. We do not supply any over the counter therapeutic goods to the general public.

## Proposal 3

3 (i) In principle we support the proposals to amend the way in which a kind of device is included on the ARTG and enhance the ability to identify devices that have been approved by the TGA for supply.

- We agree with the proposal to itemize the devices and/or various models that are supplied under the same ARTG entry and that this information is available in the public view of the ARTG.
  At the time of initial inclusion it is not always possible to be aware of all the devices or models that will become available in time under that same kind of medical device.
- When new models become available and need to be added to the ARTG inclusion a complete new application should not be necessary for a ‘same kind’ of device.
- Any cost for varying an existing inclusion should be covered by the annual licence fee as currently happens for variations to Manufacturer’s evidence.

- We would propose that the initial entry be amended/varied and a Manufacturer Declaration of Conformity for the new model be attached as evidence of the required conformity assessment.
- For current ARTG entries the proposed period of 12 months would be sufficient time for our ARTG inclusions to be updated to include the information for all models. However we would recommend that a 3 month window be allowed before the 12 month period comes into effect.

3 (ii)

- We consider that this proposal is not a practical solution to enhancing the identification of approved devices, due primarily to the labour time and cost of labeling devices and accessories with the ARTG number when imported goods are received into inventory. There is also the risk that devices could be incorrectly identified.

It should be noted that over the last three years all suppliers of medical devices to Australian public healthcare institutions have provided the ARTG numbers of medical devices and medical device accessories when including their products in the National Product Catalogue (NPC) which is an initiative from the National E-Health Transition Authority.

- In addition if proposal 3 (i) is implemented then the device will be easily identified by both the TGA and users by accessing the ARTG on the TGA website.

## Proposal 4

- For the types of medical devices we supply to end user healthcare professionals in public and private hospitals; viz. intensive care ventilators, anaesthesia workstations, patient monitoring systems, infant incubators and emergency transport ventilators, we do not see any increased value in publishing information regarding medical device assessments as proposed in proposal 4.

Our users are only interested in knowing if the device is “TGA approved”.
Comprehensive information is supplied in the accompanying Instructions for Use.

Yours sincerely,
Jim Collins
Quality & Regulatory Affairs Manager

Date: 15 December 2010