GE Healthcare

Building 4B,
21 South Street
Rydalmere NSW 2116
Australia

T 612 9846 4000
F 612 9846 4001

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

Re: October 25, 2010 Discussion Paper – TGA Reforms in Medical Devices Regulatory Framework

General Electric (GE) welcomes the Government's Discussion Paper regarding the proposals to reform the regulatory framework for medical devices to further improve the way medical devices are regulated in Australia.

GE Healthcare provides transformational medical technologies and services that are shaping a new age of patient care. Our broad expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, performance improvement and performance solutions services help healthcare providers to deliver improved health services and patient care.

As a leading healthcare medical device technology provider in Australia, GE Healthcare appreciates the opportunity to provide input on the following specific reform proposals:

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

Under the registered GMDN code, different devices/models will need to be identified. These will be visible for public view on the TGA website.

Comment: While GE Healthcare welcomes the increase in transparency, safety and performance of this amendment, due to the number of medical devices and models we have the transition period of 12 months from the date of legislative changes may not be sufficient as it will put great pressure on our very limited sponsor resources. A 2-year transition period is recommended in order to ensure a smooth and effective implementation.

Furthermore while the proposal is to have a transition period with no fees is certainly appreciated, given the current economic climate. The TGA proposal to introduce a fee to vary the inclusion after the transition period requires further clarification in order to establish the annual business impact. It is recommended that the future cost structure is made available for further discussion in order for GE Healthcare to understand the full impact of this proposal.

Proposal 3(ii) – Enhancing the identification of approved devices

Sponsors will be required to label all devices with the ARTG number in accordance essential principle 13.2 Information to be provided with medical devices – location.

Comment: While GE Healthcare recognises that this will provide consumers easy identification of medical devices approved for supply and assist in cross-referencing devices with the ARTG record, again this will result in significant effort required on local sponsor resources at the regulatory and commercial level to ensure every product has a separate label with the unique ARTG number. While sponsors currently provide their contact details on the label, a generic label is printed for this purpose. The proposed amendment will require sponsors to product specific label for each device/model resulting in increased complexity and costs in installing, servicing and maintaining medical devices. It is recommended that the TGA considers a label with a website reference to ARTG listings as an alternative option to enable a generic label to be maintained locally and also reduce the risk that a device model may be incorrectly labelled by the manufacturer. Consumers will thus be able to access and cross-reference real time the currently approved ARTG number for a specific model.

With regards to the proposed transition time frame of 12 months following the amendment of the regulations, further clarification is required to confirm if this applies to new products registrations and if this is retrospective of the manufacturers current devices that are installed. If the amendment is retrospective a 12-month implementation period is not realistic and a longer transition period will be required subject to the manufacturers active install base.

Proposal 4 – Publication of device product information on the TGA website
Increased transparency of device product information on the TGA Website, including information relating to rejected applications.

Comment: GE Healthcare supports the increasing transparency and accountability in the TGA's decision making processes and endorses the publishing of all relevant information relating to any approved registered medical devices. With regards to publishing information relating to rejected applications, it must be highlighted that some of the information provided may be commercial in confidence at that point in time and a manufacturer may consider resubmitting the application in the future based on the TGA's decision and feedback. Publishing and releasing product submission rejections may thus not be not relevant as healthcare professionals interest and concern is focused on accessing timely information of the registered medical device to improve consultations with patients.

Thank you for the opportunity to comment on the proposed reforms, GE Healthcare looks forward to continuing discussions in order to further clarify some of the amendments proposed and respective transition times.

Please do not hesitate to contact me directly on +61 2 9846 4874 or diane.day@ge.com

Yours sincerely

Diane Day
Regulatory Manager
GE Healthcare Australia Pty Ltd