CareFusion Australia comments on discussion paper on proposed changes to the regulation of devices

Proposal 1 - Reclassification of Joint Replacement Implants

CareFusion: No comment

Proposal 2 - Third Party Assessment Bodies and Supporting Reforms

2A The removal of Subregulation 4.1(1) from the medical device Regulations, so as to no longer require Australian medical device manufacturers to hold TGA conformity assessment certification;
CareFusion: This is a positive initiative.

2B The proposal to increase pre-market scrutiny for implantable medical devices by amending:
(i) Subregulation 4.1(2) of the medical device Regulations to require a TGA conformity assessment certificate to also be issued for all Class III and AIMD
(ii) Regulation 5.3 of the medical device Regulations to require applications for all Class IIb implantable and long-term surgically invasive medical devices to also be selected for an application audit prior to inclusion in the ARTG;
CareFusion: This is a positive initiative.

2C Increasing third party assessment of devices:
(i) That the TGA commence discussions with the EC over a program of confidence building with the designated Notified Bodies under the MRA, to include sharing of product assessments and joint audits of medical device manufacturers; and
(ii) That further consultation be undertaken to investigate the development of a system whereby Australian based assessment bodies can be designated to issue conformity assessment certificates to Australian manufacturers;
CareFusion: This is a positive initiative.

Proposal 3 - Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices

3(i) – Amending the way a kind of device is included on the ARTG
Sponsors will be required to identify the different models in the application form, to be assessed by the TGA prior to making a decision to include the devices on the ARTG.
CareFusion: This is achievable as sponsors are already required to hold Declaration of Conformity which should list the models. However TGA will need to issue guidance documents on how to prepare an inclusion dossier.

This comment is based on the assumption that "model" means a brand name, rather than "product code" which is for commercial transaction.

e.g. Using an arbitrary configurable product called Alpha.
Model: Alpha
Product Code: Axxxxxxxxx where A stands for Alpha, x stands for different configurations. The x codes are generated each time when a customer places an order. It will be impossible to provide all the product codes in the ARTG inclusion application.

For procedure packs, it is suggested that the 'list' of model codes provided per Inclusion does not state the revision, just the base code due to the frequency of the changes and the differing circumstances between a pack and a 'regular' imported finished good device. We say this as in this context (or in the TGA's context) a variation to an Inclusion implies an addition of a new code/SKU to the itemized list associated with the ARTG Inclusion number. It would also include any 'significant' modification to a finished device, normally meaning the functionality, operation, or inherent design of the product has changed in some way (as opposed to adding a component to a pack that has not been 'modified', but just included in the pack).

As new models become available, sponsors will be required to submit an application to vary the existing ARTG record to add a new model of that kind of device. This new model would undergo assessment if the kind of device is Class IIb or above, and if it meets the requirements for supply, will be added to the ARTG.
CareFusion: This proposal is confusing as it only applies to Class IIb or above. That means for Class IIa and below there is no value identifying all the different models when applying ARTG Inclusion for the first time. Sponsors will simply include one or two models at the first application, then add all the rest of the models later to avoid unnecessary scrutiny by the TGA.

3(ii) – Enhancing the identification of approved devices
The TGA is also proposing to amend the legislation to require sponsors of medical devices to publish the ARTG number on the information that accompanies a medical device (e.g. the product labels, instructions for use or packaging of the device).
Sponsors will be required to label all devices with the ARTG number in accordance with Regulation 10.2 (amended) and essential principle 13.2 Information to be provided with medical devices – location.
CareFusion: This is not achievable as the majority of devices in the Australian market are imported devices. Being a small market globally, requiring overseas manufacturers to create dedicated labeling, IFU or packaging for the Australian market is unrealistic. Such proposal will simply cause many manufacturers to withdraw from the Australian market, thus restricting Australians' access to many of the best and latest medical technology.

The objective of this proposal can be achieved by simply requiring the sponsors to make the ARTG information available to the users via a suitable media.

Adding an ARTG number to the product, and documenting all product codes associated with each Inclusion does not necessarily increase *the vigour of regulatory assessment*. The labelling provides a display of the ARTG number to identify the items has been approved by TGA, and the list of codes accompanying any ARTG number allows visibility of what product codes belong to which ARTG, but this does not actually mean TGA has performed any more rigour in regulatory assessment. Nothing in Proposal 3 actually involves TGA performing any additional assessment. Itemising and labelling products does not increase regulatory assessment or product safety.

There should also be no cost to industry when adding codes (i.e. making a variation) to the list of products covered by an ARTG Inclusion. If safety is truly the motive then no cost should be born by industry to provide additional information for the TGA database.

CareFusion's overall comment on proposal 3:
It seems TGA is attempting to make the regulation for medical devices the same as for medicines. This is not practical as devices are much different to medicines in how they are registered and monitored, and imposing the requirements of medicines on devices would make the process too onerous and unworkable for device companies.

- Medicines very rarely have variations or changes, medical devices regularly have changes.
- Medicines have a unique Aust R number per medicine. Devices have many multiples of product codes with the same Aust I number.

Proposal 4 - Publication of device product information on the TGA Website

- The types or classes of devices which should be included in such a scheme:
- Only higher risk classification devices such as Class III and AIMD;
- All medical devices including lower risk classification devices;
- All higher risk medical devices, and 'more interesting' lower risk devices where the technology is new or innovative for example;
- The information which should be included when published, including the depth of that information;
- Responsibility for authorship of the information (i.e. the manufacturer or the TGA);
- Responsibility for ensuring information is up to date;
- Whether to publish, or not, information relating to rejected applications.

CareFusion: This proposal is of good intent but unfortunately it is more likely to cause harm than good. It will be extremely difficult to keep the TGA website up to date. The users will be confused as there will be two sources of information, one of them may be obsolete at any point in time. The only credible source of information should be from the manufacturer, either published in their website or provided to the users directly. TGA's role should remain as the Competent Authority, not as a source of information on behalf of the manufacturers.

Rejected applications of any class should not be published as they are irrelevant and obsolete information. Publishing rejected applications does not add value but cause more confusion to the users.

Prepared by:

Neil Ross
Plant Manager ANZ

CareFusion Australia & New Zealand
6 Coronation Avenue
Kings Park NSW 2148
PO Box 4366
Marayong NSW 2148
Australia

Direct: + 61 (0) 2 9830 0114
Mobile: + 61 (0)408 622 287
Fax: 61 (0) 2 9830 1230
neil.ross@carefusion.com

Alex Leung
Quality & Regulatory Affairs Manager Asia Pacific

CareFusion
3/167 Prospect Highway
PO Box 355
Seven Hills NSW 2147
Australia

Direct: +61 2 9624 9006
Mobile: +61 439 644 760
Fax: +61 2 9624 9034
alex.leung@carefusion.com

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