Good Afternoon,

Please find below consultation feedback from Biomedical Technology Services, Queensland Health on the Medical Devices Regulatory Framework Discussion Paper dated 25 October 2010.

Proposal 3 - Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices.
Full support for both parts 1 & 2 of this proposal.
The model field should be searchable to allow for improved searchability of the ARTG.
Proposal 4 - Publication of device product information on the ARTG Website
Full support for developing this added functionality, it will be of great benefit to consumer organisations such as QH.
1. 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.
All medical devices including lower risk classification devices should be included. It is often the lower classification devices which we have the most trouble locating information on. These added features on the ARTG would improve the access to information greatly.
2. The information which should be included when published, including the depth of that information
Information which would be beneficial if it were published.
- All current information on ARTG
- Information similar to that available on FDA website (copy of ARTG certificate, Summary of Safety and Effectiveness Data, Instructions for Use, Patient Instructions, Web links to general resource information)
- Itemised list of models as per Proposal 3
- As far as practicable the identity and address of official distributors (from sponsor)
- Relevant history of sponsor, manufacturer and distributor changes etc.
- Other ARTG entries which the product may be used in combination with each other or as a system. - List or link the other ARTG #'s
- Suspended, removed or withdrawn entry (be it all entries under an ARTG number or just 1 model)
- Service manuals and amendments
- Relevant dates - expected end of serviceable life, date withdrawn from market
- Recalls of publishable (consumer) level, detail of recall, the date of recall and whether corrective action has been completed or not
- It would be great to have a Health Professional level of access where recalls of all levels could be published on the ARTG
3. Responsibility for authorship of the information (ie. the manufacturer or the TGA)
The manufacturer and sponsor should be responsible for the authorship of most information. Some of the information we have proposed such as inclusion of consumer level recalls should be authored by TGA.
4. Responsibility for ensuring the information is up to date
The sponsor should be responsible for ensuring the information is up to date.
5. Whether to publish, or not, information relating to rejected applications:
- Should all rejections be published, including lower risk classifications such as Class I and IIa;

- The information which should be released if the application is rejected;
- The reasons for rejection

We can see limited benefit in obtaining information about rejected applications except in the instances where

- The application has been rejected as the TGA believes that the product is not a medical device. This can then be used as evidence by the sponsor that the product is not required to be on the ARTG.
- The product is rejected and for whatever reason the product is still supplied in Australia prior to or post rejection. Rejection information will be beneficial in identifying a perceived breach of the Act in that the product was supplied without an ARTG number. It may also be useful in providing advice to a consumer organisation for replacement of the rejected device.
- An application is made to an ethics committee for a clinical trial or to the special access scheme then it would be beneficial to know if that device has been rejected from inclusion on ARTG

However, if a product was rejected for some reason, then the manufacturer makes the required improvements and successfully re-applies for inclusion on the ARTG, then the rejection information should be withdrawn. This information should be able to be used to judge a product against another for having had a rejected application or not.

Thanks for the opportunity to provide input into the proposed changes
Kind Regards
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