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16th December, 2010

Coordinator
Re: Comment on Reforms in the Medical Devices Regulatory Framework
Office of Devices Authorisation
PO Box 100
WODEN ACT

Via Email: odaconsult@tga.gov.au

Dear Sir / Madam

RE: Comment on Reforms in the Medical Devices Regulatory Framework

Seating Dynamics Australia Pty Ltd welcomes the opportunity to comment on the proposed reforms to the medical device framework.

Background:

Seating Dynamics is distributor for a number of global manufacturers of equipment for people with disabilities. Products include wheelchairs, cushions, back rests, postural support products and accessories. Our products are sourced from eight manufacturers, all within the USA, Canada or the UK. We employ a clinical consultant (Occupational Therapist) and a number of product experts with 20-30 years experience in the prescription and use of our products. The company is owned by 4 persons, three of whom (including myself) are wheelchair users with 104 combined years of experience of using our type of products.

We service a wide sector of people with a disability. We have a network of over 50 dealers nationwide. I believe we are in a position to offer a good perspective on the impact to the proposed changes to the regulations. In summary we see that there will be little no benefit to the consumer, despite a huge cost burden, which will passed onto the consumer (in our case these are often low income consumers due to their disability).

COMMENTS ON RECOMMENDATIONS

Proposal 3(i)

1. How does having this additional information add to the safety or quality of a device? Changing the definition of a "kind of medical device" will not enhance the identification of approved devices

2. TGA stated they were concerned that some sponsors were manipulating the process. A much more effective way to stop manipulation/breaches would be to prosecute those who are doing so and provide public notices of what punitive action was taken. This would do more to encourage compliance than the proposed changes without adding the significant cost the proposed changes would.

3. If this change is accepted then under no circumstances should any fees be charged for a variation.

4. Considering the amount of information required a 12 month transition is far too short.

Proposal 3(ii)

This is of great concern to our company, similar companies and to our dealer network. Following is summary of our concerns:

1. What is the Real Benefit to Consumer or Healthcare Sector
    a) The TGA has not developed a rationale as to why this is needed and what, if any, safety or quality benefits would flow from placing the ARTG number on the device.
    b) Medical Devices should not be compared to Medicines.
    c) This issue should be looked at in isolation and an impact statement drawn up.
    d) The regulatory impact statement needs to be done by an experienced person, or group, who understand the costs associated with manufacturing and logistics. It should not be done by someone in the TGA who only understands the process involved in preparing the document to satisfy the Finance Department rules.
    e) The Australian Standards also have labelling requirements. The way it is moving there will be multiple labels on every product/container adding to confusion and frustration to suppliers and end users.

2. Cost and Complexity
    a) This is going to be enormously expensive for the sponsor. There is no evidence of rationale that it will give a gain in safety or quality.
    b) I believe this will actually make it easier for those in breach of the TGA requirements to continue to do so. In 2010 we reported a company that had brought a significant amount of our product into the country. They are not listed as a sponsor for the product (and could not be as our manufacturing partner would not endorse them). Despite several calls to the TGA to find out what had happened with this we received no information. The company continues to use the product brought into Australia in breach of the TGA requirements for commercial use. If the labelling is brought in what would stop a company such as this taking our ARTG number and putting it on product they brought into the country? The end consumer would have no way of knowing, we would have no way of knowing and even if we did, given the lack of action of the TGA to the initial breach, what would be the use of reporting it to the TGA? These are very serious questions and lay at the heart of the issue. Why do companies such as ours invest in meeting TGA requirements when TGA offers no "teeth" in going

after companies in breach of the requirements? What benefit does the proposed label offer? It does nothing to protect the end user, nothing to protect the clinicians, nothing to protect the sponsors/manufacturers who register with the TGA.

c) Due to the increasing cost of doing business in Australia, the cost of therapeutic goods in Australia is well above the prices being offered by the USA based websites. These sites offer no service, warranty, support, advice, training, warehousing, point of contact with local regulatory bodies, product testing, product education and training etc etc. The additional costs of these proposals will again drive Australian costs up, further pushing local consumers to try and purchase products from these US based websites. The end result will be that the TGA looses all control on products and the regulatory requirements become a joke because the proper and regulated channel to market becomes obsolete. Adding cost that offer no advantage to consumers achieves only to work against the TGA's objectives.
d) One individual product such as a wheelchair for a complex rehab case may have multiple ARTG numbers (wheelchair, cushion, headrest, ECU). The consumer may only see one number thereby potentially not recognising a component that may be subject to a recall. This will only serve to confuse the user.
e) With parallel importing and TGA's in action to date on this issue, the exact same product may have more than one ARTG number. Therefore with a recall from one sponsor based on their ARTG number you may only get a small portion of the market. Again this will only serve to confuse the market.
f) It is unlikely that our parent company will be able to do this on-line successfully as it would make the products exclusively for Australia and prevent them from using a common worldwide English label product or a worldwide multi lingual product.
g) We are typical of many medium size sponsors selling their products via a range of distributors. This means that if you use the provisions of regulation 10.2 and for example, place the information on the invoice or shipping documentation, the ARTG number will be lost at the distributor when they break down the shipment.
h) We estimate the cost of adherence to this would be in the order of $70,000 to $90,000 a year. For a company with our annual turnover this is a significantly high overhead. Our estimate did not take into account the purchase of any equipment or consumables.
i) These costs do not take into account the cost associated with the controls that would need to be in place to ensure that the correct label was placed onto the carton.
j) In many cases this proposal would require sponsors to open packaging, apply labels, re-pack and re-seal. Re-packaging to the manufacturers standards would be impossible in many cases.
k) Many sponsors direct ship from factories/distribution centres overseas to their customers these shipments could consist of high volume products or a large number of diverse products. This would require the overseas factory to insert the ARTG. Given that Australia is less than 2% of the global market this cannot be effectively introduced.
l) This may prevent Australian sponsors exporting products printed with an ARTG. As in some jurisdictions it is illegal to place a number on a product that may imply approval. This would add huge costs and logistics issues to manufacturers.
m) What does the TGA suggest we do about re-usable product as they will either lose their identity after the first use or it could be destroyed or defaced over

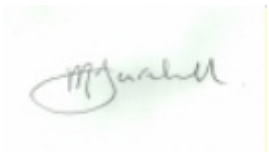
time? Many products are re-sold to other users during their usable lifetime and the ability to maintain traceability of the ARTG diminishes.

n) A transition period of 12 months is totally insufficient.
o) This will lead to withdrawal, reduced competition and in some cases for small volume items the person with the disability will not be able to access the specific product required for their condition.

3. Suggested Solutions
    a) Greatly enhance the search capability of the ARTG.
    b) Use the existing powers under the regulations to prosecute sponsors who are misusing the registration process.
    c) Provide feedback on what action has been taken to those who report breaches of the TGA requirements.
    d) Publish a regular newsletter which includes punitive action taken as a result of TGA investigations into breaches. This would do immensely more to stop sponsors and "cowboys" manipulating the TGA requirements.
    e) Encourage sponsors to have the ARTG number as part of their website.

Thank you again for the opportunity to comment on your proposals.

Yours faithfully



Malcolm Turnbull, Managing Director