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Coordinator
Re: Comment on Reforms in the Medical Devices Regulatory Framework
Office of Devices Authorisation
PO Box 100
WODEN ACT
odaconsult@tga.gov.au

Dear Sir/Madam

RE: Comment on Reforms in the Medical Devices Regulatory Framework

Red Milawa Pty Ltd trading as Magic Mobility welcomes the opportunity to comment on the proposed reforms to the medical device framework.

Background:

Magic Mobility is one of the few remaining wheelchair manufactures in Australia, we currently employ 27 staff and have distributors in every state of Australia, and we also export to the USA, UK, France, Czech Republic, Israel, South Africa, New Zealand, Greece and Italy.

We service wheelchair markets around the world so we can offer a balance prospective on your proposed changes to the ARTG. In summary we see that dangers exist in your proposals, we can see little or no benefit to the consumer despite the costs involved to us as a manufacturer; these costs would almost certainly have to be passed on the consumers, who in most cases are funded through government bodies or charities.

Comments on Recommendations

Proposal 3(i)

1. How does the additional information that will have to be provided in our case on each custom chair that we make add to the quality of the device or enhance the identification of approved devices.

2. How many staff will be supplied to check each chair that is custom made, and who will pay for the staff.

3. There are people who manipulate the TGA system, the TGA should be more proactive in weeding out these people and not trying to over regulate the people that are doing the right thing.

4. If this change is accepted then no fees should be charged for any variation.

5. The amount of information that is required to be able to carry out these changes is huge so the time line of 12 months is completely unrealistic.

Proposal 3(ii)

1. What is the real benefit to the consumer

    a) The TGA, has not developed a rational as to why having each variation to a chair checked and given a new ARTG number is needed and what benefits would be gained.

    b) Why does the TGA think this a necessary when it has not been deemed necessary by other regulatory bodies.

    c) A regulatory impact statement need to be done by an experienced group who understand the costs associated with changing the system and the implication it would have on the consumer, this should not be done by the TGA, but by the industry.

2. Potential Dangers

    a) A device like a wheelchair that has been custom made for a clients need would require checking and the variation registered with the TGA, a ARTG number gained and placed on the chair, the time that this would add to the production of a chair would be huge, the cost would also be huge, this would have to be passed on to the consumer, thereby reducing the availability of products to the consumer.

    b) With this in mind the consumers would be forced to seek out cheaper devices in a bid to cut down on cost, this would force them onto the people who already flaunt the TGA system. (these are the people that you need to be concentrating your efforts on)

3. Cost and Complexity

    a) This is going to be a hugely expensive to us as a manufacturer.

    b) Acquiring an ARTG number for each variation is unrealistic and unaffordable to the consumer.

    c) Many other jurisdictions do not allow labelling on the packaging or chairs other than the ones stated in their regulations, so this would require us as an exporter to run 2 systems.

    d) What happens when a chair is sold on after the current client no longer needs it or it is reissued by a funding body.

    e) The transition period of 12 months is completely unrealistic and unworkable.

    f) This will lead to reduced availability of equipment for the consumer.

4. Suggested Solutions

a) Due to the potential dangers, complexity and cost involved we strongly suggest that the TGA, and their group of advisers meet with the industry to get a better understanding of the objectives and requirements.

b) Use the existing powers under the regulations to seek out and prosecute the manufactures and sponsors that flaunt the regulations.

c) Custom devices such as wheelchairs should be excluded from the requirement to attain a new ARTG number as a variation of a model.

d) Publicise the prosecutions, so that bad eggs are known.

e) Work on unifying the International bodies to come up with 1 set of regulations recognised throughout the world.

Thank you for the opportunity to comment on your proposals

Yours Faithfully

John Dorning

Business Development Manager
Magic Mobility