Otto Bock®

QUALITY FOR LIFE

17th December, 2010

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

Otto Bock Australia Pty Ltd welcomes the opportunity to comment on the proposed reforms to the medical device framework.

Background:

Otto Bock is a global manufacturer of equipment for people with disabilities, including prosthetics, orthotics, wheelchairs and paediatric equipment. Our clinical staff comprises occupational therapists, physiotherapists and prosthetists and their role includes training clinicians and customers in the appropriate selection and use of equipment.

We service most sectors involving people with a disability and can therefore offer unique perspectives on the impact to the proposed changes to the regulations. In summary we see that there will be some dangers, little or 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. This proposal looks very much like revenue raising dressed up as safety and quality. Is this the first step in getting an ARTG for all devices?

2. 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

3. TGA stated they were concerned that some sponsors were manipulating the process. If a sponsor has deliberately used this process to put a device on the market then there are plenty of ways of dealing with this without passing on extra regulations and costs to the industry. Our sector of the industry has often called on the TGA to take a more pro-active monitoring role to weed out the 'cowboys'

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4. If this change is accepted then under no circumstances should any fees be charged for a variation, that would definitely be revenue raising.

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

Proposal 3(ii)

This is of great concern to our industry. We will segment our responses into 4 areas.

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) This is not in line with international harmonization. Why change the agreed global definition of a medical device to deliberately de-stabilise the harmonized definition.
    c) Why does the TGA deem this necessary in Australia when it is not deemed so in any other jurisdiction?
    d) At all times it must be remembered that devices are not medicines so the argument that medicines have the AUSTR or AUSTL is not the same.
    e) A regulator impact statement needs to be done on this issue alone so that it is not diluted by other considerations.
    f) 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.

2. Potential Dangers

    a) 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.
    b) 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.
    c) Due to the increased costs which will be particular to the Australian market, consumers will source products from on-line overseas dealers thereby by-passing all TGA regulations. This has the potential to be unsafe and dangerous to consumers.

3. Cost and Complexity

a) This is going to be enormously expensive for the sponsor with very little or no gain in safety or quality.
b) The majority of sponsors in Australia distribute for more than one manufacturer so the issue of placing the ARTG on the carton becomes more complicated and automation near impossible.
c) With this proposal our Parent company would need manufacturing runs exclusively for Australia and not in their normal production runs. It would prevent them from using a common worldwide English label product or a worldwide multi lingual product. Therefore the Australian product would be significantly more expensive
d) 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.
e) We estimate that we distribute approximately 2000 items per week and based on cost estimates of between 80 cents and $2.20 it would cost us between $80K and $220K per annum which would have to be passed onto the person with the disability. This is a high cost for a company in the low margin rehabilitation sector. These costings do not take into account of purchase of any equipment or consumables.
f) These costs do not take into occount the cost associated with the controls that would need to be in place to ensure that the correct label was placed onto the carton.
g) 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 some cases.
h) 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.
i) 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.
j) What does the TGA suggest we do about re-usable product as they will either loose 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.
k) A transition period of 12 months is totally insufficient.
l) 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.

4. Suggested Solutions

a) Due to the potential dangers, complexity, cost and lack of rationale it is strongly suggested that the TGA and their consumer group advisers meet with industry to better understand objectives and requirements.
b) Greatly enhance the search capability of the ARTG.
c) Use the existing powers under the regulations to prosecute sponsors who are misusing the registration process. Such prosecutions must also be publicised, this would do more to promote greater conformity and compliance than a million labels
d) Encourage sponsors to have the ARTG number as part of their website.
e) Re-usable devices and instruments should be excluded from the requirement to print the ARTG number as no purpose would be served if the ARTG on the device was only there are the time of delivery.

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

Yours faithfully

Terry Gallagher
Managing Director