16th 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

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

Background:

Invacare is a global manufacturer and distributor of healthcare equipment used for non-acute care including patient lifters, scooters, wheelchairs, beds and daily living aids.

Invacare Australia is a sponsor of products predominantly supplied by overseas manufacturers, many of which are common to Invacare globally. Our staff includes a wide range of occupations including occupational therapists and product specialists and their role includes training distributors and customers in the appropriate selection and use of equipment.

We service the homecare, institutional care and consumer markets and can therefore offer valid feedback on the impact to the proposed changes to the regulations. In summary we see that there will be some dangers with little or no benefit to the consumer despite a huge cost burden to our manufacturers and to us as a sponsor, which will result in a higher cost for products to the consumer.

Comments On Recommendations

Proposal 3(i)

1. It is Invacare's opinion that changing the definition of a "kind of medical device" will not enhance the identification of approved devices.

2. The TGA stated they were concerned that some sponsors were manipulating the registration process. If a sponsor has deliberately used this process to put a device on the market the TGA currently has a wide range of powers to deal with these offenders without passing on extra regulations and costs to industry. Our industry has often called on the TGA to take a more pro-active monitoring role to weed out 'fly-by-night' competitors.

3. If this change is implemented, under no circumstances should any fees be charged for future variations to include additional products to an existing ARTG entry, as this could be considered to be a revenue raising activity.

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4. Considering the amount of work required to adopt the changes (for our wide range of products), involving internal changes and overseas manufacturers, we consider a 12 month transition to be far too short; we would need a 2 year transition to make the necessary changes

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) It must be remembered that devices are not medicines so the argument that medicines have the AUSTR or AUSTL is not the same.
    e) We believe that an assessment of the regulatory impact of the proposed reforms needs to be done by the TGA including an experienced focus group, comprising healthcare professionals and industry representatives.

2. Potential Dangers

    a) An individual product such as a wheelchair for a complex rehab case may have multiple ARTG numbers (wheelchair, cushion, headrest, controller and they can be from multiple suppliers). The consumer may only see one number thereby potentially not recognising a component that may be subject to a recall. We believe that this will only serve to confuse the user.
    b) With parallel importing and TGA's inaction to date on this issue, the exact same product may have more than one ARTG number. Therefore a safety recall from one sponsor based on their ARTG number may not target all affected users. Again we believe that this will only serve to confuse the market.
    c) Due to the increased costs, consumers may tend to source products from on-line overseas dealers potentially by-passing TGA regulations. This has the potential to be unsafe and dangerous to consumers.

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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) We are typical of many medium size sponsors selling their products via a range of distributors. This means that if you place the information on the invoice or shipping documentation, the distributor may lose the ARTG number when they break down the shipment.
d) 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 due to the complexities involved.
e) 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 contributes less than 2% of our global sales this cannot be effectively introduced.
f) 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.
g) 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.
h) This will lead to withdrawal, reduced competition and in some cases, for small volume items, a user with a disability may not be able to access the specific product required for their condition.
i) Additional complexity would be encountered for outgoing inspections (from suppliers) and incoming goods inspections by sponsors to check if the correct ARTG number label has been applied to a product thus requiring a more detailed process and a higher level of competency for staff performing these inspections.

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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) Enhance the search capability and useability of the ARTG to enable easier identification of included products (eg. Search by sponsor reference number). We have provided improvement suggestions for the EBS website previously to the TGA IT team and are happy to provide further feedback on this if requested.
c) Use existing TGA powers under the regulations to prosecute sponsors who are abusing the registration process. Such prosecutions should also be publicised. We believe that this would do more to promote greater conformity and compliance than additional regulatory requirements.
d) Encourage sponsors to have the ARTG number mentioned for each product as part of their website. This low cost alternative would enable consumers and healthcare professionals to determine if a product has been included on the ARTG.
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 were only there at the time of delivery.
f) The TGA has expressed concerns that they are currently unable to track product history of adverse incidents to assess its safety. The IRIS report form currently requests the sponsor to provide an ARTG number and GMDN code for every incident so the IRIS database should be able to perform a search by ARTG number or GMDN code (for a group of products). If not the database could be improved to allow this.

Thank you again for the opportunity to comment on your proposals. Please feel free to contact me if you have any questions or require clarification on any aspect of this letter.

Yours sincerely,

Geoff Purtill
Managing Director

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