INDEPENDENT REHABILITATION SUPPLIERS ASSOCIATION

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17th December 2010

Coordinator
Re: Comment on Reforms in the Medical Devices Regulatory Framework
Office of Devices Authorisation
PO Box 100
WODEN ACT 2606
Sent via email to odaconsult@tga.gov.au

Dear Sir/Madam,

Re: Proposed Reforms to the Medical Devices Regulatory Framework – 3(i) and 3(ii)

IRSA was established in August 2000 to represent the interests of businesses who compete in the non-pharmaceutical sectors of the Australian Healthcare Industry. IRSA members manufacture, supply, service and hire a broad range of assistive technology, that support people with disabilities and older persons. Many of these items are registered on the ARTG as Class 1 Medical Devices.

IRSA welcomes the opportunity to comment on the proposed reforms to the Medical Devices Regulatory Framework. Proposals 3(i) and 3(ii) are of real concern to our industry –

1. The TGA needs to clearly articulate the need for the proposed changes. In speaking with many different suppliers, it seems that the drivers for these reforms are vague at best.
2. The impact of the reforms needs to be understood – both positive and negative. If the reforms are implemented as proposed, they will result in significantly increased costs, reduced competition, less choice for consumers with disabilities and potentially drive individuals towards unregulated importation.
3. What are the other options that will deliver genuine benefits to consumers? There are a range of alternate measures that should be considered which would not have the negative outcomes of the proposed reforms 3(i) and 3(ii).

Why are the reforms necessary?

- The TGA has not provided a justification for the proposed reforms, yet they will significantly increase the compliance burden to sponsors of Class 1 medical devices.
- This increased compliance burden will inevitably lead to increased costs which will be passed on to the consumer.
- Our industry does not understand what, if any, quality or safety benefits would flow on from the proposed reforms.
- It would appear that these reforms are not consistent with the goal of international regulatory harmonisation? Why are they necessary in Australia and not in other jurisdictions?

- If the TGA believes that some sponsors are exploiting or manipulating the existing processes, there already exists a variety of ways that breaches can be dealt with, without adding increased regulations and costs to the industry.

The potential impacts of the proposed reforms

- Reforms 3(i) and 3(ii) will significantly increase costs for sponsors of Class 1 Medical Devices.
- The consumers of Class 1 Medical Devices are generally people with disabilities and older individuals, many of whom already struggle to affordably access such devices.
- Consumers are already looking to international internet sites as a way of sourcing lower cost devices. These sites provide no presales advice, traceability, installation, fitting, warranty or after sales service and often result in the provision of inappropriate or ill fitting devices. Driving costs up will simply encourage consumers to use these sites more and more.
- The majority of sponsors in Australia source from multiple, international manufacturers and automating the process of adding the ARTG number on the item or packaging will be impossible in many instances.
- Some sponsors direct ship from their international suppliers to customers throughout Australia making it impossible to access imported devices for relabelling consistent with reform 3(ii).
- In many instances reform 3(ii) would require a sponsor to unpack, apply labels, re-pack and then re-seal the item. Apart from the significant costs involved, it would often be impossible to ensure the re-packaging meets the manufacturer's specifications.
- Sponsors who are unable to affordably comply with the labelling required under reform 3(ii) may withdraw some products from the Australian market, which limits consumer choice and reduces competition.
- A complex powered mobility and seating solution would involve many different devices each with its own ARTG number. If, for example, a seating component such as a headrest failed, the consumer would be likely to falsely identify the ARTG number by focusing on the labelling on the primary product, the powered mobility base.
- Many of the devices sold by our industry are hired out, reusable and/or are eventually on-sold and will lose their identifying label or see it degraded over time.
- There is nothing in the reforms to prevent an unscrupulous importer from labelling devices with a registered sponsor's ARTG number.
- There is also nothing to prevent a second sponsor from parallel importing an identical device through a 3rd party international intermediary. Therefore the same item could have 2 or more ARTG numbers and in the event of a recall or field service modification not all devices could be properly traced.
- The transition times associated with the proposed reforms are completely inadequate.

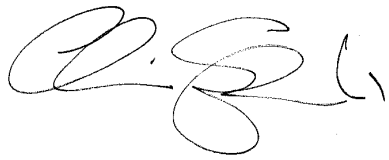
What are the options?

- The TGA and their consumer group advisors should meet directly with the industry so that the real concerns can be tabled and effective reforms agreed by all parties.
- All sponsors should be encouraged to include their relevant ARTG numbers on their websites.
- The online search capability of the ARTG needs to be significantly improved allowing easier access by all stakeholders to information on devices and sponsors.
- Devices that are reusable should be excluded from reform 3(ii) as there is no real benefit from labelling which would only reliably exist at the time of delivery.
- IRSA and our members support the prosecution of sponsors who are deliberately not complying with the regulatory processes. Information needs to be available in the public domain regarding any

sponsor who is found to be deliberately non-compliant, along with what penalties or other sanctions the TGA imposed. This single initiative would do more to improve compliance and consumer safety than either of the proposed reforms 3(i) and 3(ii).

We look forward to your response and to working with the TGA to effectively and efficiently improve the regulatory framework for all stakeholders.

Yours sincerely,



Chris Sparks
Executive Officer