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Assistive Technology
Suppliers Australasia

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TGA Proposed reform of the Regulation of Aids for People with Disabilities

I am the Executive Officer of Assistive Technology Suppliers Australasia (ATSA). ATSA is the industry organisation representing over 100 suppliers of aids to people with disabilities.

Our members are businesses of varying sizes who provide assistive technology solutions for people with disabilities, older people and their carers to increase independence and make everyday living easier. ATSA works to ensure the market for assistive technologies is competitive, efficient viable and appropriately regulated.

Thank you for the opportunity to provide a submission on behalf of our members to the recently released consultation document on Options for the future regulation of low risk products.

I am writing to make you aware, and to express our members concerns, and opposition to some of the options proposed, which would effectively amount to a de-regulation of this sector of the medical devices industry.

When regulation of medical devices commenced with the introduction of the Therapeutic Goods Act 1989 and its subordinate regulations in 1991 most products had to be entered on to the Australian Register of Therapeutic Goods prior to supply to the market. There were however two categories of goods, one of which was to be regulated but **exempt** from entry on the Register, and the second was to be **excluded** from the jurisdiction of the TGA altogether.

We understand that, recognising that some products could inadvertently be 'captured' by the Regulations, the Agency promulgated the Excluded Goods Order as a regulatory instrument declaring a number of categories of products not to be therapeutic goods and therefore outside the jurisdiction of the TGA. Among these categories of products was listed '*household and personal aids, or furniture and utensils, for the disabled;*'. This was

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intended to **exclude** devices we now commonly refer to as daily living aids, things such as purpose shaped cutlery for the arthritic patient, commodes and shower chairs, and recliner chairs designed to assist the user in sitting down or arising from the seat.

Schedule 5 of the original 1991 Regulations **exempted** '*non-powered devices used in general patient care, being devices that do not constitute or contribute to a specific diagnosis, monitoring or treatment of a medical condition; or furniture, other than powered appliances for use in diagnosis or treatment of a medical condition; or.....*' It also exempted '*non-powered orthoses or splints which do not exert traction*'.

Specifically citing these products in Schedule 5 indicated the TGA considered them to be therapeutic devices, but did not require their entry on to the Register prior to supplying them to the market.

In 2002 the Therapeutic Goods Act 1989 was amended to introduce the current medical devices regulatory framework and the Therapeutic Goods (Medical Devices) Regulations 2002 were put in place. Most of the exemptions of the previous Regulations were removed, and after a transition period which ended in October 2007, all medical devices were to be included on the Register and the manufacturer must be able to demonstrate the devices complied with the Essential Principles (of safety and performance) described in Schedule 1 of the 2002 Regulations.

In the lead up to the introduction of the new regulations the TGA undertook to present a number of seminars, workshops and conference presentations to the medical devices industry. ATSA members were always invited to attend these presentations, and at least two were held specifically focusing on ATSA members. At all of these events we were clearly told that our products would now have to be entered on the Register prior to being supplied to the market.

However in April 2016, as a result of a complaint lodged by ATSA with the TGA relating to a company supplying walking frames which were not included on the Register, we were advised the device was not a medical device and hence not regulated by the TGA. At a meeting to follow up on this advice, we were advised the TGA had taken the words '*.....household and personal aids.....*' to mean '*household [aids] and personal aids.....*'. Subsequent to this re-interpretation, a product had only to pass a single test, ie to be intended for '*household*' **or** '*personal*' rather than the dual test of '*household*' **and** '*personal*' to be considered excluded. The end result now is that the TGA considers all personal aids for people with disabilities, devices such as walking frames, wheelchairs, splints, crutches, lifting aids, in fact anything used by a person with a disability, to be **excluded** from the jurisdiction of the TGA.

It was clear from those discussions that the TGA holds the belief that such devices are all class I medical devices, and consequently of low risk. This is not true. The range of

assistive technologies which would be captured by this exclusion, and hence outside the jurisdiction of the TGA, cover the full risk classification spectrum right up to, and including class III devices and active implantable devices. We believe the TGA never considered the un-intended consequences of excluding these high risk devices from its jurisdiction.

When questioned, we advised the TGA, as examples, there were in the order of 450 Register entries for wheelchairs from 131 sponsors, 294 walking frames from 90 sponsors and 132 wheeled walking frames from 53 sponsors. The answer we received was that for these types of products entry on the Register was a notification process and that they were accepted automatically without any human intervention to check the entry was appropriate or required.

While that may be true today, that was not the case until mid to late 2008 when the automatic entry process was introduced. Prior that all applications were assessed by a reviewer before being entered on to the Register.

The large majority of entries for the three examples cited above, and other products the TGA now believes to be excluded from their jurisdiction, were manually reviewed and entered prior to the end of the transition period from old to new regulations which finished in October 2007, clearly indicating the Agency considered them to be devices which had to be included on the Register, and hence under the jurisdiction of the Therapeutic Goods Act 1989.

It is our view that this decision by the TGA, effectively pre-empted this current review and indicates the TGA has already made the decision not to regulate these products. ATSA does not consider this pre-emptive decision in the best interests of users of assistive technology devices in Australia.

Our concerns with this arbitrary decision of the TGA are many –

- The industry was not consulted at all about this decision;
- It is apparent the Branch within the TGA which made the decision did not consult or advise other Branches within the TGA as evidenced by the fact that a number of our members have undertaken product recalls under the oversight of the Recall Section within the TGA who considered the products to be medical devices;
- Further, a number of members have reported adverse events with their products to the Postmarket Monitoring Section within the TGA, who considered the products to be medical devices, and has accepted and investigated the cause and effect of the events, and in some instances suggested product recalls should be undertaken; and
- The industry was not advised of the decision and, as a consequence, has continued to pay annual fees to maintain their entries on the Register.

However the biggest danger this change of interpretation has potentially had impacts not just on our members, but the purchasers, providers and users of the products they supply. Prior to 2002 the industry was essentially left to its own devices by the TGA. They knew we were there, they knew they had jurisdiction, but chose not to assert regulatory controls except in the instances of adverse events occurring with users or product recalls.

Introduction of formal regulation and oversight, and the need for a manufacturer, through their Australian sponsor, to be able to demonstrate their products are in compliance with the Essential Principles (of safety and performance) in the Regulations has had the effect of 'tidying up' the market and poorly manufactured products with dubious safety records had essentially left the market.

Most State and private purchasing authorities, and the National Disability Insurance Scheme operators also require evidence that a product has been entered on the Register with the TGA as a condition of purchase. Indeed, we are told, by officers of the TGA that the Agency encourages purchasers to ask for evidence of inclusion on the Register to demonstrate the product, and the sponsor, is in compliance with the regulatory framework for medical devices. Our members are in discussion with these groups as we move the issue and our concerns forward.

We believe deliberately pushing these products outside the jurisdiction of the TGA has removed the safety net and once again opens the market to inferior and potentially unsafe products. We are advised officers within the NDIS have already expressed their concerns to the TGA and also with ATSA about this state of affairs.

Ours is an industry which wants regulation as a way of ensuring only quality products with a high degree of safety are prescribed and supplied to our clients, and yet we are faced with a regulatory agency which is currently abrogating their responsibility to the Australian public.

From the other examples of low risk medical devices cited in the consultation document, it is apparent the TGA wishes to extend the range of medical devices used for diagnosis or treatment in humans for which it will carry no regulatory responsibility.

ATSA calls for and strongly recommends that, in the context of this consultation and review, this decision in relation to assistive technology devices be rescinded and the TGA recognises aids for people with disabilities do indeed need to be regulated under the Therapeutic Goods Act 1989.

We note the consultation document makes the point that, even if class I medical devices such as our range of products, are removed from the jurisdiction of the Therapeutic Goods Act 1989, regulation by the ACCC and the Competition and Consumer Act 2010 is still relevant. We agree. However the ACCC openly admits its regulatory processes are 'reactive', operating only after a 'trigger event' of some form, and not 'pro-active' like

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those of the TGA which have proved effective in ensuring the safety and quality of medical devices available in our industry. Further under the ACCC regulatory framework, there are very few products for which mandatory compliance with appropriate standards is required, unlike the Essential Principles (of Safety and Performance) from Schedule 1 of the Therapeutic Goods (Medical Devices) Regulations 2002 which are applicable to all medical devices.

The 'light touch' approach used by the TGA in regulating class I medical devices, which the majority, but not all, of our products are, that of notification by the sponsor prior to place a device on the market and agreeing to undertakings under Section 41FN of the Act and conditions imposed under Section 41FO reminds sponsors they have regulatory obligations under the Act and there are consequences for non-compliance.

We would welcome the opportunity to discuss our concerns with the Medical Devices Branch of the TGA and to provide it with any further information which it may consider useful in maintaining a sensible, but light touch, regulatory approach to low risk devices in both ours, and other sectors of the industry.

Yours sincerely

[redacted]

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Executive Officer

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