

## Submission in response to:

Date: 10<sup>th</sup> August 2021

Contact: David Sinclair, Executive Officer

## **About Assistive Technology Suppliers Australia (ATSA)**

Assistive Technology Suppliers Australia (ATSA) welcomes the opportunity to respond to this RFI. ATSA is a national organisation representing assistive technology (AT) suppliers, including manufacturers, importers, distributors, retailers, tradespeople and technicians.

Our 157 members comprise businesses and not-for-profit organisations and range from small family-owned concerns to multinational organisations throughout Australia.

It is estimated that, excluding AT for communication and sensory disabilities, approximately 80% of the AT in Australia passes through the hands of ATSA members.

ATSA is a registered not-for-profit charity with the ACNC and requires that its members adhere to a comprehensive Code of Practice on the provision, sales and servicing of AT. We are also a member of the Australian Ethical Health Alliance.

## **About Assistive Technology**

All higher level AT product sold by any one of the above businesses is registered on the Australian Register of Therapeutic Goods (ARTG) as a medical device Class 1. The following TGA (Therapeutic Goods Administration) minimum requirements have to be met by AT suppliers and sponsors:

"The sponsors of Class I medical devices that do not have a measuring function and are not intended to be supplied sterile, must submit a copy of the manufacturer's <u>Declaration of Conformity</u> for the device with the <u>application to include the device in the ARTG</u>. Sponsors of these devices must also be able to provide other documentation relevant to the device (e.g., labelling, instruction for use, advertising material, and evidence of the performance of the device) to the TGA on request. Examples of Class 1 AT include manual and motorised wheelchairs, electrical beds, assistive

The costs these businesses incur in participating in this industry include - Quality Assurance Audits, NDIS Audits, TGA registrations and compliance. It is therefore important that all AT suppliers have a level playing field on digital platforms in which to provide their approved products to some of the more vulnerable people in our community people.

In this submission we will address the particular concerns that relate to the sale of Assistive Technology (AT) through digital platforms.

ATSA is concerned with the rising number of online purchase platforms for AT, as some organisations consider the sale of AT is simple and there is no skill level required in the selection. They also assume a buyer beware strategy, as the sale of AT is viewed like the selling of any consumer product.

The sale of AT is the sale of a medical device and should be treated as such, unfortunately there are some digital platforms who do not recognise this fact and inadvertently place the user/purchaser at risk high.

ATSA does not oppose online sales, provided there are appropriate warnings prior to purchase and are made with the correct level of clinical guidance/oversight along with appropriate technical support to ensure the safety of the user.

## Main areas of concern;

### 1. Flat Packs

New AT sold through digital platforms that are delivered to buyers in flat packs brings the following obvious and high risk challenges:

- a) A person with a disability may not have the physical functionality to put the flat pack together.
- b) Family or friends who put the AT device together do not have the appropriate level of technical knowledge to ensure the device is safely assembled.
- c) Most AT devices require adjustment to the individual's clinical requirements. For example, the height of a walking frame or the head, arm rest, back and cushions of a wheelchair are all tailored to each person. This "scripting" is performed by allied health professionals who accept the liability for this intervention while the supplier provides an expert on site with the person receiving the device, to ensure it is adjusted exactly to the script that has been issued.
  - 2. The impact of practices engaged in or facilitated by marketplaces to influence consumers to purchase goods that are not legal for use in public places.

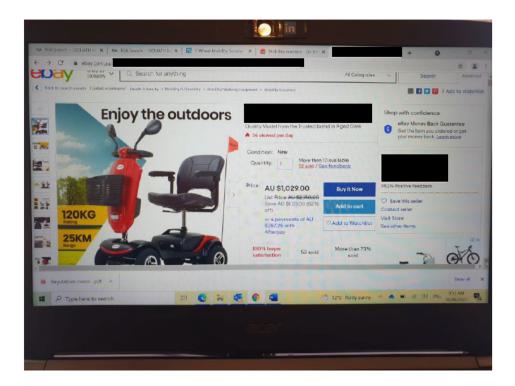
There are sellers on the general digital platforms who sell goods that may not be compliant with Australian Regulations. As an example, the NSW Road rules state

- "Mobility scooters must not travel at more than 10 kilometres per hour"
- Not to exceed 110kg (Qld it is 150kgs)
- It is also illegal for a person without a disability to use such a device
- This device could be used on private property without the need to meet the above criteria.

#### References:

- https://roadsafety.transport.nsw.gov.au/stayingsafe/pedestrians/motorisedwheelchairs/index.html
- A Guide to Safe Travel in Queensland <a href="https://www.tmr.qld.gov.au/Travel-and-transport/Disability-access-and-mobility/Travelling-with-a-wheelchair-or-mobility-scooter">https://www.tmr.qld.gov.au/Travel-and-transport/Disability-access-and-mobility/Travelling-with-a-wheelchair-or-mobility-scooter</a>

The photo below shows an electric scooter on the Australian eBay platform which has a range up to 25km/hr. While the supplier may be able to adjust the range so that it goes no faster than 10km/hr, this isn't stated in the advertisement and purchasers who are new to this product would trust that the digital platform provider & seller are complying with state and federal legislation.



Recommendation: While digital platforms may be a good channel to market for suppliers, ATSA recommends the owners of digital platforms be required to have controls in place to obtain evidence from the supplier that AT products meet the relevant TGA or Australian Standards before being promoted on the platform. The information in advertisements should reflect this compliance and warn these are medical devices, and it is recommended that they talk to their Health Care Professional before purchasing such a device.

# 3. Clinical assessment in the supply process for Assistive Technology – how does this link to current sales on general digital platforms?

It is important to understand the purchase of high level AT such as wheelchairs, walking frames or any load bearing device that comes in contact with the skin, involves a clinical assessment. This ensures the device will meet the person's individual needs without causing an adverse health event. The clinician and the supplier work together to ensure the final product is the same as that scripted by the allied health professional. The diagram in Attachment 1 illustrates this process.

There is a risk in a "non-expert" purchasing the wrong AT device from a general digital platform where the consequences could be risk rated as extreme. For example, a failure in a hoist, standing wheelchair or walking frame can result in serious injury or death. (Reference for risk rating: Australian Commission on Safety and Quality in Health Care, Risk Management Approach). The following example is from the NDIS website and illustrates the role of the allied health professional in mitigating risk:

"Li would like a bed pole to help her get out of bed easier.

Although it only costs \$35, she needs an assessment to check it's safe for her. If used incorrectly, bed poles can cause injury (or death). They're considered higher risk assistive technology. Her occupational therapist says the bed pole she wanted to buy might be dangerous for her.

The occupational therapist recommends another one that is much safer for her.

Li's planner knows that bed poles can be risky. They take the occupational therapist's recommendation into account and approve the funding for the less risky bed pole. It meets all the criteria for what we can fund."

Another example is the Vic Roads" A guide for choosing and using mobility scooters and powered wheelchairs November 2020" which states:

"Satisfactory eyesight is important, so too is concentration, reaction time, clear thinking and the ability to learn new tasks. Sitting balance and posture, co-ordination, the ability to operate the hand controls and the consistent ability to get on / off the device are also important for safe use."

Recommendation: To assist consumers, ATSA recommends digital platform owners to recommend consumers seek advice from a health professional before purchasing AT.

## 4. Ensuring level playing field for competition in a regulated environment

The Assistive Technology industry is made up of a range of business sizes from small family businesses to international companies. All higher level AT product sold by any one of these businesses is registered won the Australian Register of Therapeutic goods as a medical device Class 1. The costs that these businesses incur in participating in this industry include - Quality Assurance Audits, NDIS Audits, TGA registrations and compliance. Sellers on the general digital platforms who are in breach of the TGA requirements are able to undercut the suppliers in Australia.

Recommendation: While digital platforms may be a good channel to market for suppliers, ATSA recommends the owners of digital platforms be required to have controls in place to obtain evidence from the supplier that AT products meet the relevant TGA or Australian Standards before being promoted on the platform and that the information in advertisements reflects this compliance. The product for sale should also have appropriate warnings when appropriate along with guidance on its safe use.

## 5. Risk of sale of second hand AT

Digital platforms are now becoming a market place for second hand AT. We would like to draw the Commission's attention to the potential and significant risks this creates to consumers. We also wish to advise the following issues have also been raised with the TGA and NDIS.

Allied health professionals who script Assistive Technology rely on the equipment meeting the minimum standard and self-declaration set by the TGA. This is currently a high risk in the sale of second hand AT on digital platforms as there are not standards associated with the reissue of AT.

The question of whether a second hand or repurposed AT device still meets the manufacturer's standards needs to be addressed irrespective of the channel to market. For example, all government funded reissue services who provide second hand equipment replace the vinyl on wheelchairs, ensure the metal is still structurally sound and that all parts have been hygienically cleaned before reissue. These same controls do not exist on digital platforms and increase the risk to the consumer.

The question on who accepts the liability is not clear. If a piece of second hand AT is sold by a family member and does meet the manufacturer's standards, then is the seller liable or is it at the buyer's risk? Also, how does the buyer know about

- a) The product being required to meet the standards
- b) If the product being purchased does in fact meet the standards and
- c) The fact they have no come back if something goes wrong such as an infection from a device that was not hygienically cleaned or a bed pole with metal fatigue?

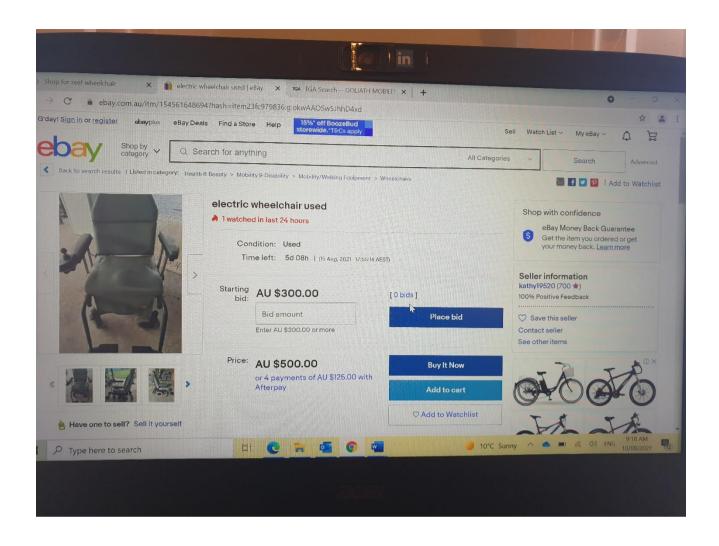
In recent discussions with 12 allied health professional bodies, there was agreement they would not accept the liability of the purchase of second hand AT equipment. This could then leave the buyer without any expert support in the purchase or set up of the AT.

While this consultation is on general digital platforms, the Commission should also be made aware of "speciality" digital platforms that only sell second hand AT such as Enabley. Again, there are no controls on the quality and safety of goods sold through these specialty market places.

The photo below is one of many examples of these high risk sales. Some of the questions the buyer needs to know to ask are –

- Does this still meet Australian standards for a medical device?
- Has the vinyl been replaced?
- Is the metal frame structurally sound?
- Can this chair be adjusted to meet my individual clinical needs?

Recommendation: ATSA supports the second hand market place for AT on the basis there are standards in place for the reissue of AT to mitigate the health risks to buyers. We recommend the ACCC supports the position that <u>all</u> digital platform providers require the seller provides evidence the product meets the safety and quality requirements of the TGA or other Australian Standards.



## FLOW CHART FOR ASSISTIVE TECHNOLOGY

Attachment 1

Person with a disability (aquired due to accident or health issue) requires assistive technology to live safely and as independently as possible.

Person receives government support or is self funded.

Government funding scheme (e.g. NDIS, Veterans Affairs, Home Care) refers person to approved allied health professional for clinical assessment. Allied health professional develops script for assistive technology required by the person and submits paper work to government scheme.

Where person is self-funded their specialist or GP makes referral.

Allied Health professional consults with AT suppliers who have product registered with TGA to source technology for the person. Options of trial period, adjustmetns required to tailor AT to person's needs are agreed between all parties.

Staff in government scheme assess report from allied health professional and approve purchase of assistive technology.

Self funded person orders AT based on advice from allied health professional.

Order is placed with supplier. Any issues in supply are between supplier and person with the disability. Where government funding is involved, the funding body may intervene to resolve any ongoing supply issue.

Supplier delivers assistive technology to person and does the set up of the technology as per the script from the allied health professional.

Supplier can received payment from the person or government scheme.