Position Paper on the sale of second hand Assistive Technology in Australia

assistive technology suppliers australia

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Contacts:
David Sinclair Executive Officer,
david.sinclair@atsa.org.au

Margaret Noonan,
Senior Policy Officer
margaret.noonan@atsa.org.au

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About Assistive Technology Suppliers Australia (ATSA)

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.

Assistive Technology

This paper refers to Assistive Technology (AT) registered with the Therapeutic Goods Administration (TGA) as a Class 1 medical device. Examples of this AT include but are not limited to wheelchairs, electric beds, bed poles/sticks, motorised scooters used for mobility purposes, walking frames, cushions for wheelchairs, hoists and other weight bearing devices.

Class 1 AT may be used by consumers in their home, work place, the community, medical or registered residential settings (e.g. aged care facility).

All other AT defined by the TGA as being exempt or excluded from the Australian Register of Therapeutic Goods (ARTG) would be considered as consumer goods under Australian Consumer Law (ACL) and the Australian Competition and Consumer Commission (ACCC). Examples of this include kettle tippers, easy to hold cutlery and other low risk devices.

The second hand market for Class 1 AT may provide savings for consumers. For example, the purchase, lease or rental of second hand AT may be more cost effective for people with changing needs such as growing children or adults with a deteriorating condition.

The inclusion of second hand AT under government funded programs may also allow finite government resources to be shared across a larger group of consumers of these programs.

Additionally, reissuing and recycling AT reduces the amount of AT discarded by consumers and ending up in waste.

In this paper ATSA provides information on the risks to consumers in the purchase of second hand Class 1 AT and the pre-purchase clinical advice required to ensure the consumer obtains the correct AT to meet their needs. We also address the next steps required to ensure second hand Class 1 AT medical devices sold in the Australian market are safe for consumers.

Background

Role of the Therapeutic Goods Administration (TGA) in relation to AT

"The TGA is responsible for regulating the supply, import, export, manufacturing and advertising of therapeutic goods."

https://www.tga.gov.au/who-we-are-what-we-do

Source Link TGA accessed 7th March 2022.

As such, The TGA maintains the Australian Register of Therapeutic Goods (ARTG) which places therapeutic goods into various classes based on risk and compliance. Only Class 1 AT entered in the ARTG can be lawfully supplied in Australia. The TGA assesses medical devices against the Essential Principles, their intended purpose and a risk-based classification to determine if the device should be in the ARTG and if so, in which class.

Additionally, in submitting an AT device to the TGA, the sponsor (importer or manufacturer) must provide evidence showing the device meets the required standards recognised in Australia. For example, ISO7176 - Wheelchairs, with sponsors having key specialist knowledge on each of the sections of this standard including but not limited to:

- Efficiency of brakes
- Static and Dynamic Stability of wheelchairs
- Maximum speed, acceleration and retardation of electric wheelchairs
- Requirements and test methods for static, impact and fatigue

strengths

- Overall dimensions, mass and turning space
- Test methods for resistance of ignition to upholstered parts
- Requirements for information disclosure, documentation and labelling

Another example is Biocompatibility Testing - materials that come in contact with the consumer is tested in certified external labs to ISO 10993-5.

The regulatory framework for medical devices spans the life of the device and includes

- pre-market assessment: conformity assessment
- market authorisation: inclusion in the ARTG
- post-market surveillance/ monitoring: continuing compliance with all regulatory, safety and performance requirements and standards.

All product recalls from the ARTG are managed by the TGA in Australia and not the ACCC.

The role of the ACCC in relation to AT

The advertising and sale of AT in Australia through marketing channels such as digital online platforms, comes under the responsibility of the ACCC.

If a medical claim is made, then the TGA is the responsible authority.

The Role of clinical advice on the use of Class 1 AT

Clinicians provide advice on the safest and most effective AT is after completing an assessment with the consumer. It is important to note government departments funding AT require the consumer to receive professional input/guidance and support. During the assessment, the consumer's physical and cognitive functions are assessed and in consultation with the consumer agreement is made on the AT required. Adjustments by the supplier or professional to the device may be necessary for the AT to meet the consumer's individual needs in the home, place of employment and community. Government programs such as the National Disability Insurance Scheme (NDIS) or the Department of Veteran's Affairs (DVA) Assistive Technology program have guidelines in regard to the assessment process used prior to the supply of AT by suppliers.

Once the AT has been prescribed, the consumer, nominated person sources a supplier and the purchase process commences. In some cases this could be an off the shelf product and in others, the supplier will need to adjust the item based on a script provided. Some AT is highly personalised where for example, body dynamic and wheelchair functionality are assessed and trialled for the "best result." In this instance, "best" is often a compromise assessed by the consensus of client, family, carer and clinician. For example, a child with cerebral palsy may require adjustments to the cushion, head rest and arms in a wheelchair in order to support the

safest posture possible for the child while in the chair.

The challenge with scripting a medical device is that it covers a broad range of physical and mental conditions, including environmental factors and the number of changing variables may mean a wheelchair may only be scripted as "suitable" for a limited period of time. Therefore, typical ACCC consumer guarantees such as "change of mind" or "functionality" are highly contestable in this set of circumstances..

Due to multiple authorities and funding streams and medical circumstance for the supply of AT, consumer complaints may take many paths They could be managed by Quality and Safeguard frameworks such as the NDIS Quality and Safeguard Commissions who raise AT issues with the registered supplier. When required, these Departments alert the TGA which then investigates the matter along with the management of any interventions required to mitigate or remove the risk to the users of the medical device, including product recall when necessary. The ACCC is unlikely to be involved in the complaint process in such matters.

Risks of second hand Class 1 AT

Risks arise when

1) There are no quality or safeguard checks undertaken on the AT by a qualified or experienced technician before it is on-sold to another consumer and/or
2) The sale is made by a private individual and not by a registered AT business with qualified staff or a government program (e.g. the Department of Veterans Affairs' Rehabilitation Appliance Program and state programs such as Enable NSW). When issued through government departments, the second hand AT is checked for quality and safety and the liability sits with the relevant Government entity.
3) A consumer purchases Class 1 AT without seeking appropriate clinical advice and buys a device which later causes harm to the consumer.

What are the risks?

A key risk with second-hand AT is that the ARTG Sponsor (manufacturer and supplier) is unlikely to have visibility of a Class 1 AT medical device in the second hand market and hence cannot advise whether the device still meets the manufacturer's intended design at the time of sale. Additionally, there is no process for the consumer or funding body to be alerted when the second hand product is older than the manufacturer's recommended life cycle.

Modifications by non-experts to prepare an AT device for second hand sale could result in an alteration of the manufacturer's design and intended purpose, thereby placing it outside the specifications listed in the ARTG. This may increase the risk to the consumer. A non-expert modification to a weight bearing AT device could also alter the performance such that the device no longer complies with the required ISO or Australian standards for safety.

Under Australian Consumer Law (ACL) the consumer has no recourse unless the seller is a business. The health and safety risks associated with using AT inappropriate for a particular consumer are well documented. A consumer who uses a wheelchair that has been altered outside the sponsored specification may be at risk of serious injury. Other examples include:

- Incorrect footrests placed on a wheelchair could allow the front casters to get caught in the plates which results in the person being 'flipped' out of their chair.
- Use of the wrong sized wheels, motor wear or gearbox damage to name a few could have significant repercussions leading to serious injury or death.
- Use of incorrect batteries or charging system can result in fire. It is important to remember that users of mobility devices may not be able to remove themselves from the powered mobility device if the batteries or charging system fitted to the AT device catch fire.
- Further examples of risks when second hand AT devices are sold on digital platforms by private sellers are provided in Attachment 1.

There is a clear lack of control over the way in which online digital platforms manage the sale of AT medical devices. Attachment 1 provides examples of second hand AT for sale online and the associated risks. Attachment 2 provides an example of new AT for sale on Amazon which has not be registered with the TGA. The responsibility to improve the safety to consumers purchasing from digital platforms sits with the newly formed Digital Platforms Branch within the ACCC.

Can we reduce or eliminate these risks?

ATSA is working to identify solutions to ensure all second hand Class 1 AT devices are subject to a quality and safety checks and that all material which comes in contact with the consumer has either been replaced or cleaned to an appropriate standard and meets ISO 10993-5.

We are also recommending relevant warnings be required so consumers know whether the device has been subject to a quality and safety check by a recognised expert. Consumers should also be informed if advice from a clinician is required to ensure the AT meets the consumer's individual physical and cognitive needs and will do no harm. Second hand AT introduces new risks to consumers including infection, or injury if the use of unsafe AT continues.

Safety protocols are required to ensure unqualified checks for wear, damage, non-compliance to manufacturer's specifications and potential loss of recall tracking mechanisms do not occur as they could result in injury or death to a consumer.

It is important to note that under the current ACCC structure, there is no consumer protection if second hand Class 1 AT is sold by an individual through market places such digital platforms. Additionally, there is a low level of understanding by private sellers of the risks and legal frameworks in the sale of medical devices resulting

in little protection for consumers in regard to the safety and quality of Class 1 AT. This risk needs to be addressed. The mechanism to better inform consumers about the risk of purchasing second hand AT is already available in the form of a Health Warning as per the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* unfortunately the general public is unaware. In particular, Division 4, Section 21 (4) of this instrument provides the following definition-

"***health warning***, in relation to a medical device (or an ingredient contained in the device), means a warning, contra-indication, precaution or restriction, that is:

(a) required under a relevant instrument to be included on the label, or in the instructions for use, of the device; and

(b) reasonably necessary to inform a decision of a consumer to purchase the device."

The current TGA mandatory statements for advertising medical devices advise consumers to read and follow the instructions before use. This may not be adequate when a consumer purchases Class 1 AT. The clinician and supplier's technical support person meet with the consumer to ensure it is adjusted correctly for their needs and the consumer is given information and training on how to safely use the device. Usually an operating manual is provided - unfortunately these tend to be lost over time. The consumers require further information to know to download the directions for use and when there is a need to have the device set up to meet their individual needs.

The approach to have improved information for consumers is further supported in the outcomes from the Report on the Right to Repair presented to the Hon. Josh Frydenberg in October 2021. In particular, in the Key Points on page 2 of the Report, the following recommendation is provided:

"A lack of consumer information about a product's repairability or durability is likely to make it difficult for some consumers to select more repairable and durable products based on their preferences, while reducing manufacturers' incentives to develop such products. To address this issue: – the Australian Government (in consultation with consumer, environmental, and industry groups) should introduce a product labelling scheme that provides repairability and/or durability information for consumers. A pilot scheme should target a limited number of white goods and consumer electronics products."

ATSA strongly recommends the inclusion of second hand Class 1 AT in such a pilot.

Additionally, ATSA has initiated discussions with an RTO to develop a training program for the supply and servicing of second hand AT. The aim is to develop a method of providing baseline training that will provide sales and repair technicians to enter the industry with skill and standards and accreditation/certification. Any second hand AT reviewed by a certified repair technician could be labelled accordingly and would not require the full health warning.

Where to from here?

Current supply pathways are governed by the TGA framework for Class 1 medical devices for the sale of new AT. However, in the second hand market action needs to be taken to create a framework for the safe purchase of second hand Class 1AT.

Recommendation 1:

ATSA strongly recommends that all sellers of second hand Class 1 AT be required to post a Health Warning stating

1) The Class 1 AT equipment should be checked by a supplier/certified repairer of AT to ensure it still meets the Essential Principles, the intended purpose and design as submitted by the sponsor to the TGA.
2) Clinical advice should be sought to ensure the medical device will safely meet their needs.

Recommendation 2:

Digital platforms to be accountable for informing sellers of the required Health Warning and to direct the seller to the original supplier of the Class 1 device for guidance where the seller is an individual and not a business. The ACCC and TGA need to work together to build appropriate protections for the consumer. ATSA is willing to assist in this work.

Recommendation 3:

A recognised training program be developed for the repair and maintenance of AT and information provided to the consumer advising the AT undergone a quality and safety check by an accredited person.

ATSA recognises the current gap in standards and accreditation/ certification in regard to the quality and safety check and the person undertaking this check. ATSA is working with an RTO to develop a training and accreditation framework for repairs and maintenance within the AT supply sector.

Recommendation 4:

The Consumer Policy Unit in Treasury to work with the TGA to include Class 1 AT in the pilot on product labelling scheme that provides repairability and/or durability information for consumers.

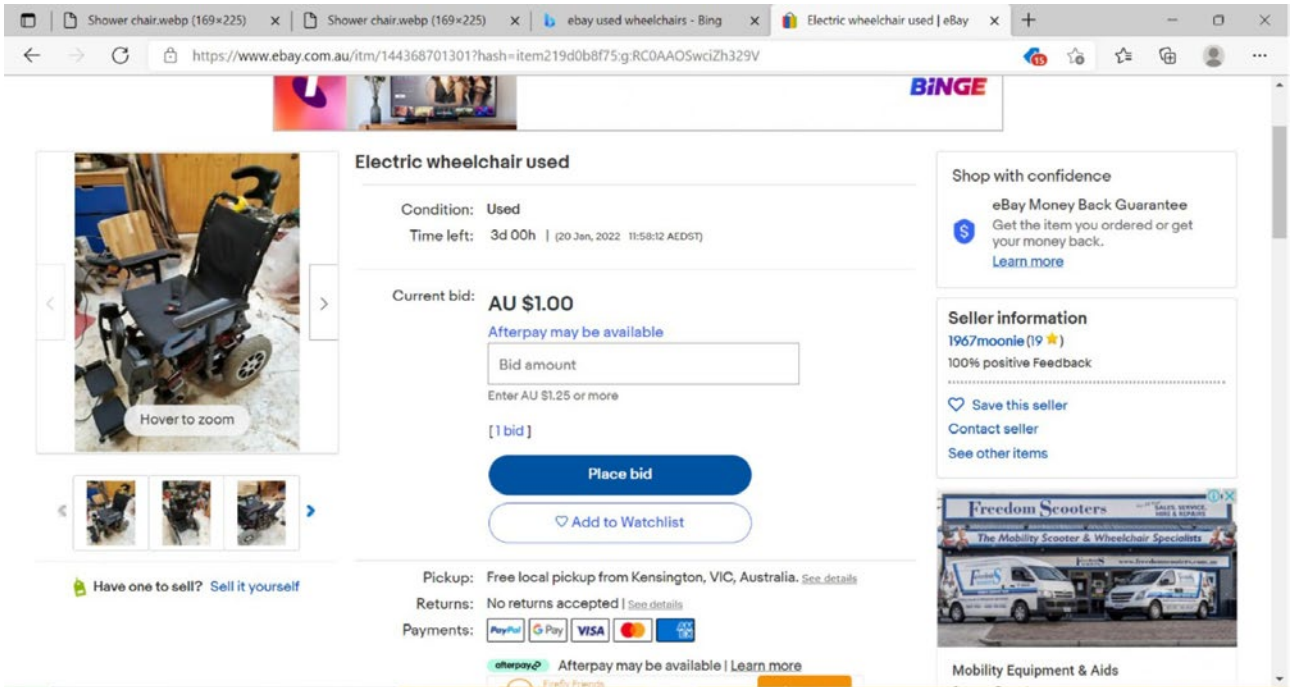
ATSA is willing to participate in discussions in regard to our submission to the Productivity Commission.

In conclusion, ATSA will continue to support and assist with activities related to the implementation of the above recommendations and other identified processes or legislative changes coming from this position paper.

ATTACHMENT 1

The items below highlight the key risks across assistive technology items which are Class 1 medical devices. We also note that in most of these examples, a clinical prescriber is required to advise if the equipment is appropriate and safe for the user. The clinical prescriber cannot assess the integrity, quality and safety of the second-hand medical device itself – this needs to be done by the supplier or a qualified/experienced expert.

EXAMPLE 1 – Adult motorised wheelchair

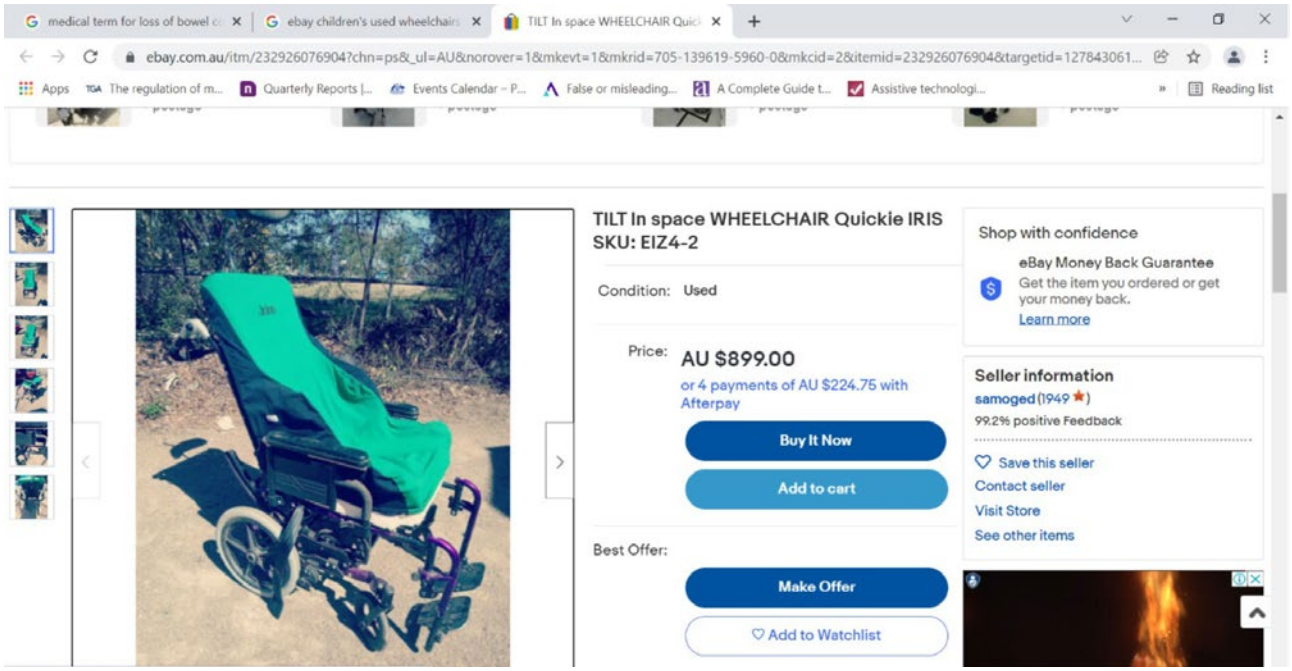


Risks

There is nothing in the advertisement to state whether the used item meets the standards required by the TGA for a motorised wheelchair or whether it has been through a quality and safety check by an expert to confirm:

- There is no sign of metal fatigue and welds are in good condition on the frame. Weld tests include simple sensory examinations (non-destructive visual examination), liquid penetrant, radiography, magnetic particle, eddy current, and ultrasonic testing.
- The vinyl has been hygienically cleaned by an expert or replaced to prevent risk of infection from old vinyl due to possible fecal incontinence or bladder leaks by previous user/s
- The battery has been tested – user could be stranded if battery goes flat
- Electrics are safe.
- Age of the chair – if this is beyond the manufacturer's warranty or support, then the item may need to be recycled rather than re-sold.
- This wheelchair may/may not be appropriate for the buyer and they should consult a clinical prescriber.

EXAMPLE 2 – Motorised paediatric tilt wheelchair



Risks

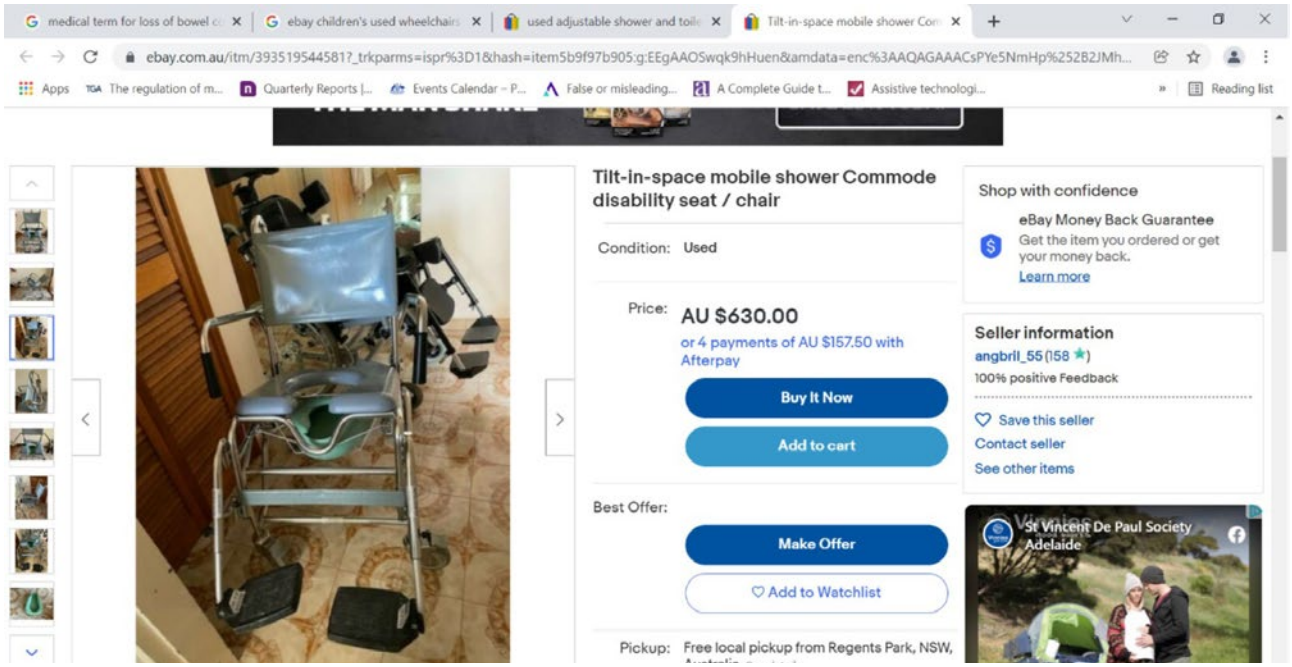
There is nothing in the advertisement to state whether the used item meets the standards required by the TGA for a motorised wheelchair or whether it has been through a quality and safety check by an expert to confirm:

- There is no sign of metal fatigue and welds are in good condition on the frame. Weld tests include simple sensory examinations (non-destructive visual examination), liquid penetrant, radiography, magnetic particle, eddy current, and ultrasonic testing.
- The vinyl and material cover has been hygienically cleaned by an expert or replaced to prevent risk of infection from old vinyl due to possible fecal incontinence or bladder leaks by previous user.
- Tilting mechanism is safe and the parts of the frame for this movement are functional and safe and will hold the chair in the selected position.
- Age of the chair – if this is beyond the manufacturer's warranty, then the item may need to be recycled rather than re-sold.

Additionally, the question the buyer needs to know to ask is will the tilting mechanise be safe for my child based on their medical condition/disability E.g. would the child be at an increased risk of choking if in the tilted position? This wheelchair may not be appropriate for the child and could have an adverse impact on their physical development and safety unless recommended by a clinical prescriber.

Note: In a presentation from the NDIS on the introduction of second hand paediatric assistive technology, the NDIS advised parents stated they wanted the second-hand items to be checked by an expert prior to sale.

EXAMPLE 3 – Tilt shower and commode chair

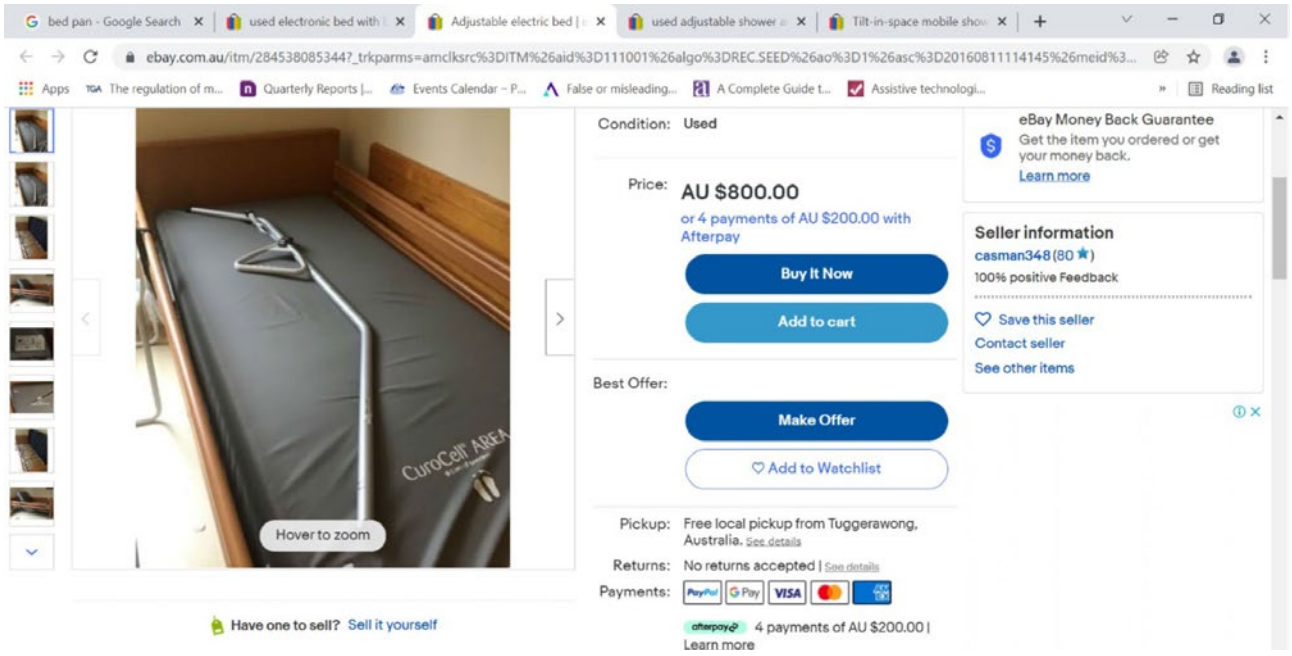


Risks:

There is nothing in the advertisement to state whether the used item meets the standards required by the TGA or if an expert has checked it to confirm

- There is no sign of metal fatigue and the nuts and bolts or welds are in good condition on the frame (NB: Weld tests include simple sensory examinations (non-destructive visual examination), liquid penetrant, radiography, magnetic particle, eddy current, and ultrasonic testing).
- The vinyl has been replaced to prevent risk of infection from old vinyl or sterilised based on hospital standards
- Footrests are safe and appropriate for the buyer and the frame components for the adjustment to the height of the footrest are structurally safe and in good working order e.g. stay in the required height position when weight is placed on the footrests.
- The bed pan has been replaced by a new one or sanitised based on hospital standards (anything less could result in a high risk of infection).
- Tilting mechanism is safe and the parts of the frame are structurally sound and electrics for this movement are functional and safe.
- Age of the chair – if this is beyond the manufacturer's warranty or service, then the item may need to be recycled rather than re-sold.

EXAMPLE 4 – Electronic bed with bed pole and triangle



Risks

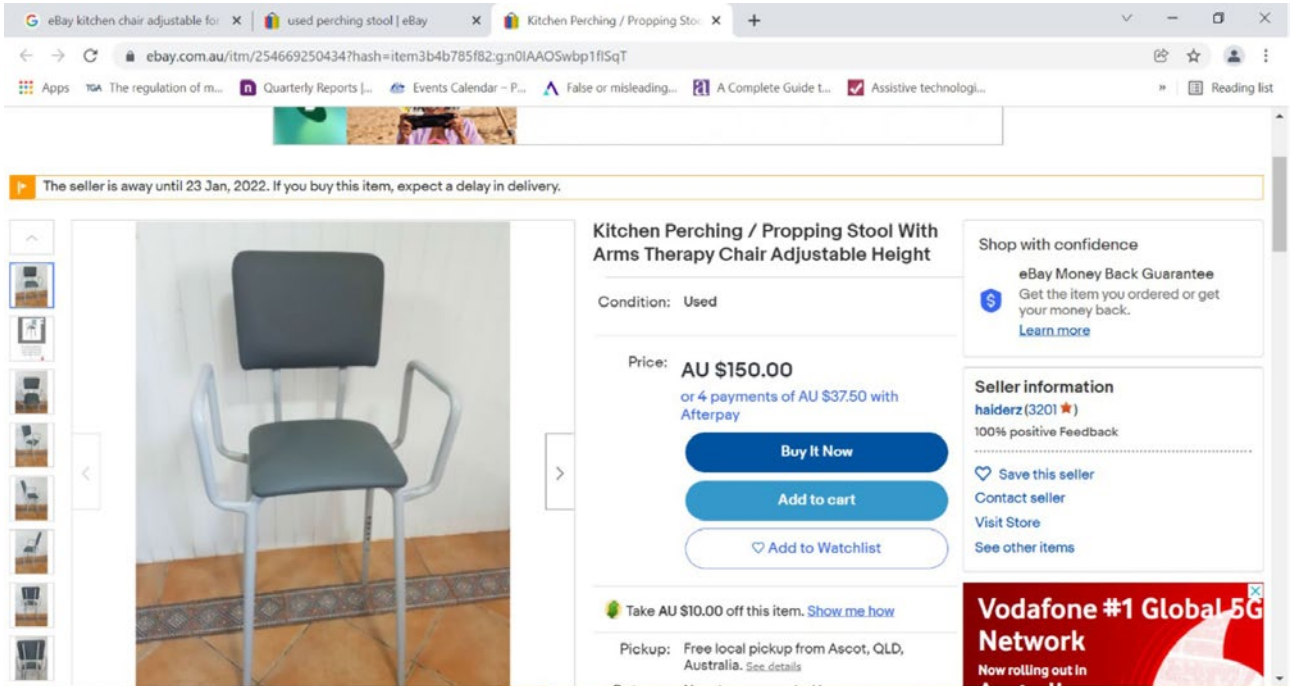
The bed rails and bed pole/stick in this advertisement are particularly high risk items. There is nothing in the advertisement to state whether the used item meets the standards required by the TGA for an electronic bed or that all of the items in the advertisement have been checked by an expert to confirm:

- There are no signs of metal fatigue and nuts and bolts plus welds are in good condition on the frame of the bed, bed post/stick and triangle. Weld tests include simple sensory examinations (non-destructive visual examination), liquid penetrant, radiography, magnetic particle, eddy current, and ultrasonic testing.
- The mattress and vinyl cover have been hygienically cleaned/replaced to prevent risk of infection.
- The frame components on the bed for the bed pole and for the pole and triangle are structurally safe and in good working order e.g. stay in the required position when weight is placed on the triangle if someone pulls themselves up. Various state governments have clinical guidelines which prescribers are expected to follow when prescribing a bed pole. For example, the SA Government October 2015 Equipment Programme, Bed Sticks, Clinical Guidelines for prescribers". Related information on the need for a clinical assessment by a prescriber should be mandatory in advertisements for these high-risk items.
- Additionally, research has been undertaken in regard to risks around entrapment in bed rails and in response, state government health departments have mandatory procedures in place around the use of bed rails. As an example , the South Eastern Sydney Local Health District have the following procedure -

Bedrails – Adult – for use in Acute, Subacute and Residential Care Settings, SESLHDPR/421 October 2020. Noting the level of response by health departments to this potential risk, the sale of these items on eBay and other online platforms presents a high risk to the end user if a prescriber is not involved in this purchase and a qualified expert has not assessed the integrity, quality and safety of this medical device.

- Age of the bed, bed stick, triangle and mattress – if these are beyond the manufacturer's warranty, then the item may need to be recycled rather than re-sold.

EXAMPLE 5 – Perching Chair – height adjustable



Risks

There is nothing in the advertisement to state whether the used item meets the standards required by the TGA or that a quality and safety check has been conducted an expert to confirm:

- There are no signs of metal fatigue and the bolts and nuts securing the back and seat to the frame are in good condition.
- The vinyl cover has been hygienically cleaned.
- The components on the frame that allow for the seat height to be adjusted hold the seat securely at each height setting.
- Age of the item – if this is beyond the manufacturer's warranty or service, then the item may need to be recycled rather than re-sold.

ATTACHMENT 2

The items below are examples of Class 1 AT which is being promoted on the Amazon digital platform and where there is no record of the device in the ARTG.