Submission in response to Treasury Consultation:

Improving consumer guarantees and supplier indemnification provisions under the Australian Consumer Law

Email for responses: consumerlaw@treasury.gov.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.

Statement of ATSA's position on Improving consumer guarantees and supplier indemnification provisions under the Australian Consumer Law

This submission refers to Assistive Technology (AT) used by people with limited function due to disability or degenerative conditions. In particular, we are focussing on AT devices which are 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 ACL. Examples of this include kettle tippers, easy to hold cutlery and other low risk devices.

In this response ATSA provides information on the level of risk to consumers in the purchase of Class 1 AT and the pre-purchase clinical advice required to ensure the consumer obtains the correct AT to meet their needs.

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." (Source: https://www.tga.gov.au/role-ga#:~:text=The%20TGA%20is%20responsible%20for%20regulating%20the%20supply%2C%20import%2C%20export,and%20advertising%20of%20therapeutic%20goods)

As such, The TGA maintains a Register (ARTG) which places therapeutic goods into various classes based on risk and compliance. Only Class 1AT 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 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.

Purchase of Second Hand AT

Second hand AT may be supplied through government programs including the Department of Veterans Affairs' Rehabilitation Appliance Program and state programs such as Enable NSW or non-government channels such as online digital platforms or private sellers. When issued through government departments, the AT is checked for Quality and Safety before being reissued and the liability sits with the relevant Government entity.

ATSA has been in discussions with the TGA, NDIA and the Ageing and Aged Care Group within the Department of Health on the need to have all second hand AT go through a quality and safety check before being sold/reissued through any channel to market. One of the key risks is that the ARTG Sponsor (manufacturer and supplier) may not have visibility of a Class 1 AT medical device in the second hand market and will not know whether the device meets the manufacturer's intended design as required by the TGA (see above) at time of the second hand sale transaction. Additionally, the product may be older than the recommended life cycle provided by the manufacturer. Modifications by non-experts to the wheel base, batteries, and materials to prepare an AT device for second hand sale could result in an alteration of the manufacturer's design and intended purpose and place it outside the registered listed ARTG specifications. This may increase the risk to the consumer. A non-expert modification to the second-hand wheelchair or other weight bearing AT device could also alter the performance such that the AT medical device no longer complies with the required ISO or Australian standards for safety.

Additionally, under ACL the consumer has no recourse unless the seller is a business. It is important to note that AT is in most cases is a prescribed medical device and purchase without clinical input/guidance and support is not wise. 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 – for example, correct footplates are placed on their wheelchair to ensure the front casters do not get caught in the plates that result in flipping the person out of their chair. Even changing a wheel, which seems like a simple task, to the wrong sized could have huge repercussions – tyre inflations, motor wear, gearbox damage, ground clearance risks, stability risks etc.

Another example of high risk to a user of AT, is the correct installation of batteries in powered mobility devices, if not done by a trained/qualified person it could lead to serous injury or death. It is important to remember that users of mobility devices may not be able to remove themselves from the powered wheelchair or mobility scooter if the batteries catch fire due the use of incorrect batteries or charging system fitted to the AT device.

Further examples of second hand AT devices and the associated risks are provided in Attachment 1.

ATSA is working with the above mentioned government departments to identify solutions to ensure all second hand Class 1 AT devices are subject to a quality and safety check 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 consumers be made aware of relevant warnings, i.e. whether the item has been subject to a quality and safety check by a recognised expert and that this level of AT may require a clinician's engagement to provide a script to ensure it is the right device to meet the consumer's individual physical and cognitive needs.

The risk of ignoring the necessity of applying recognised safety protocols for reissued AT is very high and will introduce new risks to consumers including infection, or injury if the use of unsafe AT due to unqualified checks for wear, damage, non-compliance to manufacturer's specifications and potential loss of recall tracking mechanisms.

Under the current ACCC structure, there is no consumer protection if Class 1 AT is sold by an individual through market places such online digital platforms, ATSA recommends these platforms be required to adhere to the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021*. In particular, Division 4, Section 21 (4) of the above instrument which includes the following section on health warnings:

"***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."

This approach is further supported in the outcomes from the Report on the Right to Repair presented to the Hon. Josh Frydenberg in October 21. 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 reissued 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.

The Role of Scripting for Class 1 AT

As a general rule, Class 1 AT is prescribed by a clinician after completing an assessment with the consumer. During the assessment, the consumer's physical and cognitive functions are assessed and a determination is made in consultation with the consumer on the AT required. Adjustments by the supplier or clinician to the device may be necessary to tune the AT to 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 strict guidelines in regard to the assessment process used by clinicians and the supply of AT by suppliers.

Once the AT has been prescribed, the consumer or clinician 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 the script provided by the clinician. 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 OT. 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.

Conclusion

Current supply pathways are governed well by the TGA framework for Class 1 medical devices for the sale of new AT. However, in the second hand market there is less information provided to consumers about the critical nature of the medical devices being sold. Additionally, there is a low level of understanding by 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.

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

1) Ask the seller if the AT equipment has been checked by a supplier of AT to ensure it still meets the Essential Principles, the intended purpose and design as submitted by the sponsor to the TGA.
2) Seek clinical advice as to whether the medical device will safely meet their needs.

Recommendation 2: Online digital platforms which have sellers offering second hand AT to consumers to be accountable for informing sellers of the required Health Warning and to direct the seller to the supplier of the Class 1 device for guidance where the seller is an individual and not a business.

Recommendation 3: Protocols or guidelines be developed by the TGA in regard to the reissue of used AT so consumers know the product has had a quality and safety check.

ATSA recognises the current gap in standards and accreditation/certification and is currently identifying partners to develop a training and accreditation frameworks for the sector.

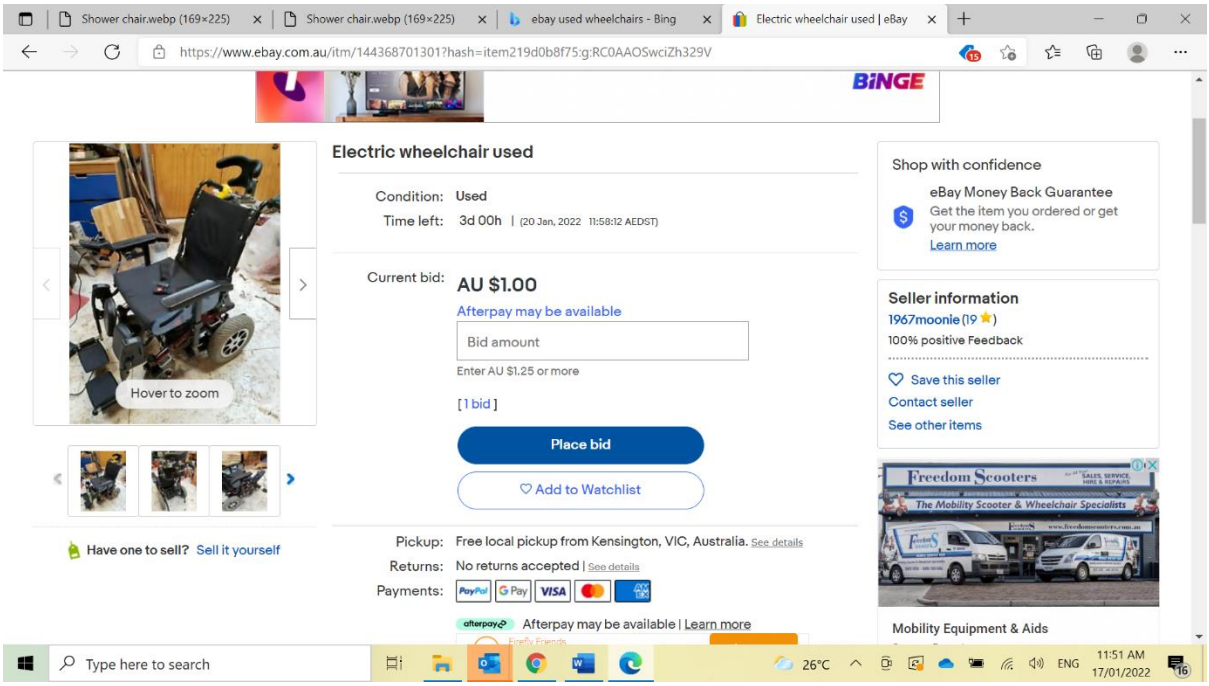
Recommendation 4: The Consumer Policy Unit, Treasury to work with the TGA to include Class 1 AT in the pilot on product labelling scheme that provides repairability and/or durability information for consumers.

ATSA is willing to participate in discussions in regard to our submission and activities related to the implementation of the above recommendations and other identified process or legislative changes coming from this Consultation process.

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*

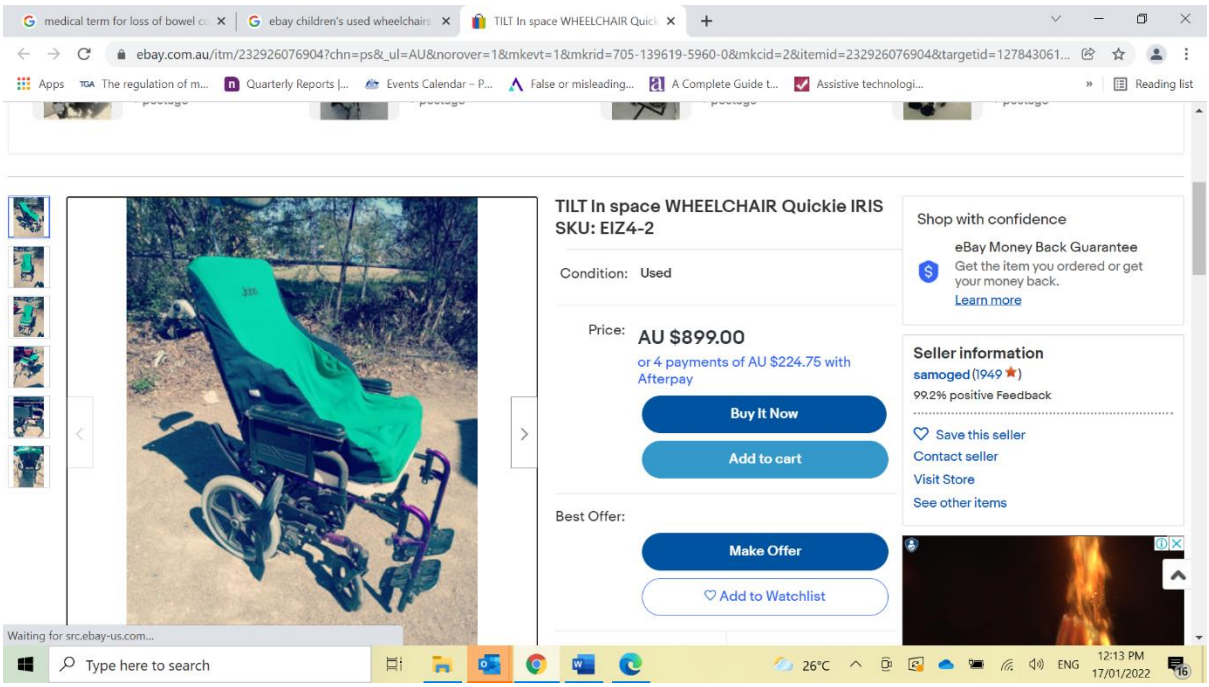


Risks

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:

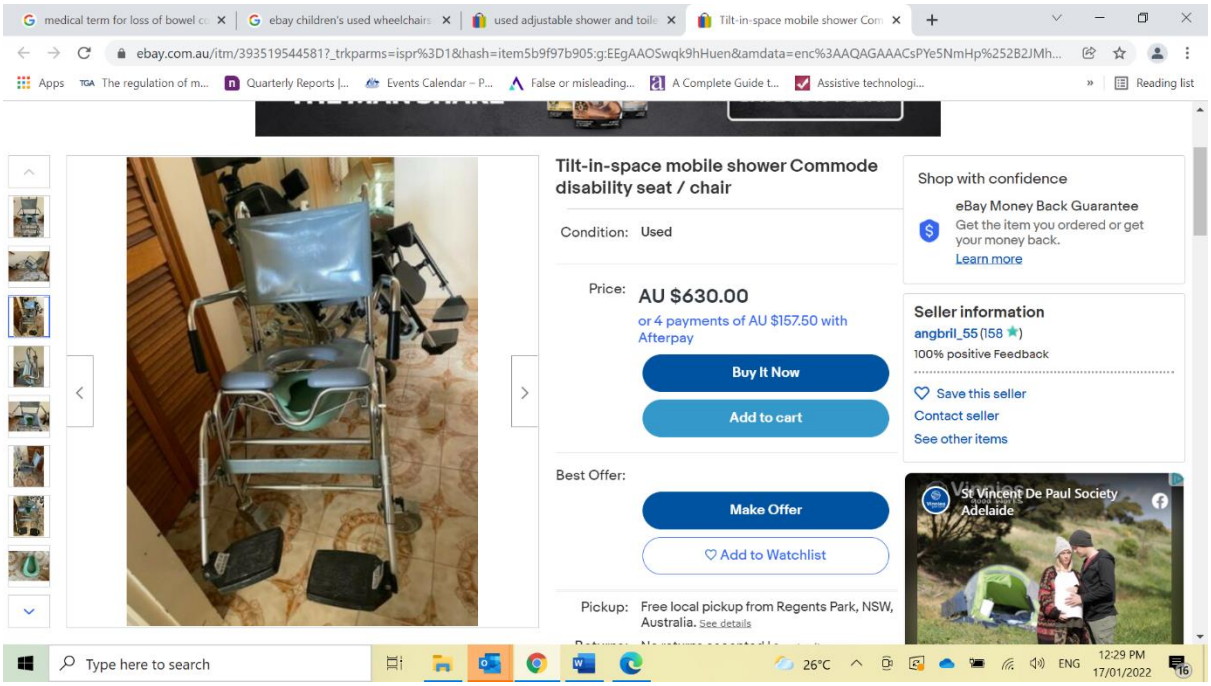
- There is no sign of metal fatigue and welds are in good condition on the frame. Weld tests include simple sensory examinations (non-destructive visual examination), liquid penetrant, radiography, magnetic particle, eddy current, and ultrasonic testing.
- The vinyl and material cover has been hygienically 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:

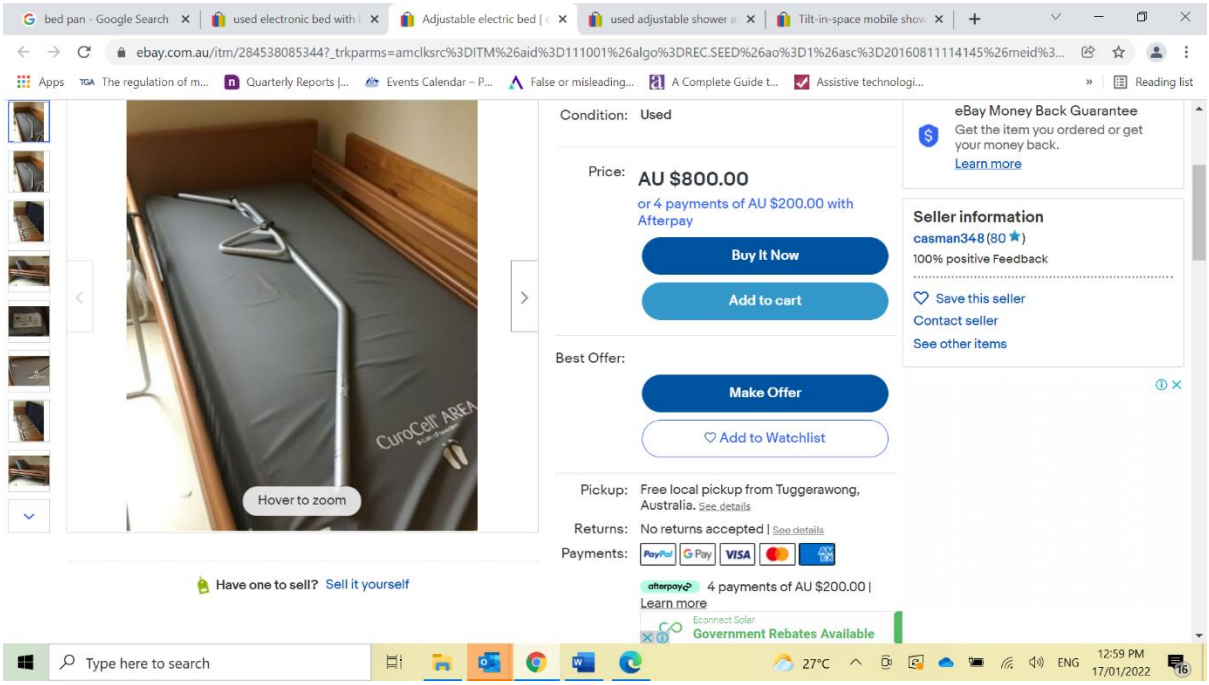


Risks

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 3 Electronic bed with bed pole and triangle*



Risks

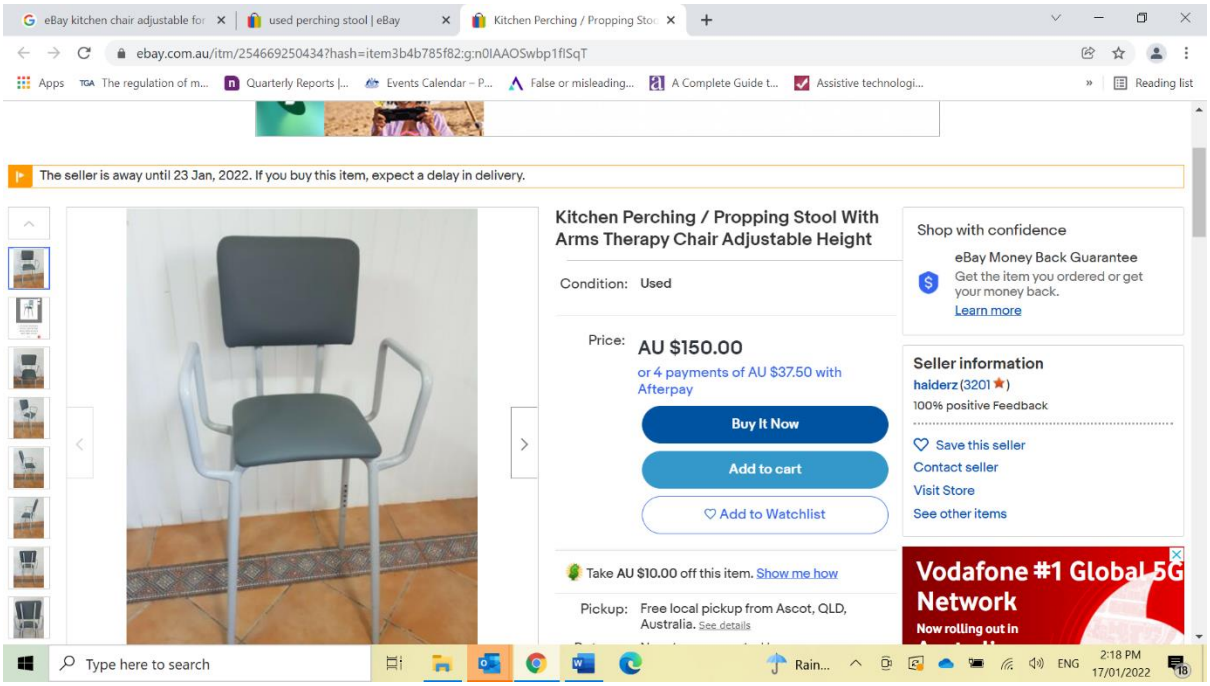
The bed rails and bed pole/stick in this advertisement are particularly high risk items. There is nothing in the advertisement to state whether the used item meets the standards required by the TGA for an electronic bed or that all of the items in the advertisement have been checked by an expert to confirm:

- 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 4 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.