Submission to the TGA Consultation – Future regulation of assistive technologies

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Who is the Assistive Technology Suppliers Australia?

ATSA is a national organisation representing assistive technology suppliers, including manufacturers, importers, distributors, retailers, tradespeople and technicians.

Our 170 members comprise businesses and not-for-profit organizations' 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 Australian Charities and Not for Profits Commission (ACNC) and requires its members to 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.

The objects of ATSA are

(a) funding and promoting:
   i) research into Assistive Technology.
   ii) the education of the public as to the availability of Assistive Technology to meet the needs of persons with a disability;
   iii) "Best practice" in the way Assistive Technology is supplied; and
   iv) community accessible Assistive Technology events;

(b) giving the Assistive Technology users and suppliers a voice that:
   i) provides positive influence on Government policy;
   ii) educates Governments and other stake holders about Assistive Technology;
   iii) promotes a robust competitive and commercially viable marketplace with the aim that Assistive Technology is available to users at a reasonable cost;
   iv) advocates to achieve excellence, quality, value and positive outcomes for suppliers, Assistive Technology users, stakeholders and the broader community;
   v) works with governments at all levels to ensure the viability of the Assistive Technology industry for the sake of those who use Assistive Technology; and
   vi) delivers quality and value in Assistive Technology solutions for people with a disability and their carers;

(c) improving the quality of Assistive Technology provision by:
   i) supporting the ongoing training and education of health care professionals;
   ii) promoting ethical business practices that safeguard the interests of users of Assistive Technology;
   iii) participating in the development of appropriate and cost-effective product standards; and
   iv) maintaining and enhancing services standards, quality and reputation of the Members for the collective mutual benefit and interests of the Members and the public;

(d) developing alliances with all industry stakeholders to:
   i) drive continued improvement in outcomes for Assistive Technology users;
   ii) minimise the total lifetime costs of Assistive Technology on society and Assistive Technology users;
   iii) ensure an open, fair and competitive market; and
   iv) promote the services, activities and events of the Company; and

undertaking such other actions or activities that are necessary, incidental or conducive to advance this Object.

Recommendations

Recommendation 1

New criteria should be developed in determining whether assistive technology (AT) should be excluded from the TGA regulations. Further consultation is required on the type of criteria. Some examples for discussion include

- ***AT which does not meet the definition of a medical device/is not intended by the manufacturer to be a medical device or***
- ***in the event of failure, the AT can be easily substituted by the intervention of a carer/family member at no risk to their safety or***
- ***AT which has a high social benefit, such as inclusion and very low therapeutic benefit.***

Recommendation 2

ATSA requests that further discussion be held on the financial impact of this proposal as part of the consultation process.

Recommendation 3

Assistive technology which has a risk to a person's safety should the device fail or be used incorrectly, should continue to be included in the ARTG.

Introductory Comments

Thank you for providing ATSA with an opportunity to submit feedback on the future regulation of assistive technologies (AT).

ATSA's position is

- AT with a higher risk should remain classified as Class 1 in the Australian Therapeutic Goods Register (ARTG).
- AT which does not meet the definition of a therapeutic good should continue to be excluded from the TGA.
- All other AT to be categorised as exempt or excluded based on set criteria.

When determining the regulation for AT, it is important to note -

a) the definition of assistive technology used by the World Health Organisation (WHO)

"Assistive technology is an umbrella term for assistive products and their related systems and services.
Assistive products help maintain or improve an individual's functioning related to cognition, communication, hearing, mobility, self-care and vision, thus enabling their health, well-being, inclusion and participation." [1] and

b) the list of AT in the ISO-9999 Assistive Technology Classification and Terminology Standard.[2]

We note the regulation of medical devices is also being considered by other government departments providing funding to consumers for AT. This raises the question of whether AT which has a high social benefit and low therapeutic benefit, but is not regulated by the TGA, will be funded? This in itself could be a determinate for how responses are made to this consultation.

In this response, ATSA has assumed the decision for regulation will be based on the risk and therapeutic benefit of AT. However, if funding bodies determine they will only fund AT listed with the TGA either as exempt or Class 1, then members would accept AT which is currently excluded as becoming exempt.

Responses to Consultation Questions

Remove exclusion – Questions:

1. ***Do you broadly agree that the current exclusion for "household and personal aids, or furniture and utensils, for people with disabilities" should be removed?***

No.

2. Why or why not?

- Currently many excluded AT products do not meet the intended purpose of a medical device. For example, assistive products for personal care that do not meet the definition

of a medical device are – ISO 9999, non-slip both and shower mats - 09 33 06 and clothes and shoes - 09 03[2].

- The failure of some excluded AT will not result in the need for allied health or medical interventions. For example, adaptive cutlery, memory devices, talking clocks or assistive products for dressing and undressing. These types of AT can be replaced by a carer/family member's intervention at no risk to the safety of that person or the consumer. The impact for the consumer is loss of independence.

- Excluded AT is often a one off purchase and not part of a support system. That is, it does not require an assessment, fitting, adapting, repairs and maintenance or training by an allied health professional or AT expert. Examples include clothing and shoes, reminder devices and clocks.

- ATSA recommends AT which is currently excluded and is better managed through other regulatory authorities should remain excluded from the TGA. For example, the following regulatory authorities have risk management processes that are specific to the type of risks associated with the following AT. They also have redress/recall processes in the event of failure of this type of AT:
  - AT for home modifications – National Construction Code and Building Code of Australia. A failure of this type of AT may require intervention by the Australian Building Codes Board.
  - Communication products – Telecommunications Act 1997. A failure of a device to be fully accessible would breach Section 255 of the Act and be a matter for the Department of Infrastructure, Transport, Regional Development, Communications and the Arts.

Recommendation 1

- *New criteria should be developed in determining whether assistive technology (AT) should be excluded from the TGA regulations. Further consultation is required on the type of criteria. Some examples for discussion include*
  - *AT which does not meet the definition of a medical device/is not intended by the manufacturer to be a medical device or*
  - *in the event of failure, the AT can be easily substituted by the intervention of a carer/family member at no risk to their safety or*
  - *AT which has a high social benefit, such as inclusion and very low therapeutic benefit.*

3. What would be the financial impact for you if the TGA removed the current exclusion for "household and personal aids, or furniture and utensils, for people with disabilities"? If possible, please provide a breakdown of the impacts (cost, time, types and estimated numbers of impacted products). This information will be used to quantify the financial impact to all affected stakeholders.

As ATSA is not privy to commercially sensitive data held by our members or, we submit the following observations in response to this question:

- There will be a significant impact if these are no longer excluded. The administrative burden to not only register devices such as cutlery and clothing, but to conduct risk assessments and meet the 15 essential principals including the need for clinical justification, if required, would be significant.
- A conservative estimate is that for each product kind from each manufacturer (say a set of cutlery), at least 40 hours or engineering time would be required to conduct, review and document risk assessments, perform testing, find and manage documented clinical evidence etc. This burden generally falls on sponsors where the manufacturers are based overseas.
- For furniture and products that bear a person's weight, we would see no change as our internal risk assessment requires us to test these products anyway.
- Moving these items to the exempt category will present challenges for the TGA in
  a) identifying the local and international manufacturers and potential sponsors
  b) providing training and ongoing support in the compliance process to these entities many of which will not have previously engaged with the TGA.
- Depending on the number of submissions to the TGA, manufacturers and sponsors may need to employ consultants/ new staff to manage compliance and the relationship with the TGA.
- Businesses would be burdened with meeting unnecessary legislative requirements, administration costs, legal costs, advisor costs for devices such as cutlery and clothing. The TGA would also be required to provide direction or support to small businesses with no experience of the TGA rather than advise them to engage private services of a Regulatory Affairs consultant. This could lead to many products being withdrawn from sale due to added burden. Additionally, the need to conduct risk assessments and meet the 13 essential principles would be significant. We understand that as an exempt product the need for clinical justification may not be required, however if this were to be included, this would also have a significant impact.
- The cost to manufacturers and sponsors would depend upon the range of AT supplied by a manufacturer and which level of classification of AT the TGA would require from manufacturers/sponsors. For example, ISO-9999 2022 codes include a class, a subclass and a division.
- To provide an idea of the number of products the TGA would have to include as exempt, one retail supplier's database alone holds over 15,500 individual AT products that are currently excluded by the TGA. These may however fit into approximately 8-10 classes as per the classification provided in ISO-9999 Assistive Technology Terminology and Classification.
- For furniture and products that bear a person's weight, manufacturers and sponsors who already have products registered on the ARTG would not be as affected as those who have not previously registered their products. The latter group would have to go through the above risk assessment and testing.
- The following questions need further consideration by the TGA and manufacturers/ sponsors:
  - How would the manufacturers be identified noting the majority of excluded AT is made overseas and imported by retailers?
  - Who would be the sponsors? Would online platforms become sponsors or are they a retail outlet?
  - What is the volume of registrations the TGA can handle up front and then over time noting the increasing number of new products entering the market?

- How many staff would the TGA require to manage the increase in the number of exempt products and the establishment and management of an additional register? What if any, additional costs would this generate for manufacturers/sponsors over time?
- How does this align with the EU and what benefits, if any, would there be to sponsors already supplying products in the EU?
- What risk is there that manufacturers stop supplying to Australia?
- For all products which are low/very low risk, what is the cost benefit to consumers, manufacturers and sponsors?

Note: As part of any transition process in moving AT from excluded to exempted medical devices, ATSA would support the introduction of a reduced fee or the exemption of fees as part of implementing any additional compliance requirements.

Recommendation Question 2

ATSA requests that further discussion be held on the financial impact of this proposal as part of the consultation process.

4. What period would be needed for your organisation to implement the proposed changes? This information will be used to inform any transitional arrangements.

- This would depend upon the range of AT supplied by a manufacturer and which level of classification of AT the TGA would require from manufacturers/sponsors. For example, ISO- 9999 2022 codes include a class, a subclass and a division. We would suggest any compliance should be at the highest level of classification.

Possible exemption/s – Questions

5. Are there assistive technology devices that should be granted an exemption in order to reduce regulatory burden for manufacturers and/or sponsors?

ATSA members will provide their input on this directly to the TGA.

6. Why or why not? If you are in favour of granting an exemption, please provide the explicit conditions under which an exemption should be granted and explain why an exemption is warranted.

ATSA has the following concerns with the proposal to move Assistive Technology from Class 1 to an exempt classification:

- Sponsors and manufacturers have committed significant resources into ensuring AT is compliant with the requirements of a Class 1 medical device and consider this an important aspect of client safety. Evidence of this is that while the TGA will not require AT manufacturers to apply the unique device identifier to their product/s, some have indicated they plan to do so. This is to ensure they have a standardised way to track individual devices and identify whether they have undergone unauthorized modifications or repairs. It should be noted that such changes can significantly increase the risk factor the consumer.

- The risk profile for AT on the ARTG is significantly higher than other AT. For example, what transparency and information on risk would be provided to the public and health care professions in the exempt register noting that the risk in regard to AT such as powered wheelchairs or bed-poles[3,4] is significantly higher than say for adaptive cutlery?

  Another example is the control modules in Powered Chairs. These are a critical component with direct impact on user safety and device operation. Unauthorized modifications or replacements of control modules can lead to safety risks such as malfunctions, leading to loss of control, unexpected stops, or acceleration, posing significant safety hazards to users.

- What support and recourse can affected individuals or families expect from the TGA and AT manufacturer in cases of injury or death attributed to an exempt AT device which is high risk?

- Will the exempt register include reporting for incidents involving exempt devices and how will this data be used to protect consumers?

- Will AT be accepted in clinical settings (hospital or other medical institutions) if it is classified as exempt and not a medical product or will it have to be classified as a medical product when used in clinical settings? Noting the TGA does not have power or influence over tenders from other government departments, what instrument/s would be changed to ensure all state and federal government contracts must not require exempt products to be registered in the ARTG?

- What will happen to the contracts (MASS, DVA, ENABLE, SWP etc) which require manufacturers to demonstrate registration on the ARTG regardless of the medical device status? Moving Class 1 AT into exempt would effectively put manufacturers and suppliers of AT in a position of breach of contract.

- How will the TGA address the need for harmonisation with international regulations, which is necessary for manufacturers to market their devices globally? For example, wheelchairs are classified as Class 1 in Europe[5] and the USA[6] . ATSA has also be advised there is some consideration being given by the European regulator to elevating Class 1 AT to a Class 2 classification. If AT is made exempt in Australia, then the alignment between Australia and Europe could potentially be further apart which seems contrary to the strategic direction being undertaken by the TGA.

- How will compliance with the Medical Device Single Audit Program (MDSAP) be affected for AT manufacturers?

- Has the TGA assessed whether the reduced regulatory burden will encourage more innovation and development of AT?

- How will the exemption affect the time and cost associated with bringing new AT devices to market?

- How will the TGA enforce compliance with advertising codes for exempt AT devices, ensuring advertisements do not make misleading or unsubstantiated claims about safety and effectiveness? Given the number of entries under exempt could be significant will the TGA have the capacity to respond to issues that arise?

- Moving existing Class 1 AT to a classification of /Exempt AT increases the risk of low quality AT being imported into Australia noting there is less compliance required .g. no clinical testing.

- Low cost, low risk AT does not require such heavy handed regulation. This would add administrative burden and costs, resulting in higher costs being passed to consumers.

- This also raises the question of whether there are any examples where exemption rather than exclusion would have prevented actual harm to an individual? Have there been any known instances reported to the ACCC of a failure of this type of product causing harm? This information would be useful in determining any criteria for products that should be excluded from the TGA.

- For manufacturers registering AT that was previously excluded, could this result in the manufacturer no longer supplying their products in the Australian market due to the cost? A number of the manufacturers of these products have not had to undertake this level of compliance in Australia or in other markets. There will be a cost in time and workforce to learn and implement the Australian registration process.

Recommendation 3

Assistive technology which has a medium to high risk to a person's safety should the device fail or be used incorrectly, should continue to be included in the ARTG.

7. Do you agree that information about exempt assistive technology devices should be collected?

Yes.

8. Why or why not? If there are reimbursement programs or schemes that could use information about exempt assistive technology devices, please indicate here the names of those programs/schemes and the department/body/agency/entity administering them.

- This would provide greater transparency to stakeholders consumers, allied health practitioners, rehabilitation engineers and funding bodies as well as the manufacturers and sponsors where an exempt device
  - has complied with conformity assessment procedures and
  - complies with the Essential Principles
  - has an adverse event report.

- There are **109** different funding sources for assistive technology and home modifications within Australia that cover the areas of aged care, disability and veterans affairs[2]. These include but are not limited to the following government departments:
  - Motor vehicle accident schemes – managed through the states.
  - Transition from hospital programs managed by state health departments

- The Rehabilitation Appliances program – managed by the Department of Veterans Affairs,
- The National Disability Insurance Scheme – Department of Social Services through the National Disability Insurance Agency.
- Home Care and the Commonwealth Home Support Programme – managed by Department of Health and Aged Care.

9. Do you agree that information about exempt assistive technology devices should be made public through a register?

Yes.

10. Why or why not?

- As noted in our response to Question 8, this would provide greater transparency to stakeholders including, consumers, allied health practitioners, medical health practitioners, rehabilitation engineers and funding bodies as well as the manufacturers and sponsors.

- The issue of an individual's privacy needs to be carefully considered where AT has been adapted to meet the clinical needs of an individual and is registered as exempt.

11. If a registry of exempt assistive technology devices is established, should information be arranged by kind of assistive technology device or by manufacturer/provider/sponsor?

- Both the ARTG and the Exempt device registers would need to have an easy read search function to make them accessible for consumers***.***

12. Why or why not?

- An exempt product database should be searchable by manufacturer, sponsor of similar devices, product code, UDI (where applied by manufacturers to their products) and device exemption category.
- Such a databased should be able to cross reference to the ARTG. This would allow anyone searching for a product they think is exempt but is in fact on the ARTG to be located.
- There needs to be an easy access data sorting menu within the database software so information in the register can be is sorted and reporting made based on the need of the stakeholder. For example, consumers may search for an assistive technology device based on the kind of device and then by the manufacturer's name. Manufacturers and sponsors may search based on name and then by device.

13. Do you agree that cost recovery measures should be introduced to recover TGA expenditure associated with the regulation of assistive technology devices?

- Yes.

14. Why or why not?

- This exists today and our members recognised the importance of having assistive technology included in the ARTG to ensure consumer safety and the work required by the TGA to complete the evaluation, monitoring and registration processes.

- This does however, raise the question of what if any, additional costs would be incurred by the TGA if AT were moved from Class 1 to exempt and would these costs be passed on to sponsors /manufacturers? Additionally, the TGA may find savings in removing AT from the ARTG in terms of reduced maintenance with the costs being borne by manufacturers through the exempt database.

Boundaries – Questions

15. Do you have feedback or comments, both generally or for specific products, on assistive technologies which are appropriate for medical device regulation, and those 'boundary' products which should not be medicalised as therapeutic goods?

- As noted in our response to Question 6, we believe the classification of AT currently in the ARTG should remain as Class 1 or Class 2 products. These devices have a higher risk as they are weight bearing, can have prolonged contact with the skin and if they fail cannot be replaced by any other type of intervention.
- Consideration should be given to whether a boundary product has a social or medical benefit, ATSA proposes the following criteria be considered:
    - Classes of AT which have primarily have a social benefit are low risk. These type of AT products can be replaced by the intervention of another person without risk to that person. For example, memory devices remind people with dementia or other neurological conditions about appointments, calling family members and what daily living activities need to be undertaken such as having a shower, getting dressed, eating meals and so on. The risk with these items is low and the social benefits such as inclusion are high. In the event of a device failure, a carer can provide the reminders required. In the case of a power wheelchair however, a carer cannot provide the mobility for the user of the wheelchair.
    - Social AT is unlikely to directly cause injury to the consumer. For example, a failure in a communication device does not directly result in an injury to a person, nor does selection of the wrong device for the consumer. A failure of a pressure mattress or cushion or the incorrect set up of such AT could, however, result in injury to the skin or underlying tissue.

Conclusion

Where assistive technology is a medical device as defined by the Act and there is potential of medium to high risk to a person's safety should the device fail or be used incorrectly, that device should be included in the ARTG.

In regard to the inclusion of additional categories/classes of assistive technology as exempt, ATSA would be willing to commit to further work with the TGA in developing selection criteria to determine when AT should be exempt and whether/how boundary products are regulated.

References

[1]. Assistive technology (who.int)

[2] It is time for nationally equitable access to assistive technology and home modifications in Australia: An equity benchmarking study

Natasha Layton, Natasha Brusco, Libby Callaway, Lauren Henley, Rosalie H. Wang

[3] Bed Stick Poles Rails Position Statement.pdf (otaus.com.au)

[4] Bed-sticks-A-guide-for-clients-and-carers-Information-sheet-2021.pdf (epc.asn.au)

[5]Annex I Directive - 93/42 - EN - medical device directive - EUR-Lex (europa.eu)

[6] CFR - Code of Federal Regulations Title 21 (fda.gov)