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SUBMISSION

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AMA submission to the TGA on proposed changes to the regulation of assistive technologies

By email: devicereforms@tga.gov.au

Introduction

The Australian Medical Association (AMA) is pleased to contribute feedback in this consultation to the Therapeutic Goods Administration (TGA).

The breadth and practicality of assistive technologies (ATs) can generate great health outcomes for Australians. Many of these technologies may be mild in application but generate an enormous difference to quality of life, enabling people with disability to perform functions they otherwise could not. They can enable independence, protect privacy and dignity and provide consistent supports to isolated and disadvantaged people.

Part of the AMA's overarching vision for a connected, consumer-centred healthcare system includes assistive technologies, where they enable individuals to receive quality care at home and enable care to be delivered where it otherwise would not be.[1]

The AMA has previously highlighted how ATs have the potential to significantly improve health outcomes in the aged-care system, through increased efficiency and coordination of care providers.[2] They also play an important role in enabling older Australians to remain independent of the care system, supporting the elderly to monitor and manage their health conditions.

When applied safely and effectively, ATs play an important role, mitigating against further traffic to health services, which is increasingly important with mounting pressure on the health system.

The scope of assistive technologies is wide. It ranges from simple everyday devices modified for easy or tailored use, such as a remote control, to walking aids and robots with more sophisticated functions.

[1] AMA Digital Health Vision statement 2021

[2] AMA Position Statement - Innovation in Aged Care 2019

The range of "household and personal aids, or furniture and utensils, for people with disabilities" is equally wide, and the interaction of artificial intelligence across technologies will contribute further to the speed of innovation and present new challenges to safety and consistency from a consumer perspective. Wearable health trackers, for example, sit among a suite of broadly adopted everyday products powered by rapidly evolving digital integration capabilities.

These capabilities introduce a degree of risk that can be managed through an appropriate level of regulation.

The AMA supports a TGA-led model of regulation focussed upon safe and appropriate use of assistive technologies, coupled with policy that will encourage further investment in the development and innovation of quality devices over time.

Advanced monitoring technologies, such as wearable sensors, ambient sensors, smartphone technologies and virtual reality testing, are examples of assistive technologies undergoing rapid innovation. They enable positive changes in aged people's health and mobility through monitoring of functional performance and provide focused and personalised care in home care and residential aged-care settings. These technologies carry the additional benefits of contributing health data and information to research regarding older people.

Similar outcomes can be achieved for people with disability if they are supported in accessing and using household and personal aids, as occurs under the NDIS scheme.

Proposal 1 — Remove the current exclusion

The AMA's position is that assistive technologies must be safe, regulated and evidence based. They must also maintain a high standard of data privacy.

We support government engagement and investment in these technologies with the knowledge that in the long term they will provide a return in improved health outcomes for older people and people with disability and a reduced burden on the health system.

The capabilities of quality assistive technologies to reduce unplanned doctor visits, laboratory tests and hospital stays should be supported, not inhibited, by regulation. However, it is important policy does not encourage undue reliance upon ATs, such that patients are discouraged from seeking appropriate care when it is required.

The AMA has advocated for clear guidelines around the use of assistive technologies in acute care settings, including who is responsible for:

- Educating and supporting the person, their family members, and carers in their technology use
- Maintaining and updating the technology
- Responding to information that the technology conveys, particularly in emergency situations.

The government's new assistive technologies and home modifications scheme is an appropriate step to ensure older Australians are supported in seeking timely access to safe technologies and home

modifications. As mentioned, the NDIS also supports people with disability in selecting the appropriate AT, including assessing the acceptable margin of risk for more complex products.[3]

For the general public, the AMA can support limited regulation as proposed.

Proposal 2 — Introduce exemptions for some assistive technologies

If the current exclusion to "household and personal aids, or furniture and utensils, for people with disabilities" was removed, the AMA considers exemption would be appropriate for this category of assistive technologies.

The range of these products and their application is wide. We recommend only those clearly found to have health applications, outcomes, and a higher degree of associated risks be considered a therapeutic good rather than a consumer good. For example, tools, equipment and technologies used as aides for daily living, basic communication, and routine daily functioning for people with disability should be considered for exemption.

ATs carrying potential risks would then be subject to TGA review and compliance with regulatory requirements where appropriate. Should a registry of exempt assistive technology devices be established, the AMA recommends it be arranged under manufacturers and sponsors.

The AMA considers the degree of regulation applied to exempt medical devices would contribute to the standardisation of safety and quality in household aids. The regulatory requirements for exempt products to meet relevant Essential Principles like adequate labelling, advertising standards and the report of adverse events are proportional to the potential risks around the use of household assistive technologies.

Applying a blanket exemption reasonably provides for these goods' exclusion from pre-market assessment or inclusion in the Australian Register of Therapeutic Goods (ARTG) before being imported, exported or supplied and will ensure suppliers are not hindered by over-regulation.

However, if exemptions were to be applied on a case-by-case basis, the NDIS' approach to classifying levels of AT risk and expense and the requirement to seek advice provides a useful model as to how an exemption arrangement may be applied.

The AMA supports the collection and monitoring of exempt technologies for the purpose of compelling suppliers to advertise fairly and adhere to safety standards. As innovation with ATs increases pace and complexity, this step will assist in mitigating potentially exploitative marketing activities targeted at the vulnerable demographic to which these products are directed.

Cost recovery measures may be reasonably applied to recover expenditure associated with regulatory activities associated with exemption of these products.

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[3] https://www.ndis.gov.au/participants/assistive-technology-explained

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See Also:

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