Allied Health Professions Australia

Submission to Consultation: Proposed amendment to the *Therapeutic Goods (Excluded Goods) Determination 2018 Assistive Technologies*

November 2021

This submission has been developed in consultation with AHPA's allied health association members.

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About AHPA and the allied health sector

AHPA is the recognised national peak association representing Australia's allied health professions. AHPA's membership collectively represents some 140,000 allied health professionals and AHPA works on behalf of all Australian allied health practitioners, including the largest rural and remote allied health workforce numbering some 14,000 professionals. AHPA is the only organisation with representation across all disciplines and settings.

With over 200,000 allied health professionals, allied health is Australia's second largest health workforce. Allied health professionals work across a diverse range of settings and sectors, providing services including diagnostic and first-contact services, preventive and maintenance-focused interventions for people with chronic and complex physical and mental illnesses, supporting pre- and post-surgical rehabilitation, and enabling participation and independence for people experiencing temporary or long-term functional limitations. Allied health also provides an essential bridge between the medical sector and social support systems such as aged care and disability, where it can represent the key formal health support in a person's life.

AHPA provides representation for the allied health sector and supports all Australian governments in the development of policies and programs relating to allied health. AHPA works with a wide range of working groups and experts across the individual allied health professions to consult, gather knowledge and expertise, and to support the implementation of key government initiatives.

Introduction

AHPA welcomes the opportunity to comment on the TGA's review of the exclusion of household and personal aids, or furniture and utensils, for people with disabilities, from regulation as therapeutic goods.

We have limited our responses to those questions of the greatest relevance to the allied health workforce. We encourage the TGA to contact us if additional information is sought on any aspects of our submission.

Responses

1. Scope

The continuing regulation of products which have a risk of significant injury should they malfunction means that come categories of assistive technology product will be regulated as medical devices. In addition to weight bearing and pressure management devices, are there other categories which may continue to be regulated as medical devices and what are the associated risks?

AHPA broadly supports the proposed scope of regulation as striking an appropriate balance between excluding low risk assistive technologies, and regulating those medical devices that when used as intended risk causing injury that would require medical attention.

From an allied health perspective it is also important to assess the balance in the context of the recent consultation on personalised medical devices which led to the *Therapeutic Goods (Excluded Goods) Amendment (Personalised Medical Devices) Determination 2021*; and the *Therapeutic Goods (Medical Devices—Specified Articles) Amendment (Personalised Medical*

Devices) Instrument 2021 (see also our comments below with respect to educative approach and transition arrangements).

The categories of weight bearing and pressure management devices are generally appropriate, but in addition, we support the submission from our member the Australian Orthotic Prosthetic Association that orthoses and prostheses as defined by the orthotic/prosthetic industry should be specified as a separate category requiring regulation, because they do not necessarily conform to the two proposed categories despite carrying a risk of significant injury if they malfunction or deteriorate.

It may also be appropriate to list a fourth 'other' category that is defined by examples and is intended to encompass other medical devices that may not clearly conform to the weight bearing and pressure management categories. We refer to the submission from the Australian Rehabilitation & Assistive Technology Association concerning 'mounting of life maintaining equipment' and 'maintaining or correcting anatomical alignment' as two such examples.

2. Practicality

Does the proposed scope for assistive technology exclusion work in practice?
• Are there products which would be excluded but should continue to be regulated as medical devices?
• Are there products which would continue to be regulated as medical devices which would be better treated as consumer products?

Subject to our comments about scope, clarity, educative approach and transition arrangements, AHPA's view is that the proposed amendment is generally practical.

However, we support the concern of our member Audiology Australia regarding the inappropriateness of separating similar assistive technology products under two separate regulatory systems due to their having different risk classifications, such as hearing aid remote controls.

3. Clarity

Is the proposed text of the exemption sufficiently clear for stakeholders? If not, do you have suggestions on how it might be better framed or worded?

The actual wording of the exemption seems relatively straightforward. However, based on the past experience of our members, we recommend that either the determination or the guidance document should refer to as many conceivable examples as possible, particularly of those devices that will not be excluded and which might require new registration.

We also note that 'health care settings' are not defined in the *Therapeutic Goods Act 1989*, nor in the *Therapeutic Goods (Excluded Goods) Determination 2018*. Although the guidance document offers some interpretation via examples (p4), it is still not clear how the definition relates to, for instance, the diverse contexts in which various health practitioners, as defined under the Act, provide services.

4. Products coming into the ARTG

Do you anticipate the need for products to be newly included in the ARTG? Can you provide examples of those products, the scope of changes you expect, etc? Are these higher risks medical devices, or additional low risk (but potentially harmful) products?

No comment.

5. Products cancelled from the ARTG

Do you anticipate cancellations of ARTG entries for existing assistive technologies to be required? Can you provide examples of those products, the scope of changes you expect, etc?

No comment.

6. Educative approach

Does the approach to the transition seem reasonable? Is 12 months an appropriate timeframe for managing the transition?

The timeframe seems reasonable, but only if relevant suppliers and providers, including their peak bodies, are actively informed and assisted to understand the changes. This is best done by including webinars or similar interactive processes, not simply via making written material available on the TGA website.

To illustrate, AHPA's experience of the recent consultation process regarding personalised medical devices was that despite a webinar early in the process, many allied health providers were still not aware of the proposed changes and associated notification requirements, and were not easily able to ascertain whether devices they used were implicated, and if so, to what degree.

While we appreciate the efforts of the TGA to convey the issues, some of the confusion among our members appeared due to their perceiving the information made available as complex and overly reliant on an understanding of the administration of therapeutic goods that they did not possess. See also our comments on transition arrangements below.

7. Transition arrangements

Are any additional transitional arrangements required? If so, what are the issues to be addressed by such arrangements? Are some sectors likely to be more impacted than others?

It is important that those suppliers and providers most likely to be affected by the proposed determination, particularly where new registration of devices is required, are informed and engaged at the earliest opportunity and assisted to comply in a timely manner.

This is not currently occurring consistently with respect to allied health. For example, despite being the peak national body for allied health professions, AHPA was only alerted to this consultation by a member and consequently has had little time to respond.

With regard to the recent TGA consultation concerning personalised medical devices, due to the member uncertainty referred to in our comments on the educative approach, AHPA was forced to produce its own interpretive guideline and engage in frequent communication with members anxious about their obligations to submit a Transition Notification Form (TNF) by 25 August 2021. This was a particular concern for those allied health providers making their own products from pre-supplied materials and who found it difficult to ascertain whether they should regard themselves as manufacturers and to what extent the patient-matched devices could be aggregated for the purposes of a TNF.

On 23 August 2021 – less than 2 days before the deadline – we were then informed that certain materials and other articles used as the basis of products such as splints would now be deemed to be medical devices in their own right and will therefore need to be registered by the supplier, so there was no need for allied health professionals to register those devices themselves. While we

welcomed this change in approach, it came too late for the allied health practitioners who were working to the 25 August deadline.

An ongoing active stakeholder engagement between the TGA and allied health peak bodies would have greatly assisted the process.

8. Do you have any feedback on the draft guidance document?

AHPA makes no specific comment due to time constraints, but notes that overall this document, despite providing some helpful examples, appears quite complex to the layperson in comparison to the explanation in the consultation document itself. As we suggest in relation to our recommended educative approach, provider and supplier knowledge of and compliance with new determinations and other regulatory changes would be greatly facilitated by a community legal education approach.

9. Do you have any other feedback on the proposed exclusion of low risk assistive technologies from the therapeutic goods regulatory framework?

AHPA endorses the submission from our member Audiology Australia concerning the potential impact of the proposed change on assistive listening devices currently available through the Department of Health's Hearing Services Program.