THE AUSTRALIAN ORTHOTIC PROSTHETIC ASSOCIATION

# Feedback for consultation

Options for amendment to the *Therapeutic Goods (Excluded Goods) Determination 2018*

# Orthotics and Prosthetics in Australia

Orthotist/prosthetists assess the physical and functional limitations of people resulting from disease, illness, trauma and disability, including limb amputation, diabetes, arthritis and neuromuscular conditions, such as stroke. Orthotic and prosthetic services may involve the provision of orthoses and prostheses to restore function, prevent deterioration, and improve quality of life. Orthotist/prosthetists are commonly employed in Australian hospitals, private clinics, research institutions as well as rural and remote regions, working independently and as part of multidisciplinary healthcare teams to support the Australian community.

Orthotist/prosthetists are tertiary qualified allied health professionals. An Australian Qualification Framework level 7 is required to practice as an orthotist/prosthetist in Australia, consistent with education standards for other allied health professions. Orthotic/prosthetic students complete training alongside physiotherapy, podiatry and occupational therapy students.

The Australian Orthotic Prosthetic Association (AOPA) is the peak professional body for orthotist/prosthetists in Australia, with certified practitioners comprising 80% of the practicing profession. AOPA is responsible for regulating the profession and is a founding member of the National Alliance of Self Regulating Health Professions (NASRHP) in partnership with other professional organisations, including Speech Pathology Australia, the Australian Association of Social Workers and Exercise and Sports Science Australia. AOPA is recognised by the Commonwealth Government as the assessing authority responsible for conducting migration skill assessments for orthotist/prosthetists.

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# Executive Summary

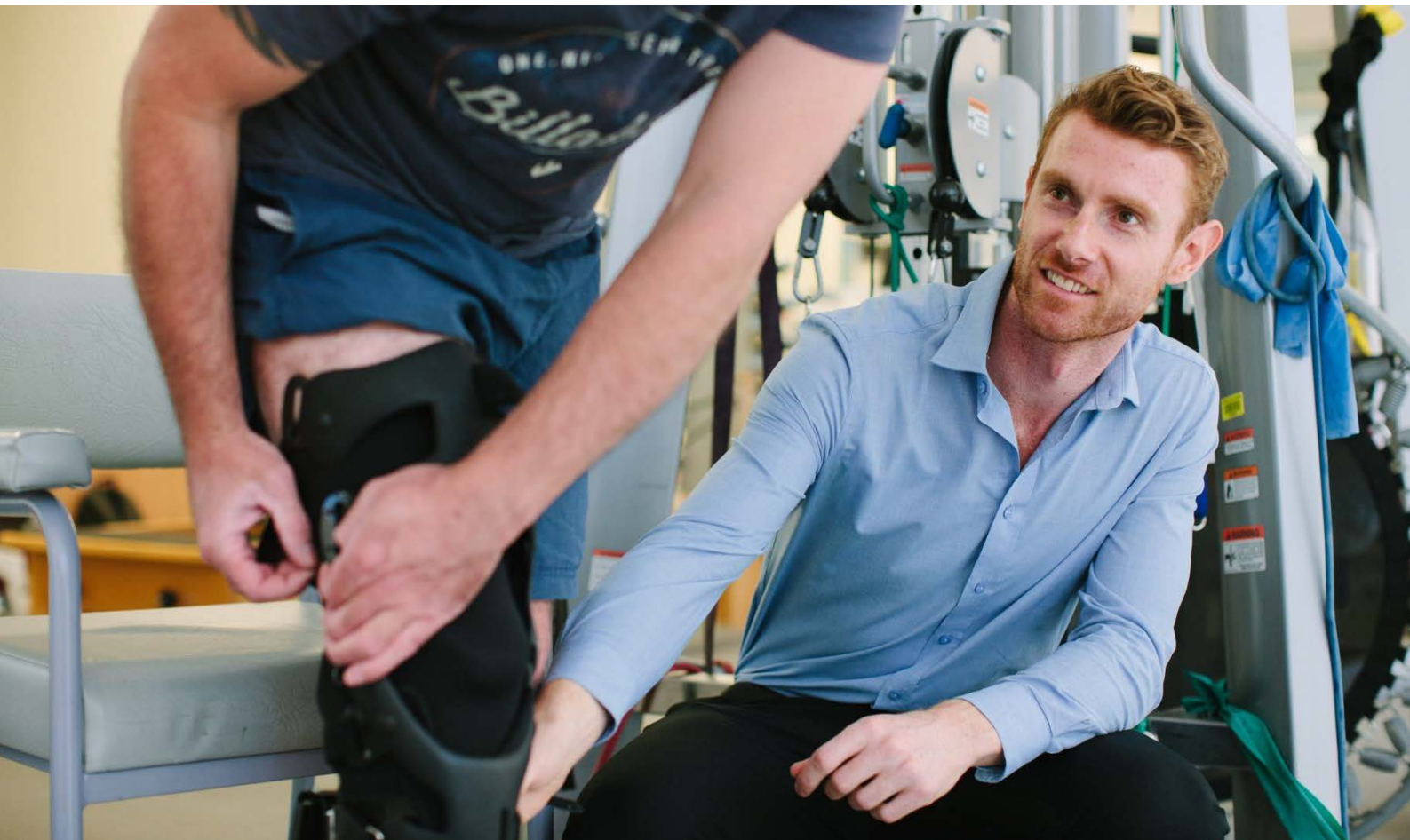
## The Australian Orthotic Prosthetic Association (AOPA) fully supports the regulation of orthoses and prostheses as medical devices.

The Australian Orthotic Prosthetic Association (AOPA) fully supports the regulation of orthoses and prostheses as medical devices. Whilst AOPA regulates the professional standards of certified Orthotist/Prosthetists in Australia, the Therapeutic Goods Act is the only specific mechanism in place to ensure the quality and safety of orthoses and prostheses.

The Therapeutic Goods Administration (TGA) play a vital role in the regulation of medical devices and it is AOPA's belief that all orthoses, prostheses and componentry should be regulated by The Commission.

AOPA welcomes the TGA's efforts to redefine medical devices used by people with disabilities and shift the current defintion of "household aids, or furniture or utensils, for people with disabilities" towards the internationally understood term, "assistive technology".

AOPA is pleased to provide the TGA with the following feedback regarding the clarification of the excluded goods determination.



# Impact of the Excluded Good Determination

Orthoses and prostheses and their integral components are currently regulated by the Therapeutic Goods Act, through compliance with the Essential Principles as custom-made medical devices and through the Australian Register of Therapeutic Goods (ARTG).

AOPA fully supports the regulation of orthoses and prostheses as medical devices. Currently all orthoses and prostheses are regulated by the Therapeutic Goods Act, through compliance with the Essential Principles as custom-made medical devices and the regulation of integral components through the Australian Register of Therapeutic Goods (ARTG). The consultation titled "Products used for and by people with disabilities - options for amendment to the Therapeutic Goods (Excluded Goods) Determination 2018" provides three options to clarify which products intended for use for, or by, people with disabilities are *excluded goods*. AOPA supports the adoption of option 2 as outlined in the consultation paper which will maintain the current regulation status of orthoses and prostheses and all integral components. In this case AOPA foresees few, if any unintended consequences.

AOPA believes a lack of regulation of orthoses and prostheses raises significant risks to the public. Despite orthoses and prostheses being listed as a Class I low risk devices, they have the risk of serious and long-term harm if inappropriately designed, manufactured, or monitored. We believe this risk is best managed regulation as a medical device by the TGA.

### Risks associated with weight-bearing devices

Lower limb orthoses and prostheses are among the most common assistive technology provided in Australia for persons with a disability. These devices are designed to take a person's weight to allow activities such as standing, walking and running. Should these devices experience critical failure due to poor device design or manufacture, the result could be catastrophic to the individual and other members of the community, such as critical failure whilst crossing the road, resulting in a fall.

### Risks associated with functional failure

Many other orthoses and prostheses, while not weight bearing, can also result in catastrophic harm if they experienced critical failure. Such examples include:

- A prefabricated unloading knee orthosis designed to provide a twisting force to relieve pressure on knee cartilage, has misaligned forces.
- A prosthetic hand opening while a child rides a bike
- A spinal brace not maintaining rigidity and appropriate support whilst being worn.

All the above examples may result in harm to the consumer whom may require additional care or treatment to address the damage caused by the medical device's functional failure.

### Risks associated with skin contact and direct application

Whist critical failure represents an obvious risk, many orthoses also present a risk of harm due to the nature of their application, such as the insertion of halo pins as part of a halo traction orthosis that meets the ARTG requirements and is appropriately supplied. There are numerous examples of high risk orthotic and prosthetic services, which to date have been appropriately regulated by the TGA.

## Current risk management

Currently regulatory oversight provided by the TGA protects consumers against faulty or poor quality orthotic/prosthetic devices.

In order to mitigate risk associated with critical failure of a weight bearing device, all componentry used in the device must hold clinical evidence sufficient to demonstrate an appropriate level of safety and performance and must be listed on the ARTG; this would include (but is not limited to) shock attenuators, prosthetic feet and knees.

When considering if a custom made orthosis is able to be safely used by a consumer, compliance with Essential Principles 1.3 (ensure medical devices perform in the way intended) and 1.1 (a medical device will not compromise the clinical condition or safety of a patient) will reduce risks of critical and functional failure of medical devices.

To ensure orthotic and prosthetic components are safe to use against skin and won't cause irritation or allergic reaction, the manufacturer or sponsor of a component must ensure there is sufficient clinical evidence to demonstrate the component does not cause an adverse reaction when applied to the skin.

The Essential Principles and the requirements of the ARTG set out minimum safety requirements which help to minimise the possibility of critical failure and adverse outcomes for people with disabilities. If orthoses and prostheses are removed from the TGA regulatory oversight, there is no requirement to conform to these minimum safety standards that are in place to protect consumers from risk of device failure and adverse events.

## AOPA recommends adoption of Option Two

Orthoses, prostheses and their integral componentry must continue to be regulated by the TGA if risk to consumers is to continue to be systematically mitigated. AOPA supports the adoption of option 2 for this reason.

As highlighted in the consultation paper;

> *"the option should also ensure that the specified products pose little or no risk to consumers, should these products not perform as specified"*

Under option 2, if an orthosis fails to provide the correct forces and harms the individual, the orthosis must be reported to the TGA as an adverse or significant event. Under option 1a or 1b no reporting or minimum standards are required regarding performance.

While there are significant immediate consequences of poor orthotic or prosthetic device quality experienced by the individual, there are also significant societal costs. For instance, any instant of hospital admission, such as resulting from fractures after a fall, may result in periods of being non-ambulatory which negatively affects mobility and functional capacity, employment, community participation and the need for carer support services. As a result, non-ambulant individuals may require major home modifications and wheelchair provision. Additionally, people who have used orthoses and prostheses that have failed to perform their required function may desist from utilising this technology completely, thus missing out on opportunities to improve their function and quality of life.

The design and structure of an orthosis/prosthesis does not necessarily equate to the level of risk the device holds; an orthosis of simple design may be used by a client with a complex clinical presentation, thus standards applicable to the orthosis must be analogous with the complex clinical presentation. A significant risk is posed to consumers of orthoses and prostheses if option 1A or 1B is adopted. Currently proactive regulation from the TGA ensures medical devices are safe and held to a basic standard. Under option 1A or 1B, assistive technology would be regulated by the ACCC/Fair trading model which does not have the necessary legislative authority and mechanisms that are required to effectively regulate medical devices. Therefore, AOPA unequivocally supports option 2 and the inclusion of all orthoses, prostheses, prefabricated and custom-made, including integral components, as medical devices regulated by the TGA.

AOPA looks forward to working with the TGA as the regulation of the orthotic and prosthetic sector Is reviewed, including consideration of previous consultations relating to 3D printing. We would gladly provide representation on future Working Parties to ensure expertise relating to orthoses, prostheses and 3D printing Is provided.

# Feedback as requested from the TGA

**Do you agree that the definition "household and personal aids, or furniture and utensils, for people with disabilities" should be replaced with a list of specified products determining these products to be excluded goods and of another list in Schedule 2 determining the products to be excluded goods when these products are used, advertised or presented for supply in a particular way?**

Yes, AOPA agree that the definition should be replaced with a list of specified products that are excluded.

**If 'yes', could you specify which products provided in Appendix A should be excluded (unconditionally or where they are used, advertised or presented for supply in a particular way), and which should be regulated as medical devices? Please provide your reasons for the suggestions having regard to the real or perceived risks associated with the use of the specified products.**

AOPA believe the following list of items should continue to be regulated as medical devices:

- All orthoses, including limb and truncal as currently listed in Appendix 1
- All orthotic components, currently listed as external limb orthotic component in Appendix 1
- All prosthetic components, currently listed as external limb prosthetic component in Appendix 1
- All orthotic and prosthetic consumable items, currently listed as Accessory in Appendix 1

Full definitions for each of these devices, as well as extensive clinical examples are provided in table 1 on page 10. In providing these definitions, AOPA has adopted accepted ISO:9999 terminology which is reflective of current best practice. AOPA supports the continued regulation of custom-made orthoses and prostheses which incorporate the above-mentioned orthotic and prosthetic components through manufacturer compliance with the EPs.

**Do you know other therapeutic goods intended for people with disabilities that should be excluded via the Determination (whether excluded unconditionally or where they are used, advertised or presented for supply in a particular way)? If yes, please provide description of the product group, and the reasons why.**

AOPA do not have any recommendations on the exclusion of other assistive technologies.

**What impacts—including any that are unintended—do you anticipate this change may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?**

Currently all orthoses and prostheses and their Integral componentry are regulated in some way by the Therapeutic Goods Act. If option 2 is adopted, and orthoses and prostheses are maintained as regulated medical devices, then the regulation of orthoses and prostheses will remain unchanged. In this case AOPA foresees few, if any unintended consequences. AOPA fully supports the regulation of orthoses and prostheses as medical devices.

As orthoses and prostheses are defined as assistive technology, under option 1A or 1B they would be excluded from the TGA. AOPA is concerned about the lack of regulation of orthoses and prostheses as well as orthotic and prosthetic componentry.

The consequences of providing orthoses and prostheses without meeting minimum standards for device quality and safety are extensive, affecting both the individual accessing the service as well as other members of the community. Without the regulatory safeguards relating to minimum standards specific to therapeutic devices may result in the increased likelihood of injury as a result of a device being poorly fitted, performing ineffectually, experiencing critical failure or dis-attachment. For example, a prosthetic hand failing or becoming unattached while riding a bike or dropping something. A knee orthosis failing while walking across the street, resulting in a fall and further injury. Risks may be longer term, such as developing tendon or ligament strain or damage to joint cartilage as a result of using wrist flexion to open a prosthetic hand when there is insufficient wrist anatomy to handle this long term. Or as a result of these things, decisions not pursue future orthoses or prostheses because of negative experiences.

**What products are excluded under current arrangements, but would no longer be excluded under the list of specific products, and so require inclusion in the ARTG?**

There are no orthoses or prostheses currently excluded from regulation by the Therapeutic Goods Act. There are currently no orthosis or prosthesis components excluded from the ARTG requirements unless sponsors have used the Schedule 1, item 9 definition ". . . personal aids . . ." in their assessment of therapeutic goods. We expect that few sponsors of orthotic and prosthetic components would have adopted this definition and therefore adoption of option 2 will likely have minimal impact.

**Do you have any other options to clarify the meaning of Item 9, Schedule 1 of the Determination?**

No, option 2 presented in the consultation paper will suffice.

**Do you think the description(s) of any other items currently included in Schedule 1 or Schedule 2 of the Determination should be clarified, and if yes, why?**

Yes, as mentioned above, AOPA believe the terminology used to describe orthotic and prosthetic devices currently listed in appendix A in schedule 1 and 2 does not meet current best practice ISO:9999 terminology. In light of this, AOPA has provided alternate descriptions to replace the existing categories representing prosthetic and orthotic devices in appendix A. We provide the industry-accepted definitions for device types, appropriate naming of device according to body part, as well as relevant clinical examples to demonstrate how this classification encompasses all possible types of orthoses and prostheses and can be readily understood by all stakeholders. Please refer to table 1 for details.

**Are there any further issues and questions we should consider when implementing this change (including areas that can/should be clarified in our guidance)?**

AOPA do not have any further issues or questions to consider.

**Do you have any comments regarding the transitional arrangements proposed in this paper? This includes comments on the quantum of products which may shift into or out of the regulatory framework under each option, and any advice on costs and benefits to the sector in these changes?**

AOPA believes it would be beneficial for all stakeholders for the TGA to clearly communicate any future changes and hold a period of transition. It may also be beneficial for the TGA to host webinars or workshops surrounding any changes relating to the TGA and assist stakeholders in understanding their roles. AOPA also believes decision tress should be used in order to clarity the process for manufacturers and orthotic/prosthetic practitioners

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