



**Australian
Pedorthic
Medical
Grade
Footwear
Association**

Australian Pedorthic Medical Grade Footwear Association Inc

ABN 84 854 582 883

PO Box 5144, Prestons NSW 2170

Telephone (02) 9823 0684 Facsimile (02) 9610 7965

Email info@apmgfa.org.au

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Parliamentary and Management Group
Office of Devices, Blood and Tissues
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir,

Australian Medical Devices Guidance Document Number XX – Custom Made Medical Devices

The Australian Pedorthic Medical Grade Footwear Association (APMGFA) represents the Pedorthic Industry in Australia.

Pedorthics is the professional field concerned with the provision of medical grade footwear (MGF), orthotics appliances and appropriate advice to a patient after assessment and analysis of the patient's problems. This includes the provision of pre-fabricated footwear, alteration of prefabricated footwear, custom designed and manufactured footwear/orthotics appliances and advice on the need and application of medical grade footwear and orthotic appliances.

It is our understanding that orthotics and footwear marketed as an appliance to assist with the management of a medical problem are considered Medical Devices and come under that meaning for the purpose of registration with TGA. In particular the definition of a medical device "... alleviation of or compensation for an injury or handicap" leads us to draw this conclusion. This is the reason we have submitted our comments to your committee.

Over recent years the APMGFA has introduced formal training and registration of Pedorthist and we now award the credentials for Certified Pedorthists (CPed). Other registrations include CRetPed for those retailing prefabricated MGF and related devices with limited fitting adjustment to those products, CPed for those that provide custom made orthoses and modify prefabricated footwear as well as the CPed CM for those pedorthists that specialise in custom making of orthotic devices and MGF. More details about APMGFA can be found on our website www.apmgfa.org.au.

A Pedorthist is a specialist in using footwear - which includes shoes, shoe modifications, orthoses and other pedorthic devices - to solve problems in, or related to, the foot and lower limb.

Primarily, a Pedorthist will select, make and/or modify footwear and foot control devices to help people maintain or regain as much mobility as possible or to optimize their lower extremity biomechanics.

When ability to walk is affected, everything that surrounds or touches a foot - whether it is foot orthoses (commonly known as orthotics or arch supports), shoes, boots, slippers, sandals, socks, hosiery, night splints, bandages, braces, partial-foot prosthetics, or other devices - interacts with a foot; this makes footwear a crucial part of a recommended treatment plan.

We know that we have a role in the health of our patients. In the area of preventative health care such as treatment of diabetic foot conditions, the Pedorthists is a valued team member alongside the Podiatrist and Medical Practitioner and therefore have something to contribute to the successful implementation of the Primary Health Care Strategy. Our submission is basically a comment on some of the requirements in the guideline. In general we believe a guideline of this type will be useful to our members.

We will be pleased to provide further comment and input if required.

Yours truly,

Casper Ozinga
Secretary
Australian Pedorthic Medical Grade Footwear Association.

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We have recognised for some time that it will be necessary for many of our members to register with TGA. Up until the publication of this guideline the specific requirements and process for registering has not been generally known.

It should be noted that at present few, if any, members of APMGFA have TGA registration and their products listed on the register. However it is recognised that in due course all the products sold by the members will need to be on the register.

Pedorthic products usually fall into a low risk category and are classified as “Other Class I medical device”.

Due to the structure of the industry the manufacture of the prefabricated medical grade and other footwear is usually done overseas. In situations when the prefabricated footwear requires modification or a custom made shoe/orthotic is required, it is done by a Pedorthist who is usually situated in a “small business”.

The size of the industry is approximately 400 businesses in Australia and most of these will be one person concerns.

The strict, individual adherence to the requirements within the guidelines will be of significant additional financial burden to our members. Assessment of each of these businesses would also constitute a significant financial cost. It is unlikely that the Australian market for medical grade footwear under the existing structure could carry this burden.

Within our industry we have worked on ensuring the competency of our members. In the CPed training, depending on their designation, the individuals are trained to work from a referral, or without a referral, doing their own Pedorthic assessment as well as to recognise a low risk v/s a high risk situation and provide the appropriate product and service. Low risk v/s high risk within the Pedorthic / medical grade footwear context relates to issues for example insensate feet like the diabetic foot related risks or similar. This may not compare to what TGA sees at low or high risk. CPeds, depending on their designation are trained in the manufacture of the orthotic/footwear and have the appropriate equipment to custom make or modify the device.

We have recognised the need for a “quality management system” environment for the industry and several years ago developed and supplied an industry based operations manual based on the ISO 9001 Standards. Many of the CPed CM (custom makers) and CPed (modifiers) implemented their management systems using these guidelines. In general there has been no independent assessment of the implementation of these guidelines.

The Guideline document explains the requirement of the regulations in terms that can be easily followed and we would be pleased to support the implementation of its requirements.

Our areas of concern in the document include:

Participants that supply the footwear

Ours is a small industry that has traditionally been supplied by ethnic and family based trained persons and some vocationally trained persons. Many have not upgraded training in many years.

The implementation of the requirements of the regulation will add a significant cost to those already working in the industry and given the length of time they have operated, there will be resistance to change.

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The APMGFA can work towards making our members aware of the requirements and providing resources to assist with them, however we only represent a fraction of the total market.

For this purpose we identify three significant groups within the total market

1. Group 'a' have upgraded their qualifications and now hold the highest qualification attainable in Australia.
2. Group 'b' have access to the training and qualification process but have resisted or declined to upgrade.

Government and Private funding and regulating bodies have not yet supported the qualification and training process. This is a very significant bar to this group moving forward.

(Queensland Health has now supported this in writing and only qualified Pedorthist can supply medical grade footwear to this body.

<http://www.health.qld.gov.au/mass/docs/procedures/massmgfprocfeb09.pdf>
Chapter 6. MASS LIST OF MEDICAL GRADE FOOTWEAR SUPPLIERS..... 5)

To move this group forward, greater qualification and achieving the aims of TGA regulation, Government bodies must help support the measures of APMGFA to upgrade the industry.

APMGFA seeks active support from TGA for it's training and requests direct support in the document for the qualification of C.Ped. APMGFA is willing to work with TGA on this.

These people are not likely to implement systems required by the guidelines.

3. Group 'c' have difficulty accessing the training and qualification process due to distance barriers. Until government and private funding and regulatory bodies actively support the training qualification, the logistics of APMGFA holding training and qualification processes in areas available to all of Australia is impossible.

These people are not likely to implement systems required by the guidelines.

The cost of reaching the rest of the market may need to be considered and how they will be reached. In many cases those outside the APMGFA are not members of any representative association.

Some specific examples

- Modifications by local shoe repairers

Many modifications to footwear are currently performed by local shoe repairers. Given the definitions on pg 12 of the guideline, the incorporation of materials not primarily intended for the original product, would make these businesses manufacturers of "customised medical devices".

The additional of soling materials, raises and rocker soles etc are significant changes to function of the footwear.

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- Shoe retailers providing footwear to people with medical conditions

Many hi risk conditions require specific footwear.

General retailers of footwear are not trained nor do they enquire about specific conditions of the lower limb of the person being fitted.

These people are not likely to implement systems required by the guidelines.

- Supply by prescribers

We recognise that the position of the Podorthist in the supply of the medical device is analogous to a pharmacist i.e. we respond to a referral and work with another medical practitioner to meet the patients needs. There is a practice in the industry for podiatrists to prescribe and supply orthotics. Our interpretation of the guidelines is that this will no longer be permitted, however the wording is still vague and may permit the existing conflicts of interest to persist.

We suggest that stronger wording such as

“The manufacture and supply of a medical device shall be separated from the prescription of the device, such that the prescriber is in a position to confirm the fulfilment and success of the medical device without financial benefit.”

- Untrained / unregistered suppliers

There is a significant number of suppliers of medical grade footwear that have no qualification or registration, to demonstrate competency to supply. These same people are unlikely to implement the systems requirements detailed in the guidelines. Given the cost of implementation, we ask if TGA have given consideration to policing the requirements.

Amount of records required

It is clear that the guidelines specify a large quantity of records that need to be prepared and maintained. Given the recognised low risk of the orthotics and medical grade footwear produced by members of APMGFA, it is suggested that the manufacturer be given some flexibility to reduce the records and retention of the records based on a risk assessment.

Information required for the user

The footwear provided by Podorthists is very similar to the regular footwear worn by people excluding those needing a custom made product. In most cases there is no need for special instruction or advice on the use as the users have been wearing similar devices most of their life.

It is suggested that the amount of information that needs to be supplied to the user is decided by doing a risk assessment of the needs of the patient. If it becomes mandatory for the information to be supplied in every case, there will be a significant increase in cost, and it is unlikely the information will be used.

Distinction between manufacturer and sponsor

The definitions of sponsor and manufacturer have been cleared up and the responsibilities of each have been identified.

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One area of concern is if a product is imported without the intent to be used as a custom made medical device, but subsequently becomes one due to application and perhaps minor modification; what is the role of the manufacturer/sponsor? For example a shoe with extra depth for comfort is imported and subsequently modified by the addition of a rocker sole and minor orthotic device. Who is the manufacturer, who is the sponsor and what records and instructions are required.

Degree of customisation permitted of pre-fabricated footwear

Pre-fabricated footwear is generally imported into Australia and sold by pedorthic retailers. What degree does modification of this footwear require before it becomes custom made?

In most cases the materials used for the modification are not provided by the manufacturer, but rather come from general stores of sole material and leather.

In other cases the modification is carried out by the stretching and changing of the footwear without the use of additional material.

It is suggested that some scale be developed that will distinguish the difference between “custom made” and “customised” footwear. This scale may depend upon value added or degree of modification.

Classification

On page 14 of the guideline there is a clause “Depending on the classification of the devices, the manufacturer may need to have those processes and their quality management system assessed by a conformity assessment body.” Given that most of the work done by Pedorthists is in Class I, will there be a requirement for this assessment?

We have covered some of our concerns, particularly cost, in our previous submission on third party assessment bodies.

Custom Made Medical Devices ...using many different materials...not originally intended to be used....a medical device (page 14)

Many components of custom made footwear and (also used in the modifying or pre-made footwear) are sourced from commercial footwear manufacturing supply chains, none of which will be interested in conforming to any TGA requirements.

An example being the leather used in lining a custom made boot or the sole units used on custom made footwear were originally pre-made for mass construction of commercial footwear.

With responsibility residing with the manufacturer to comply with the essential principles there may be no way of his/her judging aspects of compliance to certain areas of the essential principles due to the lack of knowledge of the raw material given by supplier.

Areas such as Chemical, Physical and Biological properties, Sterility, Infection and microbial contamination.

Essential Principles

On page 15, there is reference to the “Essential Principles”. We have reviewed the list and suggest that a number of the principles do not apply to footwear. Is there provision for the manufacturer to identify that a principle is “not applicable” and thus assume that compliance is deemed. The principles that we suggest are obviously not applicable to footwear include:

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- Handling and storage
- Chemical, physical and biological properties
- Infection and microbial contamination
- Sterility
- Risks associated with any internal energy source

Risk Management

Recognising the basics of Risk Assessment, Planning and Implementation, should there be some provision for review and audit of the risk assessment by a third party or should the manufacturer be responsible for the plan until something goes wrong and then authorities make some ruling.

Labelling of Custom Made Medical Devices

It is recognised that there is provision for the labelling on the device to be separate and in the package, however often the custom made footwear is provided without labelling and often without packaging.

It is assumed that provision of the information in a brochure and handed to the patient at the time of fitting will be sufficient.

Size of text

The use of text that is only one millimetre seems to be too small. Users of medical devices are often also visually impaired and the use of one millimetre text would appear to be a waste of effort.

In general, APMGFA is in support of the implementation of the guidelines and looks forward to working with TGA to improve the provision of medical grade footwear to Australians.

We suggest that our association is well placed to assist with the roll-out into the pedorthic industry; however the cost of this work may require some subsidy from TGA or DoHA to make it possible.

We would be pleased to work with TGA and DoHA to develop a full proposal if required.