



**Australian  
Pedorthic  
Medical  
Grade  
Footwear  
Association**

## **Australian Pedorthic Medical Grade Footwear Association Inc**

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27 March 2009

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

Dear Sir,

### **Use of third party conformity assessment bodies for medical devices supplied in Australia**

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. This is the reason we have submitted this discussion paper 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](http://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. In our submission, which follows this introductory letter, we have documented our response to the questions you propose on page 10 of your discussion paper.

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

Yours truly,

Casper Ozinga  
Secretary  
Australian Pedorthic Medical Grade Footwear Association.

## APMGFA submission to TGA Consultation Paper

### Use of Third Party Conformity Assessment Bodies for Medical Devices Supplied in Australia

We have considered the issues highlighted in the consultation paper and used the same sequence and headings as given in the paper.

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 assessment of each of these businesses would constitute a significant financial cost and it is unlikely that the Australian market for medical grade footwear could carry this burden, and is unlikely to reduce any risk involved in the supply of the product.

We believe that although the medical grade footwear is a Medical Device under the meaning of the act, a more realistic approach is to ensure the individuals in the industry are adequately qualified. The APMGFA CPed certification and registration system is the appropriate endorsement for this type of product.

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 following issues to be discussed are the three broad categories detailed in the consultation paper:***

#### ***1. What role should the TGA have in issuing conformity assessment certificates?***

We have no firm position on the position TGA should take in the issuing of a conformity assessment certificate. We recognise the conflict of interest issues that may arise if a manufacturer is able to choose an assessment body based on a perceived potential for an easier assessment.

These conflicts of interest have been handled well by the certification industry through an accreditation body such as the Joint Accreditation System for Australian and New Zealand (JASANZ.)

## APMGFA submission to TGA Consultation Paper

### Use of Third Party Conformity Assessment Bodies for Medical Devices Supplied in Australia

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We believe it is beneficial for the registration of conformity assessment certificates to be held and available on a central register similar to the current TGA register and strongly support the maintenance of this system.

On the question on the role of TGA, at the very least they should continue to manage the register and if third party assessment bodies are engaged, then the register of these bodies should also be managed either by TGA or a body such as JASANZ.

#### ***Should the TGA continue to have a role in issuing conformity assessment certificates?***

The issuing of the conformity assessment certificate should be managed by the assessment body that conduct the audit and makes the recommendation for the issue of the certificate. We do not support a system where some organisation performs the assessment and then TGA issues the conformity certificate.

In this scenario, the assessment body would issue the conformity assessment certificate and TGA could then license the sale or export of the medical device.

The reason for allowing other assessment bodies to enter the process is if they are able to offer the assessment service at a lower cost than TGA. A review of the TGA fees suggests that the existing pricing is significantly higher than comparable assessment systems.

#### ***Should the TGA continue to have sole responsibility for issuing certificates for Australian made devices intended for supply in Australia and/or for devices containing a designated material?***

The only problem we have with TGA having sole responsibility for the issuing of certificates for Australian made devices is the cost of the service. In areas where there is competition for the assessment service significant cost reductions can be made taking into account the risk involved in the use of the product and the size of the organisation.

As indicated in our preface, the Australian manufacturers of custom made MGF and orthotics and those that modify the prefabricated footwear are very small businesses – less than ten and often only one employee. The imposition of the cost of assessment in the order of several thousand dollars would appear to be unwarranted and will result in many providers leaving the industry. We base our costing on the extract from the schedule of fees on the website.

<b>Evaluation Fees</b>	<b>Fee \$</b>
Evaluation for assessing whether a listable or listed device is safe for the purposes for which it is to be used	13,700

There needs to be adjustment for significantly lower risk and smaller businesses.

#### ***Should the TGA be required to issue conformity assessment certificates for specific classes and/or types of devices, for example high risk devices?***

Input to the forum for high risk devices is outside of the scope of our organisation due to our recognised low risk status.

#### ***II. What requirements, if any, should apply if third party assessment was available for Australian device manufacturers intending to supply in Australia and/or for ones containing designated materials?***

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Any organisation that wants to provide third party assessments should be capable of assessing and making decisions to the same standard as TGA currently provides. It is recognised that TGA may be subject to international requirements for recognition of the assessment bodies; however it is our understanding that international standards for Conformity Assessment Bodies exist such as ISO 17021 (Conformity assessment - Requirements for bodies providing audit and certification of management systems), which may be applicable to this question.

Any organisation providing the decision on the conformance of the manufacturer should be itself accredited to an appropriate standard.

It is assumed that internationally assessment companies meet a standard such as this.

#### ***Should legislation specify that external bodies undertaking assessments be resident in Australia?***

We have no input to this question as it is envisaged that if our members require assessment they will engage a resident body. We do recognise that international manufacturers who do some manufacture in Australia may wish to use that same body in Australia that they use in their home country.

#### ***Should the TGA have a role in accrediting these Australian external bodies?***

It is our opinion that TGA is the appropriate body for setting the standards for the third party accreditation bodies. It is our opinion that whichever body is responsible for the accreditation of external assessment bodies will be able to demonstrate sufficient separation from the applicant body to not pose any conflict of interest.

Should TGA continue to be one of the assessment bodies it will need to meet the same standards as the other bodies and may be construed to be a direct competitor. If this is the case then it is assumed that TGA would not be in a position to assess the third party.

In this situation we imagine that TGA will be one of the key stakeholder in developing the scheme requirements for the assessment bodies that assess manufacturers of medical device, but will not be one of the bodies that does the assessment. We do not believe that maintaining the register, which is essentially an administrative role subject to public scrutiny poses a conflict of interest as one of the assessment bodies.

#### ***III. If external bodies are allowed to undertake assessments of Australian made devices and/or ones with a designated material should they be permitted to issue certificates or should they provide reviews for the TGA to assess and then the TGA issue a certificate based on its review.***

The response to this matter depends upon the operational role of TGA in the final model. If TGA remains one of the assessment organisations, then it would be inappropriate for it to be passing judgement on its competitor's recommendations. However if TGA removes itself from the assessment process entirely and only participates in the review of the assessment reports and having input into the development of the standards, then it could contribute in this manner.

In summary, the APMGFA has no objection to the TGA continuing as the sole assessment body in Australia for Medical Devices, however if it is decided that other third party assessment organisation will be permitted to enter this space then steps will need to be taken to ensure the management of conflicts of interest.

## **APMGFA submission to TGA Consultation Paper**

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Any change however will need the participation of a body such as JASANZ to ensure degree of confidence in the assessment process.

Our major concern is the cost of the accreditation process and we would be pleased to work with the TGA and DoHA to develop a model for the accreditation of the CPeds. It is recognised that this require some funding.

A model that may work would be similar to our understanding of the accreditation processes used by General Practitioners and Pharmacy. Our understanding is that the government provided funding for the development of the accreditation standards/guidelines for compliance with the standards and also funded the accreditation / assessment of the businesses.

We would be pleased to discuss with TGA the cost of such a system, but envisage that it would be significantly less than either of the two primary health care providers. If there is some provision for such a system we would be pleased to review the full requirements and develop a funding proposal.