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**Aged Care**
**Association**
**Beauty Salons & Therapists**
**Child Care**
**Chiropractor**
**Dentist**
**Division of General Practice**
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**Family Day Care**
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## Importation of Dental Appliances and Equipment

Paul Baker and Lauren Stalley of Meridian Lawyers, on behalf of Guild Insurance, analyse and discuss the legal issues flowing from the use of dental appliances and equipment imported from overseas by practitioners on their patients in Australia.

This article will address issues touching on this situation in the context of the legislative requirements, related duty of care aspects, and professional indemnity insurance considerations.

Over the past six months there has been extensive media coverage on the issue of importation of dental appliances and equipment and the alleged risk presented to the Australian public. The chief concerns centre on the contention that a number of these dental appliances and equipment manufactured overseas do not conform to the same high standards as Australian manufacturing.

On top of this, there have been reports of incidents of injuries suffered by members of the public when such devices and materials have failed in one form or another.

**The Legislation**

There are two legislative instruments dealing with medical devices operating within Australia. They are the *Therapeutic Goods Act* (the TGA Act) and the *Therapeutic Goods (Medical Devices) Regulations* 2002.

The TGA Act requires that all medical devices are required to be registered on the Australian Register of Therapeutic Goods (ARTG). Therefore the first issue for consideration is whether a particular device falls within the scope of the TGA Act.

Section 41BD of the TGA Act, among other things, defines a medical device as:-

*(a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:*

*(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;*

*(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;*

1. *(iii) investigation, replacement or modification of the anatomy or of a physiological process;*
2. *(iv) control of conception;*

*and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or*

*(aa) any instrument, apparatus, appliance, material or other article specified under subsection (2A); or*

*(ab) any instrument, apparatus, appliance, material or other article that is included in a class of instruments, apparatus, appliances, materials or other articles specified under subsection (2B); or*

*(b) an accessory to an instrument, apparatus, appliance, material or other article covered by paragraph (a), (aa) or (ab).*

This definition encompasses dental devices such as amalgam, water-based cements, powered dental equipment, implants and materials of biological origin. In confirming this position, the Therapeutic Goods Administration ("TGA") recently published that therapeutic goods may not be supplied in Australia or exported unless the product is included in the ARTG by an Australian sponsor. It is an offence to use and/or import a product that is not on the ARTG.

While the current regulatory system operating within Australia for medical devices came into force on 4 October 2002, stricter legislative amendments have recently been flagged by the

TGA in the wake of recent media coverage. Specifically, it is understood that the TGA procedures are to be enhanced to require new standardised procedures relevant not only to registration and use of medical devices falling under the TGA Act, but also in relation to other matters including:-

- The nature and extent of documentation required to be kept by the manufacturer concerning the design, production and intended performance of the device;
- Aspects confirming that the device complies with the requirements that would essentially be in place if the device was being sought to be registered in Australia known as the Essential Principles.

This means that evidence will need to be presented confirming that, among other things:-

- The use of the medical device will not compromise health and safety;
- Design and construction of medical devices conform with safety principles generally;
- The medical device must be confirmed as being suitable for intended purposes with those purposes being stated;
- Confirmation the medical devices will not be adversely affected by transport or storage; and
- Confirmation and evidence that the benefits of medical devices will outweigh any side effects.

This is a complex and vexed issue which requires extensive consideration based on the particular device proposed to be used in dental treatment.

One issue that has been raised is whether a TGA approved medical device can be imported into Australia and used in the treatment of the importer or a member of the importer's immediate family. The simple answer appears to be yes; schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations* 2002 allows such use.

Another question raised is whether custom-made dentures require TGA approval. Custom-made medical devices are specifically excluded from the regime of the TGA Act. Literature published by the TGA in 2008 under the Australian Medical Devices Guidance documents states that dental appliances such as crowns, bridges and dentures used to replace natural teeth are deemed to encompass a custom-made medical device and therefore are exempt from the registration and other requirements imposed under the TGA Act.

Queries have also been raised as to whether amalgams and other components used in dental treatment are required to be registered under the TGA Act. This is a difficult question in the context that each individual material needs to be considered in the context of the condition in section 41BD of the Act (see definition earlier in this article). In each instance it is necessary for the dental practitioner to determine whether the material will be used in the prevention or treatment or alleviation of a disease or injury or disability, or in the replacement or modification of the anatomy or a physiological process. To our way of thinking it is highly arguable that in almost all circumstances they will require registration as a medical device. A legal duty rests on the dental practitioner to confirm that compliance of such material is as required under the ARTG.

**Trade Practices Act**

A further complicating legislative aspect concerns the application of section 74 of the *Trade Practices Act* ("the TPA Act"). The TPA Act stipulates that if a corporation imports goods into Australia which was not the manufacturer of the goods and if at the time of the importation the manufacturer of the goods does not have a place of business in Australia, the corporation importing the goods shall be deemed by the TPA Act to be the actual manufacturer.

If a dental practice utilises a service or other corporate entity for the supply of dental appliances and equipment, that entity will be deemed to be the manufacturer of the imported equipment with a resulting legal liability attaching if such equipment fails and/or causes injury.

**Common Law Position**

A dental practitioner owes a patient a general duty of care. That duty extends to the practitioner taking reasonable care for the patient's safety. If injury arises a patient could contend that the duty of care was breached, particularly if evidence can be adduced that the device or appliance utilised was manufactured overseas and was of an inferior quality or faulty.

While no precedent case dealing with these exact circumstances has been identified in Australia, the potential obviously arises for a patient who suffers injury as a result of the use of an imported appliance or device to pursue legal redress against the practitioner as well as the manufacturer.

From a legal procedural perspective plaintiff lawyers will ordinarily pursue the easiest course of redress, particularly if the manufacturer is an overseas entity, heightening the likelihood of a claim being made against the practitioner direct in these circumstances. While the practitioner can seek an indemnity from the manufacturer, jurisdictional and legal complications often arise. The potential costs and uncertain prospects of recovery can result in indemnity against the manufacturer not being pursued.

In these circumstances, and assuming insurance coverage is available it will be the dentist's scheme which bears the costs of any damages payment.

**Profesional Indemnity Insurance Considerations**

Queries have been raised as to whether a dental practitioner's indemnity policy of insurance respond to a claim arising from the failure of a dental appliance or equipment imported from overseas and which causes injury to a patient.

If one refers to the Guild Insurance policy, the coverage is stated to extend to a claim for bodily injury or damage to property arising from goods sold and advice on goods sold where the nature, condition or quality of such goods causes such injury. However, for the policy to respond it is necessary for a defect or deficiency in the goods to be established.

Insurance cover will be available to a practitioner in certain circumstances however it is important to note that cover would not extend in circumstances where goods sold or supplied by a dentist occurred with prior knowledge of any defect or deficiency in their nature, condition or quality.

Finally, practitioners should be aware that the indemnity insurer in circumstances where an injury of this nature occurs would undoubtedly seek to be indemnified by the manufacturer of the goods by reason of their asserted defective nature. This gives rise to a myriad of complications where the manufacturer is ultimately deemed to be the dental corporation importing such goods or equipment or devices.

**Conclusion**

The use of imported devices and equipment can give rise to complex legal and insurance considerations and extreme caution is urged if practitioners are seriously contemplating pursuing this course. It is critical that appropriate legal advice is obtained to ensure that

appropriate insurance cover is held both from a manufacturing and a professional indemnity/goods sold and delivered perspective.

## News by Profession

- Aged Care ( 1 )
- Association ( 2 )
- Audiologist ( 1 )
- Child Care ( 5 )
- Chiropractor ( 6 )
- Dental Prosthetist and Dental Technician ( 1 )
- Dentist ( 4 )
- Exercise and Sports Science Practitioner ( 2 )
- Family Day Care ( 1 )
- Fitness Professional or Personal Trainer ( 1 )
- Neighbourhood Houses ( 6 )
- Nurse ( 1 )
- Optometrist ( 5 )
- Osteopath ( 4 )
- Pharmacist ( 3 )
- Physiotherapist ( 8 )
- Podiatrist ( 4 )
- Speech Pathologist ( 2 )
- Veterinarian ( 6 )