cc Nicola Rosseck

Australian Government

Department of Health
Therapeutic Goods Administration

Mr Chris Bourke MLA
Standing Committee on Health, Ageing and Community and Social Services
GPO Box 1020
CANBERRA ACT 2601

Our Reference: R14/999285

Dear Mr Bourke MLA

Subject: TGA Submission to the Inquiry into sourcing and supply of dental appliances to Australian dental practitioners from overseas

The Therapeutic Goods Administration (TGA) is pleased to contribute towards the Australian Capital Territory Standing Committee on Health, Ageing and Community and Social Services into the sourcing and supply of dental appliances to Australian dental practitioners from overseas.

The TGA's overall purpose is to protect public health and safety by regulating therapeutic goods that are supplied in or exported from Australia. The role of the TGA is to apply the therapeutic goods legislation, primarily the *Therapeutic Goods Act 1989* (the Act). Further, it is important to note that the TGA does not regulate dental care practitioners, dental technicians, nor their practices.

However, there are aspects of the TGA's regulatory remit which may be relevant to your inquiry, in particular, the TGA's regulation of medical devices included on the Australian Register of Therapeutic Goods and specifically custom-made devices. In this regard, I attach an overview of what the TGA is responsible for as well as a summary of how the TGA regulates these devices.

The TGA has been actively working with dental industry peak associations regarding regulation of custom made devices. I have met with the Chief Executive Officer of the Australian Dental Association and the Chair of the Australian Dental Board of Australia on these matters. These organisations have undertaken to remind dentists of their legal obligations in relation to custom- made dental products and to consider adopting the United Kingdom approach of requiring a statement of manufacture be provided to patients.

Please contact me if you would like to discuss any of these matters further.

Yours sincerely,

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What does the TGA do?

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health. The TGA's overall purpose is to protect public health and safety by regulating therapeutic goods that are supplied either imported or manufactured, or exported from Australia. At the same time the TGA aims to ensure that the Australian community has access, within a reasonable timeframe, to new therapeutic goods.

How does the TGA regulate?

The Australian community expects therapeutic goods in the marketplace to be safe, of high quality and of a standard at least equal to that of comparable countries. The TGA regulates therapeutic goods through:

- pre-market assessment;
- post-market monitoring and enforcement of standards; and
- licensing of Australian manufacturers and verifying overseas manufacturers' compliance with the same standards as their Australian counterparts.

Therapeutic goods must be listed, registered or included on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia, unless specifically exempt under the Act.

What are 'therapeutic goods'?

In relation to the evaluation, assessment and monitoring done by the TGA, therapeutic goods are broadly defined as products for use in humans in connection with:

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury
- influencing inhibiting or modifying a physiological process
- testing the susceptibility of persons to a disease or ailment
- influencing, controlling or preventing conception; and
- testing for pregnancy.

This includes products that are:

- used as an ingredient or component in the manufacture of therapeutic goods; or
- used to replace or modify of parts of the anatomy.

Risk based approach

The TGA approves and regulates products based on an assessment of risks against benefits. All therapeutic goods carry potential risks, some of which are minor, some potentially serious. The TGA applies scientific and clinical expertise to its decision-making to ensure that the benefits of a product outweigh any risk.

The level of TGA regulatory control increases with the level of risk the medicine or device can pose. Risk information is used by the TGA when deciding how to approve a medication for supply. For example, a low-risk product may be safely sold through supermarkets, while higher-risk products may only be supplied with a prescription.

The TGA's approach to risk management involves:

- identifying, assessing and evaluating the risks posed by therapeutic products
- applying any measures necessary for treating the risks posed; and
- monitoring and reviewing risks over time.

The risk-benefit approach assures consumers that the products they take are safe for their intended use, while still providing access to products that are essential to their health needs.

The regulation of medical devices

Medical devices are used on humans, have therapeutic benefits and generally have a physical or mechanical effect on the body or are used to measure or monitor functions of the body[1]. Many dental appliances and prostheses fall within the definition of a medical device.

Under the Act, medical devices must be included on the ARTG prior to supply in Australia unless exempt from that requirement. In order to be included on the ARTG, devices must have the necessary conformity assessment certification to ensure they are of acceptable safety and quality, and perform as intended. An application must then be made to the TGA to include the device on the ARTG, supported by the appropriate conformity assessment certification.

The level of assessment conducted by the TGA at the point of application for ARTG inclusion can depend on the following main items:

- the risk classification of the device (the lowest being Class I and the highest Class III and Active Implantable Medical Devices); and
- whether the TGA or an overseas body issued the conformity assessment certificate.

Conformity assessment

Conformity assessment is the systematic examination of evidence generated, and procedures undertaken, by the manufacturer to determine that a medical device is safe and performs as intended and therefore conforms to the Essential Principles[2].

The Essential Principles set out the requirements relating to the safety and performance characteristics of medical devices. There are six general Essential Principles that apply to all devices and a further nine Essential Principles that apply to devices on a case-by-case basis.

General Principles that apply to all devices

- use of medical devices not to compromise health and safety
- design and construction of medical devices to conform to safety principles

[1] A definition of 'medical devices' is set out in section 41BD of the Therapeutic Goods Act 1989
[2] Schedule 1 of the Therapeutic Goods (Medical Device) Regulations 2002

- medical devices to be suitable for intended purpose
- long-term safety
- medical devices not to be adversely affected by transport of storage
- benefits of medical devices to outweigh any side effects

Principles about design and construction

- chemical, physical and biological properties
- infection and microbial contamination
- construction and environmental properties
- medical devices with a measuring function
- protection against radiation
- medical devices connected to or equipped with an energy source
- information to be provided with medical devices
- clinical evidence
- principles applying to IVD medical devices only

The regulatory framework provides flexibility for manufacturers and caters for technological advances and changes in the development of new medical devices. It does not mandate the means by which a manufacturer must prove that they have met the Essential Principles.

It is the responsibility of the manufacturer to gather the evidence required to demonstrate compliance with the Essential Principles. In order to do that, manufacturers must comply with a minimum set of conformity assessment procedures defined in legislation which are based on the level of risk of the device.

The regulatory framework provides flexibility for manufacturers and caters for technological advances and changes in the development of new medical devices. It does not mandate the means by which a manufacturer must prove that they have met the Essential Principles.

The medical devices regulatory framework has a classification system for medical devices[3]. The higher the risk associated with the device, the more onerous the requirements for evidence to demonstrate compliance with the Essential Principles. The classification of dental appliances and prostheses varies according to the risk associated with the device. For example:

- an implantable dental device, such a root canal post, may be classified as being of low to medium risk (Class IIa)
- a dental chair may be low risk (Class I) or low to medium risk (Class IIa) if the chair includes provision to channel liquid or gas to be administered to the patient
- reusable surgical instruments are generally low risk (Class 1) medical devices
- the equipment used to disinfect reusable surgical instruments would generally be medium to high risk (Class IIb).

[3] The medical device classification system is outlined in s.41BD of the *Therapeutic Goods Act 1989*, and Regulation 3.2 and Schedule 2 of the Therapeutic Goods (Medical Devices) Regulations 2002.

Custom-made medical devices

According to the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations), custom-made medical devices are a subset of medical devices, which are:

- made specifically in accordance with a request by a health professional specifying its design characteristics or construction; and
- intended to be used only in relation to a particular individual, or by a health professional to meet special needs arising in the course of his or her practice.

However, custom-made medical devices do not include medical device that have been adapted or modified to accommodate an individual patient.

In practice dental prostheses are often (although not always) regulated as custom-made medical devices based on the definition above. Custom-made devices are exempt from inclusion on the ARTG, due to the relatively low risk of custom-made devices and the impracticalities of the TGA assessing such devices given every device supplied has been custom-made for a particular patient. Manufacturers of custom-made devices are required to meet safety and quality requirements, with manufacturers required to address the Essential Principles in a statement that must be prepared in accordance the Regulations[4].

Dental practitioners and others who import and/or supply custom-made devices are the 'sponsors' of these medical devices and therefore assume responsibility for ensuring the products meet Australian regulatory requirements. Specifically in relation to custom-made medical devices, sponsors are required to ensure that their name and address are provided with the device in such a way that a user of the device can readily identify the sponsor[5].

It is also mandatory for sponsors (and manufacturers) to report adverse events[6] associated with a medical device, for example:

- any malfunction or deterioration in the characteristics of the device
- any inadequacy in the design, production, labelling, instructions for use or advertising material for the device
- any use of the device that has led to, or potentially may lead to, the death or serious deterioration in the health of the patient or user of the custom made device
- any information relating to technical or medical reason for a malfunction or deterioration of a custom made device that had led the manufacturer to recover the device

In addition, the dental professional prescribing the custom-made device is responsible for specifying its design characteristics or construction. However, the therapeutic goods legislation does not extend to regulating clinical practices and as such providing information to patients such as whether the custom-made device is manufactured overseas is a matter for the health professional.

[4] Item 7.2 (2) Part 7 Schedule 3 of the Therapeutic Goods (Medical Device) Regulations 2002
[5] Regulation 10.2 and 10.3 of the Therapeutic Goods (Medical Device) Regulations 2002
[6] Failure to do so is a criminal offense under section 41MP of the Therapeutic Goods Act 1989