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Subject: Proposed changes to Personalised Medical Devices June 2021

To whom it may concern,

The Proposed refinements to the regulation of personalized medical devices, V3.0 June2021.

Yes, I am of the opinion that that some products should be excluded from the regulation of the

TGA.

The intention of the TGA to regulate personalised medical appliances in the dental industry seems to have been ill thought out and placed in with general medical devices. Medical devices

are usually standard in design and have conformity.

In the dental Industry personalised medical devices fall into many categories,

Class1 devices manufactured by pressure and heat molding ie; mouthguards retainers or using acrylic and Stainless steel wire bent in a standard design framework. Their use is short to moderate term and constructed with minimal effort.

Class IIa devices are devices that are worn inter orally for a fixed term/ long term device. These

are usually cemented in ie; Rapid Maxillary Expanders, quadhelix, Transpalatal arches, Lingual

arches and Bonded Retainers. Some of these devices stay attached permanently, but the majority are removed within 12 months. Each of these personalised medical devices are generically standard with alterations for each patient decided by the health professional.

The intended purpose of each of these devices is determined by a registered health professional which are university trained specialists. ie; orthodontists, Dentists

" The manufacturer assigns the intended purpose of the medical device" (3rd paragraph)

All devices manufactured by a Dental technician are created in accordance to a prescription and

design guidelines assigned by a health professional ie; Orthodontist, Dentist. A dental technician is not a health professional, rather a dental health auxiliary.

The design is not decided by the Dental technician at any stage. The Dental professional decides on the personalised medical device which is needed, its design and its construction, the dental technician then builds it to the specifications of the health professional. Dental technicians are not privy to x-rays or any images or other diagnostic records that would determine the design of the personalised medical device.

To place the onus on the dental technician for the design and or materials used in the manufacturing of the personalised medical device is implying that they have the same level of training as a health professional with higher tertiary tuition.

Dental technicians are trained to manufacture from a prescription that has a design of the appliance and the preferred materials to be used to produce the finished device, it is totally unjustified to hold the dental technician responsible for any conformity assessment on this basis.

“Conformity assessment procedures are requirements placed on the manufacturer of a medical device. They include controls around the manufacture (design and construction)” (4th paragraph)

In definition the meaning of Design is to plan or draw, producing the look, function or workings of a building, garment or other object before it is manufactured or built. In all industries there are designers, engineers and then builders/ manufacturers.

Therefore, a dental technician is the manufacturer, has no input into the design, or the mechanics of the final device. If the final device is not made to the specifications of the health professional, then the device will be rejected, the dental technician reprimanded and credibility in the industry lost.

The dental technician should not be held liable and legally responsible for the design created by a Health Professional specialist, which has sent instructions to the dental technician on design and final manufacture. It makes no sense that upon the return of the device to said specialist, the dental technician must then provide written instructions on how to use the device, and

materials used in the construction of device.

As a leading manufacturer of personalised medical devices in [redacted] I am off the opinion that all the appliances manufactured by my dental laboratory, should fall into the category of being “adequately managed and should be excluded from regulation by the TGA”.

My support for this is based on the fact that all appliances I manufacture must be of a high/exacting standard in order for the Orthodontist or Dentists (“the Health Professional”) to dispense to their patients. If I do not meet these very high expectations, then I would very quickly find myself out of a job.

“Information to be supplied with your Device.

Manufacturers of custom-made medical devices must supply written statements prepared in relation to each of the custom-made medical devices they manufacture. The statements must include, at minimum, the following information:

1. the name and business address of the manufacturer.
2. information identifying the device or, where relevant, the contents of the packaging.
3. a statement to the effect the device is intended to be used only in relation to a particular individual (who may be a health professional);
4. the name of the individual to whom the device is intended to be used.
5. the name and business address of the health professional who provided the specifications for the device.
6. the particular design characteristics or construction of the device as specified by the health professional who provided the specifications; and
7. a statement to the effect the device complies with the applicable provisions of the Essential Principles. If the device does not comply with all applicable provisions, then a statement must be included explaining which provisions it does not comply with and the reasons why.

The statement must be signed and dated by a person authorised by the manufacturer of the device and include details of the person's name and position.

It is the legal manufacturer of the device under section 41BD of the Act who must compile the

statement, including where manufacturing steps are outsourced.

Manufacturers may choose to use the statement template included as Appendix 2 to the guidance document Personalised Medical Devices (including 3D-printed devices).

Manufacturers may choose to supply the statement digitally, provided sufficient information is

provided with both the statement and the device to allow the user to correctly match the two."

The highlighted step is burdensome on the dental technician in that they have technically made

the device for the health professional, which have the specialist knowledge in design and how to fit the device, activate it if it needs to be activated, and yet the dental technician is being asked to provide all this information to the practitioner. This step I believe is not essential and could be reduced to the dental technician keeping records of the type of appliance, patient name and practitioner's name. The onus must be on the final provider of the product to provide

this information to the consumer/ patient. This is being currently performed by the end user ie,

orthodontist/dentist ('The Health Professional") Dental technicians have no contact with patients at any stage of the process.

Dental technicians are manufacturers of devices that we only purchase from legitimate companies operating in Australia, all companies contacted for material fact sheets have provided this information. Some components used in the manufacture of some devices are precision made overseas, and then incorporated in the device. I am of the belief that if these companies comply with the TGA approval process then our products will be of a high standard

with high quality components.

In conclusion, I am aware that the TGA is well intentioned in keeping manufacturing standards,

and patient health and safety standards at the highest level. The proposed changes overall are burdensome on Dental technicians, the level of recording and reporting is excessive and will be

duplicated by health professionals that are actually dealing with the patient.

" It is considered that where a medical device has been "prescribed" by a registered health professional and is manufactured by a qualified or accredited professional according to the

specifications provided by the healthcare practitioner, risks can be adequately mitigated."(Page 11). It is evident that the education and qualifications of Dentists and Orthodontists and their ability to mitigate risks relating to quality, safety and performance of goods being supplied
in Australia are more than adequate.

As a business owner and major manufacturer of Orthodontic Medical Devices in Western Australia, the proposed changes are of concern. If the TGA keeps the original registration of all devices in the categories of Class I and Class IIa without the "proposed changes to an alternative mechanism for the reducing the regulatory burden for patient matched medical devices" I fear that it will be detrimental to Dental laboratories in the dental industry. Many Dental Laboratories in Australia run on extremely low margins and the cost of the registrations and adhering to regulatory frameworks will have a detrimental effect on many of us. I agree with the statement that all dental laboratories in Australia should be owned and run by an Australian qualified dental technician. I am afraid that if Dental laboratories across Australia are put under unnecessary regulatory and financial pressure the result could eventuate that devices maybe manufactured off- shore, thereby weakening the intentions of the proposed regulations.

Yours Faithfully,

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