AUSTRALIAN DENTAL ASSOCIATION

[redacted]

14 July 2021

[redacted]
Medical Devices & Product Quality Division
Health Products Regulation Group
Australian Government Department of Health
PO Box 100
Woden ACT 2606

By Email: [redacted]

Dear [redacted]

Re: Proposed refinements to the regulation of personalised medical devices

Thank you for providing the Australian Dental Association (ADA) with the opportunity to respond to the consultation on Proposed refinements to the regulation of personalised medical devices.

As you may be aware, the ADA is the peak representative body for dentists in Australia. Our 17,000 members include dentists who work across both the public and private sector, across 14 specialty areas of practice, in education and research roles and dentist students currently completing their entry to practice qualification.

The ADA is pleased that the Department of Health has taken on board the concerns raised by the ADA and others involved in the dental sector and tried to reflect these concerns through the changes proposed in the consultation paper. We support the proposed principles.

- Reduction or removal of unnecessary regulatory burden
- Applying an appropriate level of oversight which is commensurate with the risk of the device, and
- Ensuring the Australian regulatory requirements for medical devices are met, thereby ensuring devices are safe and fit for their intended purpose.

The regulation of therapeutic goods in Australia, and in particular medical devices, needs to be robust to ensure patient safety, of that there is no question. However, we believe that the current regulatory framework has been tailored to medical devices rather than dental devices and appliances and is not fit for purpose in the dental sector. The ADA supports the need for regulation on moderate to high-risk devices such as dental implants but believes the risk posed by many patient-matched dental devices and appliances is extremely low compared with high-risk medical devices such as joint replacements, intrauterine devices, breast implants etc. This is demonstrated by the very low number of adverse reports recorded both in Australia and across other countries.

In fact, a very real risk to the public comes from direct-to-consumer dental appliances such as clear aligners, sleep apnoea devices and tooth bleaching kits when they are provided by non-dentists and the regulatory framework should seek to address this issue more vigorously rather than place additional compliance on registered health practitioners.

Registered dental practitioners are already regulated under the National Registration and Accreditation Scheme which requires that all dental practitioners **"**P*ractice in accordance with the current and accepted evidence base of the dental profession" and further "Facilitate the quality use of therapeutic products based on the best available evidence and the patient's needs"* and *"Participate in systems of quality assurance and improvement"*. In 2011, the ADA introduced a voluntary dental practice accreditation scheme which now has more than 3000 dental practices going through quality improvement processes. This program has been recognised as the most successful voluntary program internationally and is testament to the importance dentist place on the provision of quality care. We therefore request that any additional regulations placed on these small mostly family-based businesses are commensurate with the risk.

We believe that it is also important to understand that technical work such as the manufacture of a dental device is also captured in the Health Practitioner Regulation National Law Act 2009 (National Law0. Under Section 121:

Restricted dental acts

(1) A person must not carry out a restricted dental act unless the person—

(a)is registered in the dental profession or medical profession and carries out the restricted dental act in accordance with any requirements specified in an approved registration standard; or

(b)is a student who carries out the restricted dental act in the course of activities undertaken as part of—

(i)an approved program of study for the dental profession or medical profession; or

(ii)clinical training in the dental profession or medical profession; or

(c)carries out the restricted dental act in the course of carrying out technical work on the written order of a person registered in the dentists or dental prosthetists division of the dental profession; or

(d)is a person, or a member of a class of persons, prescribed under a regulation as being authorised to carry out the restricted dental act or restricted dental acts generally.

(2) In this section—

restricted dental act means any of the following acts—

(a)performing any irreversible procedure on the human teeth or jaw or associated structures;

(b)correcting malpositions of the human teeth or jaw or associated structures;

(c)fitting or intra-orally adjusting artificial teeth or corrective or restorative dental appliances for a person;

(d)performing any irreversible procedure on, or the giving of any treatment or advice to, a person that is preparatory to or for the purpose of fitting, inserting, adjusting, fixing, constructing, repairing or renewing artificial dentures or a restorative dental appliance.

technical work means the mechanical construction or the renewal or repair of artificial dentures or restorative dental appliances.

Dentists may manufacturer the dental device within their own practice laboratory, employ a dental prosthetist or technician or another suitably skilled team member to make the device to their instructions. Alternatively, they may outsource the manufacture of that device to laboratory. It is reasonable to assume that Section 121(1)(c) of the National Law has been inserted to allow technicians who are not covered under the National Law to perform restricted dental acts at the written direction of a prosthetist or a dentist only. It is therefore important to ensure that where reference is made to a dental technician, reference should also be made to a dentist.

In response to the specific questions raised in the discussion paper we offer the following comments. While we would support the exclusion and exemption of some dental devices based on risk, we are concerned that creating a list of exclusions and exemptions may create unintended consequences such as the list being outdated as soon as it is created. New treatment modalities are continuously emerging and to have a static list rather than a principle-based assessment process could limit innovation.

Secondly, we believe that some of the risk of adverse reactions comes from the raw materials used in the creation of a dental device rather than the manufacturing process itself. It will be difficult to get agreement on which raw materials should be exempt and which ones included across the sector given the range of knowledge and level of expertise that exists across five different professional groups and the ability to recognise and treat adverse events. Clarification will also be required on whether or not there would still be a requirement on the manufacturer to report adverse events if the material or device is not listed on the ARTG. Removing all raw materials from the ARTG will shift the responsibility from major supply companies and this could potentially add to the confusion between the technician and the prescribing practitioner as to who has ultimate accountability.

The problem as we see it that needs to be resolved is the more foundational issue of the risk classification system. The risk posed by a medical device is established through factors such as duration of use and level of invasiveness. Currently any device which enters the oral cavity is captured as invasive according to this definition:

> *An **invasive medical device** is one that is intended by the manufacturer to be used, in whole or in part, inside the body of a human being. This includes devices that enter a body orifice or that penetrate the surface of the body, or that enter the body in the context of a surgical operation. A medical device that touches the surface of the eye, such as a contact lens, is considered to be in a body orifice.*

The mouth is indeed a body orifice, but devices placed within it, do not offer the same risk as a device that is implanted such as a joint prosthesis. The oral cavity contains in excess of 20 billion bacteria which reproduce multiple times in any given day. No device other than those implanted under surgical conditions are sterile at the time they are placed.

The second issue with the classification system is the duration or intended use of the device against which a device should be assessed. The current decision tools states that duration of use is defined as:

> ***Transient use:*** *intended to be used continuously for less than 60 minutes.*
>
> ***Short-term use:*** *intended to be used continuously for at least 60 minutes but not more than 30 days.*
>
> ***Long-term use:*** *intended for continuous use for more than 30 days.*

Because of these definitions most patient matched dental devices are categorised as long-term use even when they are not intended to be worn continuously. For example, a removable retainer manufactured for a patient to wear following a course of fixed orthodontic banding is manufactured to a standard that will ensure it remains effective for at least 6-12 months on issue however the patient is advised to only wear it overnight and remove for cleaning. Although it is not worn continuously, it is being caught up in the definition because it is intended to be used for more than 30 days. It should also be noted that risk from these devices does not necessarily increase due to their longevity.

A simple solution would be to add an additional assessment criteria as outlined below.

> ***Transient use:*** *intended to be used continuously for less than 60 minutes.*
>
> ***Short-term use:*** *intended to be used continuously for at least 60 minutes but not more than 30 days.*
>
> ***Long-term use (removable):*** *intended for intermittent use for more than 30 days.*
>
> ***Long-term use (fixed):*** *intended for continuous use for more than 30 days.*

This would result in many patient-matched dental devices being reclassified from Class 11a to Class 1. The key difference is that as these devices are removable, non-sterile and non-measuring they post less risk than a fixed device. In considering if this would have any unintended consequences on patient-matched medical devices, the ADA believes any impact should be minimal as most high-risk devices would continue to meet the classification of a Class IIb or Class III device. Furthermore, the ADA believes that the inclusion of this additional assessment criteria would address the concerns of other manufacturers of patient matched appliances such as orthotists and prosthetists.

A secondary benefit of this approach is that the additional costs that would be incurred by a dentist manufacturing patient matched dental devices that are subject to greater regulatory processes such as conformity assessment will not be realised and therefore patient fees would not increase as a result. This is important for many disadvantaged in the population who already face significant barriers to accessing oral health care. Similarly, this would also create less impact on the many small dental laboratories who operate within Australia who would not be able to continue to operate if the costs involved in conformity assessment processes are not contained.

There are several examples offered where an exemption might be issued under the proposals to exempt that need further consideration.

As mentioned previously, practice accreditation is an existing and well-established program within dental practices. Established under the first edition of the National Safety and Quality Health Service Standards, dental practices have remained assessed against the first edition while specific primary care standards were developed. These standards are due to be released in the coming weeks and will apply to primary care settings. 85% of all dental services are offered through the primary care sector and will transition to accreditation through these standards in the near future. It will therefore be important that these standards are considered equivalent to the Health Services standards.

Secondly, there is reference to dental technicians holding a recognised qualification under the AQF. Having such a requirement could have a limiting factor on workforce development in the future by not allowing laboratories to take on staff on an apprentice-based model of learning and skill development.

Third, there is currently no accreditation program for dental laboratories nor does the Oral Health Professional Association exist anymore. Accreditation schemes need to be structured and supported and continue to develop to make sure they are not a tick box exercise, or a sit and forget approach and this requires significant investment from professional associations, engagement with consumers and recognised accreditation agencies endorsed by the International Society for Quality in Health Care to ensure the program of accreditation is fit for purpose.

These comments also apply in relation to the list of examples that could be subject to alterative conformity assessment procedures. The proposals to exempt are certainly welcome but require further thought based on the comments above.

While not discussed in the consultation paper, the ADA would still like to see work undertaken to consolidate the categories of devices that would need to be registered so that the number of types of devices to be registered by dentist from November 2024 are reduced to a minimum.

The ADA would be happy to expand on the comments made in this submission. Should you have any further question please do not hesitate to contact Mr Damian Mitsch CEO at [redacted] or [redacted]

Yours sincerely,

[redacted]

Dr R. Mark Hutton
President