14 July 2021

[redacted]
First Assistant Secretary
Therapeutic Goods Administration
[redacted]
[redacted]

Dear Ms [redacted]

RE: PROPOSED REFINEMENTS TO THE REGULATION OF PERSONALISED MEDICAL DEVICES

The Australian Dental Prosthetists Association (ADPA), is the peak professional association representing registered dental prosthetists throughout Australia. Our Association's principal purpose is to advance, improve, support and foster the interests, development and status of dental prosthetists and to increase awareness and recognition of the profession across all sectors of society.

ADPA takes this opportunity to thank the TGA for its proactive approach to the concerns raised by the dental industry and profession. The proposed refinements are a step in the right direction, and we acknowledge the work that has gone into this proposal.

Dental prosthetists are registered dental practitioners who also often manufacture their own medical devices. Dental prosthetists train as dental technicians as part of their qualification, it is important in this respect to view dental prosthetists as dental technicians not just registered health practitioners under the TGA framework. A majority of our members additionally own dental laboratories and supply medical devices to the wider dental profession. It is for this reason that ADPA has been lobbying for the interests of both dental prosthetists and dental technicians.

Australian Dental Prosthetists Association Ltd. [redacted]

ADPA's main concerns with the current regulations are as follows:

1. The costs associated with compliance and the subsequent impact this will have on the cost of dentistry.
2. The administrative burden associated with compliance and the subsequent impact this will have on the cost of dentistry.
3. The number and complexity of GMDN's that apply to various dental devices.
4. The move towards materials and products deemed raw materials and therefore being removed from the ARTG.
5. The lack of a transition period available for graduate students post-August 2021 and;
6. The minimal impact the framework will have on the outsourcing of medical devices overseas.

These concerns are covered in ADPA's responses to TGA's questions on the proposed refinements below.

EXCLUSION

Do you agree with the rationale for the proposed exclusion of products? If not, why not?

ADPA supports the exclusion of mouthguards along with teeth whitening trays and medicaments as per the *Therapeutic Goods (Excluded Goods) Determination 2018* we however suggest TGA consults with the Australian Dental Association (ADA) on the current draft of the *Australian Schedule of Dental Services and Glossary* (2022) noting the definition of a mouthguard (item number 151) may change which will significantly impact the dental profession by having two classes of mouthguards (one excluded and one included).

ADPA has serious concerns about the use of study models under classification rule 5.4 under Schedule 2 of the Regulations. A denture is classified as a Class I medical device, however under the current regulations a physical anatomical model i.e., a study model used for treatment planning and diagnosis would be classified as a Class IIa. The risks associated with the use of a physical anatomical model are extremely low (if at all) and are to the patient's benefit from a treatment planning perspective. We assume under the proposed refinements the suggested exclusion of *physical impressions of a patient's anatomy and models cast from these* (2021, p. 12) covers the use of study models and resolves this issue however we ask for clarification on whether this is the case. ADPA believes study models should be excluded from regulation.

Australian Dental Prosthetists Association Ltd. [redacted]

ADPA does not agree with the exclusion of polymers and resins used in the manufacture of a medical device. We refer to international data on adverse events indicating it is most often the materials that result in adverse events rather than the medical device itself. Please see the below table highlighting the top 20 dental devices associated with adverse events as per the Federal Drug Administration (The Journal of the American Dental Association, 2015, p. 107).

Device name	Frequency (%)
1. Endosseous dental implant (Root Form)	15267 (53.5)
2. Ethylene oxide homopolymer and/or carboxymethylcellulose sodium denture adhesive	1426 (5.0)
3. Bone cutting instrument and accessories (Driver Wire And Bone Drill Manual)	1278 (4.5)
4. Dental Hand instrument (endodontic file)	815 (2.9)
5. Bone plate	760 (2.7)
6. Dental cement	630 (2.2)
7. Ultrasonic scaler	565 (2.0)
8. Dental hand piece and accessories	523 (1.8)
9. Total temporomandibular joint prosthesis	505 (1.8)
10. Intraoral dental drill	458 (1.6)
11. Carboxymethylcellulose sodium and/or polyvinyl methylether maleic acid calcium-sodium double salt denture adhesive	455 (1.6)
12. Dental injecting needle	306 (1.1)
13. Orthodontic appliance and accessories	288 (1.0)
14. Bone cutting instrument and accessories (Bone Drill Powered)	283 (1.0)
15. Intraoral source x-ray system	252 (0.9)
16. Intraoral devices for snoring and obstructive sleep apnea	243 (0.9)
17. Dental bur	217 (0.8)
18. Bone grafting material - synthetic	209 (0.7)
19. Bone grafting material with biologic component	186 (0.7)
20. Resin tooth bonding agent	182 (0.6)

Australian Dental Prosthetists Association Ltd. [redacted]

With the removal of raw materials from the ARTG, the data TGA collects in relation to adverse events will be greatly skewed and not reflective of the real issue/s; this data will show an issue with a denture for example, rather than the materials (e.g., resin, acrylic etc) used to manufacture the denture. We argue raw materials should stay on the ARTG – this has the full support of the dental industry and the dental professions. We note ingredients for therapeutic goods are regulated by the TGA, we would suggest the same should apply to the raw materials utilised in manufacturing a medical device. This data shows materials pose a safety risk to patients however with the removal of materials from the ARTG the onus of ensuring these materials have been manufactured in adherence to the Essential Principles falls on both dental technicians and the health practitioner rather than the material supplier/manufacturer.

We highly recommend denture repair kits and denture adhesives are not excluded from regulation, these pose a risk to patient safety, particularly adhesives containing zinc (Federal Drug Administration, 2019). We would also query whether dental amalgams and reline materials constitute part of the excluded products list - again we would argue these pose a risk to patients and require regulation.

Finally, we would appreciate clarification and discussion on the impact exclusion or exemption has on the advertising of products or medical devices.

Are the risks posed by the products adequately managed if they are excluded from regulation by the TGA? Please explain your response, including by providing examples that illustrate and/or support your position.

ADPA has highlighted above the adverse events associated with materials used in the manufacture of medical devices. To adequately manage the risks associated with medical devices it is important for the materials used to manufacture these medical devices to be regulated by TGA to some extent. This helps ensure that manufacturers of medical devices can meet the requirements under the Essential Principles.

Are there further products that meet the principles proposed for exclusion? What are they and why should they be excluded?
Please provide an explanation for why:

- **the product represents no, or insignificant levels, of risk; or**
- **the product does not meet the definition of a medical device.**

ADPA recommends the TGA consult with the ADA in regards to the proposed new definition of a mouthguard under the Australian Schedule of Dental Services and Glossary (2022, p. 27). The proposal defines a mouthguard (item number 151) as the '*construction, provision and delivery of a mouthguard, using a model. The mouthguard is intended to prevent or mitigate sports injuries or soft tissue injuries that could occur from parafunction*.' This definition could potentially result in two classifications of mouthguards, one excluded (those used as personal protection equipment (PPE) for sports purposes) and those regulated (mouthguards intended to prevent soft tissue injuries from parafunction). We would recommend mouthguards used to prevent or mitigate injuries resulting from parafunction also being excluded due to the minimal risks associated with mouthguard use.

RECOMMENDATIONS

1. That TGA consults with the Australian Dental Association on the proposed changes to item number 151 mouthguard under the draft Australian Schedule of Dental Services and Glossary.
    a. That if necessary, mouthguards used to avoid soft tissue damage as a result of parafunction are added to the list of excluded devices.
2. That study models are covered under the exclusion of *physical impressions of a patient's anatomy and models cast from these*
3. That raw materials associated with adverse events are not excluded from regulation.
4. That TGA clarifies the impact exclusion or exemption has on advertising.

EXEMPTION

Do you agree with the rationale for the proposed exemption of Class I non-sterile, non-measuring patient-matched devices when produced under the circumstances listed in this consultation paper? If not, why not?

ADPA agrees with the rationale behind exempting Class I non-sterile non-measuring patient-matched devices. We support a blanket rule that any Class I non-sterile non-measuring device **manufactured in Australia** be exempt from listing on the ARTG.

We do however note reference to the example: *By a dental laboratory accredited by the Oral Health Professional Association and The devices they produce are intended to be used by a patient of a healthcare facility, registered provider or AHPRA-registered health professional* (2021, p. 12). We suggest the wording be amended to say "by a dental laboratory endorsed by the relevant professional association and…" on the basis that the Oral Health Professionals Association is no longer in operation. We also note that the ADPA constitution covers dental technicians under our membership. We would suggest that adding the works 'relevant profession association' would ensure that there is no possible interpretation of anti-competitive behaviour.
We would be hesitant to list an association in the regulations that is:

a) to our knowledge currently inoperable and;
b) does not have exclusive coverage of dental technicians.

We suggest avoiding the use of the term accredited as it may be confused with dental accreditation under the *National Safety and Quality Health Standards* (2021), instead, we would recommend utilising the term dental laboratory endorsement. It is important to note dental accreditation is a comprehensive process involving national standards and auditing processes, we believe the use of the word accreditation could cause confusion for patients and the general public.

While the examples list dental prosthetists and dental technicians (2021, p. 12), we assume this exemption would apply to all Ahpra registered dental practitioners and would therefore suggest that future guidance document examples refer to Ahpra registered dental practitioners and dental technicians.

We ask TGA to clarify a health practitioner's responsibility regarding outsourcing the manufacture of the proposed exempt devices to dental technicians without a recognised qualification under the Australian Qualifications Framework or a non-accredited laboratory and how this will be monitored by TGA. We also query how TGA would monitor a health practitioner's Ahpra registration and whether conditions on a health practitioners' registration may impact this exemption.

We also query the differentiation between a dental laboratory and a dental technician (i.e., why is both a dental technician with a suitable qualification under the Australian Qualification Framework listed as well as a dental laboratory accredited by the Oral Health Professional Association)? If a dental laboratory is accredited (refer to our previous comments re: endorsement rather than accreditation) and employs dental technicians without the relevant qualification how would this work (noting both requirements under the examples of accreditation and dental technicians with a recognised qualification)? Which option prevails? We believe further discussions are required in this area, however, believe the examples and proposal is a good starting point but requires further refinement.

Finally, we believe any medical device that is outsourced overseas including Class I non-sterile non-measuring patient-matched medical devices should not be exempt and should require listing on the ARTG. We believe this needs to be made clear in future guidance documents.

Can the risks posed by the Class I non-sterile, non-measuring patient-matched medical devices when produced under the circumstances listed in this consultation paper be adequately managed if they are exempted from inclusion in the ARTG? Please explain your response, including by providing examples that illustrate and/or support your position.

ADPA believes the risks posed can be adequately managed if they are exempted. We would suggest dental-related training, education and resources on the Essential Principles and adverse event reporting to help ensure these risks continue to be managed and is delivered promptly.

Are there further circumstances where Class I non-sterile, non-measuring patient-matched devices could be exempt? If so, what measures are in place to manage the risks associated with the devices?

Please provide details:

- **describe the specific circumstances that are in place (such as qualifications, accreditation, certification, etc) to ensure that the risks associated with the manufacture of the devices have been managed and the Australian regulatory requirements for medical devices have been met before they are supplied.**

ADPA supports a blanket rule for all Class I non-sterile, non-measuring patient-matched devices **manufactured in Australia** by a registered health practitioner or dental technician being exempt. We believe the criteria for this exemption (i.e., the criteria for dental technicians and dental laboratories) needs further refinement noting our concerns raised above, however, we agree with the overall intent of the proposal.

We would also like to clarify what (if any) reporting requirements would exist under this proposal? Would there still be a requirement to advise TGA of the fact Class I devices are being manufactured or a declaration of conformity?

ADPA queries the statement contained in the proposed refinements paper '*a further impact of exempting these kinds of devices from inclusion in the ARTG is that they would not be able to be advertised to consumers'* (2021, p. 13) and would appreciate clarification on this. For example, would a dental prosthetist under this statement be able to advertise they manufacture dentures?

RECOMMENDATIONS

5. That all Class I devices manufactured in Australia by an Ahpra registered health practitioner or dental technician is made exempt from listing on the ARTG.

6. That all references to the Oral Health Professional Association are replaced with 'by the relevant professional association'

7. That the word accreditation is replaced with 'endorsement'

8. That the examples refer to dental practitioners and dental technicians rather than dental prosthetists and dental technicians.

9. That TGA clarifies a health practitioners' responsibility when outsourcing the manufacture of a Class I non-sterile non-measuring devices to a dental technician without a recognised qualification.

10. That TGA clarifies how it will monitor Ahpra registration and dental technician's qualifications.

11. That TGA clarifies the differentiation between a dental laboratory and a dental technician and highlights which area prevails.

12. TGA to clarify reporting requirements under the exemption category.

13. That TGA provides dental-related training on the Essential Principles and adverse events.

14. That TGA clarifies the statement *A further impact of exempting these kinds of devices from inclusion in the ARTG is that they would not be able to be advertised to consumers.*

ALTERNATIVE CONFORMITY ASSESSMENT PROCEDURES

Do you agree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched devices when produced under the circumstances listed in this consultation paper? If not, why not?

We appreciate TGA's recognition of the Dental Sector Working Groups (DSWG) concerns regarding third-party conformity assessments which potentially resolves some of the cost and compliance burden on small owners. We recommend that this alternative conformity assessment apply to all Class IIa patient-matched medical devices manufactured in Australia by a registered health practitioner or dental technician. We encourage further discussion in refining the examples relating to dental technicians and dental laboratories. ADPA strongly recommends any Class IIa device manufactured overseas should not be able to access this proposed alternative conformity assessment option.

Do you agree that the risks associated with the proposed Class IIa patient-matched devices when produced under the circumstances listed in this consultation paper could be adequately managed through the proposed alternative conformity assessment procedure? Please explain your response, including by providing examples that illustrate and/or support your position.

The DSWG dental professionals are working on a dental laboratory endorsement template for TGA's consideration. We believe that if a dental laboratory can provide evidence of compliance such as documentation under this standard this will provide sufficient evidence of appropriate manufacturing standards and will ensure risks are appropriately managed. Additionally, we believe this will provide health practitioners and patients with peace of mind and will help maintain patient safety.

Are there further circumstances where an alternative conformity assessment procedure for Class IIa patient-matched devices would be appropriate? If so, what measures are in place to manage the risks associated with the devices?

As long as this option is available for all Class IIa patient-matched medical devices manufactured in Australia and that the dental technician and dental laboratory examples are refined to be

appropriate and achievable we do not believe further circumstances warrant an alternative conformity assessment.

Are there any Class IIa patient-matched devices that should not be subject to an alternative conformity assessment procedure? What are they and why not?

Class IIa patient-matched medical devices manufactured overseas should not have access to alternative conformity assessment procedures. There are three reasons for this. First, we believe we should be supporting Australian manufacturing and believe the Australian Government similarly supports this under the Australian Government's 'Modern Manufacturing Strategy' (Department of Industry, 2021). We believe the qualifications of dental technicians are not consistent internationally and that the Australian standard should be upheld. We believe the only assurance that the processes used by overseas manufacturers are of a quality standard is by requiring a third-party conformity assessment. Most importantly we believe patient safety is paramount and outsourcing overseas can impact this, a third-party conformity assessment may help mitigate the risks associated with overseas manufacturing.

RECOMMENDATIONS

15. That the alternative conformity assessment only applies to patient-matched medical devices manufactured in Australia.
16. That the alternative conformity assessment is available for all Class IIa devices.
17. That the proposal relating to dental technicians and dental laboratories are further refined.

GENERAL QUESTIONS

Are there alternative mechanisms for reducing the regulatory burden for patient-matched medical devices without compromising patient health and safety that you would like to propose?

We would suggest dental practitioner information on adverse events and post-market surveillance be made available for the dental profession. We also believe it is essential that academic institutions are engaged as part of the consultation process for medical device regulation and in particular this framework. It is important to ensure our dental students (both current and future) are

appropriately educated in the Essential Principles, adverse events etc so there is national consistency moving forward. Finally, we strongly support there being standards and templates developed in consultation with the professional peak associations such as quality management system templates. These standards and templates should be developed as a matter of urgency. We also believe it is important for the public (patients) to be aware of TGA's role and the fact that Australian manufacturers of medical devices comply with the TGA's requirements. This could be done through resources made available to health practitioners for use on their websites, in their marketing and information they provide to patients. Moving forward consultation with dental professionals, peak bodies and academic institutions is critical in developing and ensuring the success of any new framework. ADPA believes checklists, in themselves are not sufficient in proving manufacturer compliance, we believe documentation needs to be in place to support compliance. We do not believe there is a requirement for third party inspections and/or practice audits, compliance can be demonstrated through qualifications and documentation etc.

RECOMMENDATIONS

18. We recommend resources and training on adverse events and post-market surveillance for the dental profession.

19. That TGA works with academic institutions and ensures the Essential Principles, adverse events etc are incorporated into the existing training programs.

20. That TGA provides resources for health professionals to help increase patient awareness of TGA's role and the regulation of medical devices.

ADDITIONAL COMMENTS

We strongly recommend the inclusion of a transitional period for newly graduated health practitioners and dental technicians and ask that this be incorporated into the proposed refinements. We note our considerable concern over the impact the current framework will have on graduate students post-August 2021. While most dental practitioners will have a chance to spread out the costs and administrative burden involved in ARTG registration and third-party conformity assessments, graduates will not only deal with the upfront cost of registration and

leasing/purchasing a dental practice/laboratory, but they will also deal with the upfront costs of ARTG registration and third-party conformity assessment.

While the proposals made by the TGA will significantly mitigate the burden involved with compliance we believe it is important that graduates are given the time and education to meet their compliance requirements under the framework.

RECOMMENDATIONS

21. That graduate health practitioners and dental technicians are given access to a transitional period under the proposed refinements.

Thank you for the opportunity to provide valuable feedback on the proposed refinements. ADPA believes the proposals potentially negate the considerable cost and compliance burden of the current framework, however, there are still further refinements required to ensure the framework is achievable.

If you have any questions or concerns, please do not hesitate to contact me directly on [redacted] or at [redacted]

We look forward to continuing our work with you on this important matter.

Yours sincerely,

[redacted]

[redacted]

AUSTRALIAN DENTAL PROSTHETISTS ASSOCIATION

Enc.

ADPA RECOMMENDATIONS

1. That TGA consults with the Australian Dental Association on the proposed changes to item number 151 mouthguard under the draft Australian Schedule of Dental Services and Glossary.
    a. That if necessary mouthguards used to avoid soft tissue damage as a result of parafunction are added to the list of excluded devices.
2. That study models are covered under the exclusion of *physical impressions of a patient's anatomy and models case from these*
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4. That TGA clarifies the impact exclusion has on advertising.
5. That all Class I devices manufactured in Australia by an Ahpra registered health practitioner or dental technician is made exempt from listing on the ARTG.
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9. That TGA clarifies a health practitioners' responsibility when outsourcing the manufacture of Class I non-sterile non-measuring devices to a dental technician without a recognised qualification.
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15. That the alternative conformity assessment only applies to patient-matched medical devices manufactured in Australia.
16. That the alternative conformity assessment is available for all Class IIa devices.
17. That the proposal relating to dental technicians and dental laboratories are further refined.

18. We recommend resources and training on adverse events and post-market surveillance for the dental profession.
19. That TGA works with academic institutions and ensures the Essential Principles, adverse events etc are incorporated into the existing training programs.
20. That TGA provides resources for health professionals to help increase patient awareness of TGA's role and the regulation of medical devices.
21. That graduate health practitioners and dental technicians are given access to a transitional period under the proposed refinements.

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