16 July 2021

Ms Tracey Duffy
First Assistant Secretary
Therapeutic Goods Administration
136 Narrabundah Lane
SYMONSTON ACT 2601

Email: [redacted]
CC: [redacted]

Dear Ms Duffy,

RE: TGA PERSONALISED MEDICAL DEVICE REFINEMENTS

Thank you for arranging the *Australian Dental Sector Working Group* (DSWG) face to face/virtual meeting on Friday 9 April 2021 and more recently on Tuesday 29 June 2021. As representatives of the dental professions, we appreciated the opportunity to voice our questions and concerns on the day and look forward to continuing this dialogue. We also appreciate TGA's finalised Terms of Reference and Communique. We do however ask that either a recording of future meetings is made available, or minutes are circulated within a fortnight of the meeting.

We note the recent consultation on the proposed refinements to the regulation of personalised medical devices and appreciate the fact that the draft proposal recognises and responds to the significant concerns raised by the dental professions at the initial DSWG. We have included the DSWG professions views on the proposals as well as pointed out areas requiring clarification and/or further discussion.

INTRODUCTION

The peak professional associations in attendance represent the 24,994 registered dental practitioners in Australia (Dental Board of Australia, 2020, p. 5). In addition, the two dental technicians in attendance, Mr David Rodwell and Mr Tony Minichilli represent the 3000+ dental technicians in Australia (Health Workforce Australia, 2014, p. 71). We, therefore, contend those who participated in the dental working group represent the voice of the dental profession in Australia.

There are three main points we bring to TGA's attention:

1. While oral health is synonymous with general health, 38.8% of Australians avoid or delay dental care due to cost (Australian Institute of Health and Welfare, 2020).
2. Overall, $10.5 billion is spent on dental services annually, the Australian Government contributes $1,580 million towards this (Australian Institute of Health and Welfare, 2020).
3. Oral health status is socially determined i.e., social inequality (populations of lower socioeconomic status, Aboriginal and Torres Strait Islanders and older Australians) directly correlates with poorer oral health outcomes (Sanders, AE., 2007, p viii).

We raise these points to highlight the cruciality of oral health in maintaining general health, however, note the significant barriers in accessing oral health care – namely cost and social inequality. We also highlight the limited funding of oral health which is largely recognised as an individual expense. In other words, oral health is already seen as a cost burden to many Australians, this issue is compounded for vulnerable populations. While we recognise the importance of the personalised medical device framework, we stipulate that this must be balanced with the cost and administrative burden placed on the dental profession and the potential financial impact this will have on the end-user – our patients.

CLASSIFICATIONS & RISK

While we recognise the current classification structure under the Regulations (*Therapeutic Goods (Medical Devices) Regulations* (Cth) Pts 1-2) we believe there is further work to be done in this space.

We note TGA contends that the level of risk related to dental devices is unknown due to adverse events not being reported. The dental professions argue that this is directly related to the quality of manufacturing that currently exists and the low risk associated with these products.

Noting there is limited data within an Australian context we have sourced overseas data on the level of risk for dental devices and their adverse events. TGA may be interested to know that 53.5% of the dental devices associated with adverse events pertain to endosseous implants (The Journal of the American Dental Association, 2015, p. 102), 77.3% of these were in relation to the implant failing to osseointegrate (The Journal of the American Dental Association, 2015, p. 105); we, therefore, agree that there is a higher risk for implant devices or surgically invasive devices warranting a Class IIb classification. We do however disagree that a fixed dental device, particularly one that is completely removed from the oral cavity within 12-18 months (such as many orthodontic fixed devices) warrants a Class IIa classification. We do not believe the current classification structure appropriately recognises the low risk associated with medium-term dental devices and suggest this warrants further discussion at the next DSWG.

The below table highlights the main adverse events as listed by the Food and Drug Administration over five years (extracted from The Journal of the American Dental Association, 2015, p. 107). The table

highlights raw materials and dental instruments registered by the dental supplier are the main contributors to adverse events, Class IIa devices account for less than 1% of adverse events.

Device name	Frequency (Percentage)
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)

Table 1: FDA Five-year Adverse Events related to dental devices

It is still unclear how TGA intends on translating the new framework to ensure adverse event reporting occurs. For example, the current Personalised Medical Device (including 3D-printed devices) guidance document, only refers to adverse events concerning custom-made medical devices (2021c, p. 23). We believe that if the TGA is concerned about the under-reporting of adverse events this should be reflected within the patient-matched medical devices section of the guidance.

Additionally, we note reference to the word 'continuously' under Schedule 2 Part 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002.* As there is currently no definition included in the Regulations the ordinary meaning would be utilised under the *plain meaning rule*. The ordinary meaning of continuous as outlined in the Macquarie Dictionary is:

Continuous

1. having the parts in immediate connection, unbroken.

2. uninterrupted in time; without cessation.

3. Grammar denoting a verb aspect, or other verb category, which indicates action or state going on at a temporal point of reference. For example, the present continuous form of the verb do is is (*sic)* doing, as in the sentence She is doing it.

We believe that any removable orthodontic device such as an aligner a removable "plate" for moving teeth or a retainer would not be continuous under this definition, and if not excluded, would therefore fit the classification rule for Class I. We would appreciate the TGA's views on this.

CLASSIFICATIONS

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 denture adhesive (one of which was the second-highest reported adverse event). 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 patient-matched medical device.

We also contend that those devices used as an interim measure such as orthodontic appliances should move down a classification based on their level of risk. It is also important to note that the orthodontic appliances listed under number 13 of table 1 include accessories and braces (adaptable medical device); the 1% of adverse events reported above is not a true reflection of the risk related to orthodontic patient-matched medical devices. You will note that fixed dental restorative devices such as crown, bridge and veneers are not listed in the top 20 devices associated with adverse events. Fixed restorative devices are listed as Class IIa based on the length of time they remain in the oral cavity, however, what we hope this data points out is that length of time does not necessarily equate to increased risk within dentistry. As we indicated earlier, we believe there is work to be done in this space and we would welcome the opportunity to discuss this with TGA further. We recognise the classification structure applies to all medical devices however we also note the legislation bases this classification structure on the level of risk - given the international evidence on dental devices and adverse events, the level of risk for Class IIa or lower devices is insignificant.

GMDN's

The dental profession has accumulated a list of 48 GMDN's that potentially apply to manufactured dental devices; with a number of these devices classified as Class IIa, we believe the likelihood of being able to comply with these regulations is low due to the cost and administrative burdens. As a result, we have reviewed all applicable GMDN's and have identified what we consider to be a list of achievable and overarching codes (please refer to *Appendix one*) that will not only ensure compliance but will also reduce the regulatory burden of those manufacturing crucial dental devices. We would ask for TGA's support in applying for these new GMDN codes with the GMDN Agency. Additionally, we believe the classifications linked with these GMDN's require review as highlighted earlier. The proposed codes are outlined in Table 2 and defined in Appendix one.

Overarching Medical Device	GMDN	GMDN Description	Dental Devices Covered	Classification	Comments
PROSTHESIS FOR DENTAL RESTORATION - SELF REMOVABLE	38587	Denture <specify>	Partial denture, complete upper denture, complete lower denture, overdenture	Class I	Listed on TGA business services - previously utilised through the GMDN Agency
PROSTHESIS FOR DENTAL RESTORATION - FIXED OR BONDED	NEW	Existing Crown, Bridge, Onlay, Inlay and Veneer GMDN's	Permanent and Temporary Dental Crown/Bridge, Veneers, onlays (cusps), inlays	Class IIa – *we would support a lower classification for this based on the level of risk*	This would require a new GMDN.
APPLIANCE FOR CORRECTION AND/OR STABILISATION OF DENTAL ANATOMY - FIXED OR BONDED	34690	Orthodontic appliance <specify> [fixed/bonded]	Orthodontic space maintainer, palate expansion appliance, arch development appliance, bite correcting appliance, retainer (bonded)	Class IIa – *we believe these devices should be a lower classification or exempt from third-party conformity assessment*	Listed on TGA business services - previously utilised through the GMDN Agency
APPLIANCE FOR CORRECTION AND/OR STABILISATION OF DENTAL ANATOMY - SELF REMOVABLE	34690	Orthodontic appliance <specify> [removable]	Occlusal Splint, sleep-disordered breathing orthosis (mandible and tongue-training), functional appliances, tooth moving appliances Suggested excluded devices: Positioning tray, retainer (removable), aligner	Class I	Listed on TGA business services - previously utilised through the GMDN Agency

Table 2: List of overarching GMDN Codes for dental devices (Please refer to *Appendix one* for further information)

We note that TGA has stipulated we can utilise overarching GMDN's and/or GMDN's that match the description of what is manufactured. We believe the above GMDN's and descriptions best reflect the appropriate level of risk as well as ensures compliance is both manageable and less cost-prohibitive. As noted, we intend to apply for new GMDN codes via the GMDN agency to ensure the definition fits within the new framework and ask for TGA's support with this.

DENTAL GRADUATES

Additionally, we note our considerable concern over the impact this framework will have on graduate students post-August 2021. While most dental practitioners will have a chance to spread out the costs involved in ARTG registration and potential third-party conformity assessments, graduates will not only deal with the upfront cost of registration and leasing/purchasing a dental practice/laboratory, they will also deal with the upfront costs of ARTG registration etc. As the peak professional associations, we are ill-equipped to aid these graduates on QMS and ARTG registration etc noting the fast-approaching deadline and the fact that we are still working through these issues with TGA. We believe a transitional period should apply to new graduates up until the end of th1 November 2024 and ask that TGA review this urgently.

COMPLIANCE COSTS

While the dental professions support the regulation of medical devices and see the changes as a positive move toward consistency and safety within the industry, costs and regulatory burden must be balanced with the aims of the framework. If compliance costs are inhibitive this will have a direct impact on patient costs potentially increasing the barriers to oral health services. An additional concern is the increased likelihood that small businesses will be unable to achieve compliance based on cost and will close as a result. We believe the current conformity costs will greatly disadvantage most small dental laboratories in Australia and discourage dental practitioners who manufacture devices. Furthermore, there is a likelihood that practitioners will increasingly send work overseas resulting in further pressure on local laboratories to compete. The only way local manufacturing will be able to continue to exist is for imported medical devices to be banned or compliance costs for local businesses to be significantly reduced.

CONSULTATION

We ask that the working group are updated as new information comes to light and/or before the publication of new resources/guidance, this will help us assist our members when they are made aware of new resources.

We appreciate TGA is working with numerous stakeholders and the situation is changing frequently which is why we believe the working group is an ideal communication platform that should be utilised moving forward.

On that note, we ask that the working group are involved directly in the development of the Medical Device Production System (MDPS) framework, Unique Device Identification (UDI) as well as discussions on Raw Materials. Consultation and communication are essential in making sure this new framework achieves TGA's and indeed our aims.

RAW MATERIALS

In respect to raw materials, we ask for clarification on the definition and how this applies to componentry. Again, we note ingredients are regulated by the TGA and would argue the same should apply to materials noting the risk factors as highlighted earlier. We note the definition of Medical Device under the *Therapeutic Goods Act 1989* (Cth) (s 41BD) includes materials (whether used alone or in combination and including the software necessary for its proper application) and would appreciate clarification on why this would not include materials. Table 3 (below) lists materials/components frequently used in dentistry and would appreciate TGA's feedback on which of these are adaptable medical devices, raw materials, accessories and/or medical devices.

GMDN	Device
35697	Applicator, dental, resin
46125	Carboxymethylcellulose sodium denture adhesive
60661	Carboxymethylcellulose sodium/polymer denture adhesive, zinc-containing
46127	Carboxymethylcellulose sodium/polymer denture adhesive, zinc-free
62390	Ceramic dental inlay adhesive solution
47906	Custom-made dental composite resin kit
38643	Dental acrylic resin
46307	Dental Anchor
63963	Dental appliance/prosthesis connector
35858	Dental casting noble alloy
35857	Dental casting non-noble alloy
62477	Dental composite resin kit
45236	Dental crown/bridge resin, temporary
57949	Dental guided surgery reference plate
63349	Dental implant suprastructure, permanent, custom-made
16658	Dental impression material adhesive
45232	Dental material, desensitizing resin
36311	Dental occlusal splint, preformed, reusable
44727	Dental porcelain/ceramic restoration kit
16727	Dental prosthesis restorative material, unfilled resin
61647	Dental prosthesis/implant abutment screw
63626	Dental prosthesis-component adhesive
44728	Dental shaded pontic kit
38608	Dental wrought alloy
57948	Dental guided surgery reference pin
63530	Dental guided surgery registration/navigation fiducial marker
64502	Dental implant suprastructure aligner

GMDN	Device
64012	Dental implant suprastructure, temporary, custom-made
61646	Dental prosthesis/implant abutment screw analog, reusable
55831	Denture base resin kit, self-cured
16730	Denture base resin, cured
58288	Denture base resin, thermoplastic
42879	Denture clasp, metal, custom-made
34770	Denture reliner, elastic, long-term
35862	Impression material, dental, agar
35863	Impression material, dental, alginate
34799	Impression material, dental, compound
35864	Impression material, dental, polyether
35865	Impression material, dental, polysulfide
35866	Impression material, dental, silicone
34807	Impression material, dental, wax
46128	Karaya denture adhesive
46124	Karaya/acacia denture adhesive, high sodium borate
46129	Karaya/acacia denture adhesive, low sodium borate
46130	Karaya/ethylene oxide homopolymer denture adhesive
38578	Magnetic dental precision attachment
48185	Oral intake restriction kit
46536	Orthodontic anchoring screw
63997	Orthodontic appliance positioning tray, basic
41397	Orthodontic archwire
46581	Orthodontic bracket metal
58937	Orthodontic bracket, ceramic
46582	Orthodontic bracket, plastic single use
62074	Orthodontic inter-arch elastic band
65436	Orthodontic resin positioning tray
31797	Orthodontic spring
64010	Orthodontic appliance positioning tray, preloaded
42374	Orthodontic clasp, metal wire, custom-made
40734	Orthodontic clasp, metal, custom-made
38603	Resilient dental precision attachment
35870	Resin-composite dental cement
38610	Root canal post, custom-made
55848	Screw endosteal dental implant, one-piece

Table 3: Dental materials, components etc commonly used in dentistry

To assist you in progressing our feedback, we have written below the areas we seek clarification on as well as our suggestions.

1. Consider the inclusion of specific advice on adverse events in the Guidance document.
2. Review the classification levels based on risk rather than length of use or incorporate a medium-term use classification.
3. Provide feedback on the definition of continuous and removable devices.
4. Review and comment on the suggested GMDN list.
5. Provide support to the DSWG Professions in applying for these GMDN codes through the GMDN agency.
6. TGA guidance documents and templates for Essential principles (that apply to dental only), ARTG registration, adverse events, and instructions for use templates.
7. Implementation of a transitional period for dental graduates.
8. Review of dental materials regulation; noting the differences between true raw materials and modified/manipulated materials. We believe work is required regarding defining classes of materials and fully support the regulation of materials that pose a risk.
9. Ensure the working group is involved in and/or consulted any future publications, guidelines or clarification points relating to the personalised medical device framework.
10. Ensure the working group is part of the MDPS, UDI and raw materials discussions.
11. Clarification of dental components listed and whether these are medical devices, adaptable medical devices, accessories, or raw materials.

PROPOSED REFINEMENTS

EXCLUSIONS

Overall, the DSWG Professions agree with the exclusion of products from regulation. We support the exclusion of mouthguards and teeth whitening trays however recommend exercising caution with the exclusion of teeth whitening products. We believe it is important to refer to The *Poisons Standard* (SUSMP) when specifically excluding teeth whitening products and suggest supporting materials be made available to dental practitioners to assist in understanding the risks associated with these products. With the Dental Board of Australia (DBA) stepping back from an active regulatory role with tooth bleaching it is more important than ever for the TGA to remain vigilant regarding these materials.

We note that teeth whitening trays are potentially seen as a cosmetic rather than therapeutic good (deeming them excluded) and would argue the same concept applies to retainers, positioning trays and aligners and therefore these should be included in the list of excluded devices.

The DSWG Professions do not agree with the exclusion of polymers and resins used in the manufacture of medical devices and refer to Table 1 highlighting the risks associated with these materials. Further, we believe denture adhesives (particularly those containing zinc) and denture repair kits require regulation based on risk (Federal Drug Administration, 2019). We would appreciate clarification on whether dental amalgams and reline materials would be excluded from regulation, we would again ask that these are not excluded based on risk.

We fully support the exclusion of study models (physical and/or virtual models) noting the risk to the patient is zero as they are either purely diagnostic or an interim step in the manufacturing process of some devices. They are not “worn” by a patient. We assume study models would constitute *physical impressions of a patient’s anatomy and models cast from these* (TGA, 2021a, p. 10) and would appreciate TGA’s clarification on this point.

We note in the proposed refinements there are examples provided relating to dental prosthetists and dental technicians. Dental practitioner sub-divisions such as dental prosthetists should be avoided in TGA documentation as the general public may assume the examples only apply to that subdivision rather than all Ahpra registered dental practitioners. We recommend utilising the term dental practitioners which encompasses dentists, dental specialists, dental hygienists, oral health therapists as well as dental prosthetists.

We believe that further discussion is required on the advertising of excluded devices.

RECOMMENDATIONS - EXCLUSIONS

1. **Teeth Whitening medicaments exclusion should be read in conjunction with the Poisons Standard with supporting documentation available to practitioners and consumers.**
2. **Retainers, positioning trays and aligners added to the list of exclusions.**
3. **Polymers, resins, denture repair kits and denture adhesives should be removed from the exclusion list and continue to be regulated by TGA.**
4. **Clarification on whether the wording 'as part of physical impressions of a patient's anatomy and models cast from these' incorporates study models.**
5. **Future guidance and consultation documents to refer to dental practitioners and dental technicians rather than dental practitioner subdivisions (e.g. dental prosthetists).**
6. **Further discussion required on the advertising of excluded devices.**

EXEMPTIONS

The DSWG Professions agree with a blanket Class I non-sterile non-measuring exemption for all dental devices manufactured in Australia by a registered dental practitioner, appropriately qualified dental technician or endorsed dental laboratory. The DSWG professions believe this exemption should not apply to medical devices manufactured overseas.

We note reference to the example in the Consultation: proposed refinements to the regulation of personalised medical devices (2021a, p. 12):

> *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.*

We highly recommend the removal of any reference to the Oral Health Professional Association noting the association is not operating. Instead, we recommend amending the wording to '*by a dental laboratory endorsed by the relevant professional association'*, which recognises the fact that some associations have or may have the capability of representing dental technicians.

We suggest avoiding the use of the term accreditation as this can be confused with dental practice accreditation under the *National Safety and Quality Health Standards* (NSQHS, 2021) which is a thoroughly regulated and comprehensive accreditation process, we would suggest instead utilising the term 'endorsed' or 'certified' as an alternative.

The DSWG Professions are working on a quality assurance standard for dental laboratories for TGA's consideration. We recognise the need for dental laboratories to comply with the essential principles as well as want to ensure this standard is consistent and robust across all dental professions (i.e. including Ahpra registered health practitioners running dental laboratories). Once this is finalised, we would appreciate TGA's input on the implementation of this standard.

We note that the proposed refinements refer to the dental practitioner subdivisions (e.g., dental prosthetists) and suggest that future consultation and/or guidance papers refer to dental practitioners and dental technicians. On this note, we assume the examples provided relating to dental prosthetists also apply to all registered dental practitioners including dentists, orthodontists, oral health therapists, hygienists etc?

We refer to the proposed refinements document exemption examples below (2021a, p. 11-12)

> *Examples where Class I (low-risk) patient-matched medical devices could be exempted are where they are being manufactured:*
>
> - *By a dental technician who holds a recognised qualification under the Australian Qualifications Framework and The devices they produce are intended to be used by a patient of a healthcare facility, registered provider or AHPRA-registered health professional.*

- *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.*

Under these potential exemptions, what would a health practitioner's responsibility be regarding outsourcing the manufacture of Class I non-sterile non-measuring devices to:

a) A dental technician without a recognised qualification under the Australian Qualifications Framework or
b) To a dental laboratory that has not been endorsed by the relevant professional association.

What would a dental laboratories responsibility be concerning employing a dental technician without a recognised qualification under the Australian Qualifications Framework?

How does TGA propose to monitor this compliance?

The DSWG professions agree with the intent of the exemptions however we believe further discussion and refinement is required about how this proposed framework would translate in practical terms to dental technicians, dental laboratories, and dental practitioners.

We query whether there would be any reporting requirements for exempt Class I devices such as the previous requirement to notify TGA of a custom-made medical device within two months of initial supply?

As noted in the previous section – exclusions, we would also appreciate further clarification and discussion on the impact of medical device exemption on advertising health-related services.

RECOMMENDATIONS - EXEMPTIONS

1. **A blanket rule for all Class I non-sterile non-measuring medical devices manufactured in Australia by a registered dental practitioner, appropriately qualified dental technician or endorsed dental laboratory to be exempt from listing on the ARTG.**
2. **Class I non-sterile non-measuring medical devices outsourced and manufactured overseas must require listing on the ARTG.**
3. **All references to the Oral Health Profession Association should be replaced with 'by the relevant professional association'.**
4. **Alternative wording used for describing accreditation – suggested terminology includes 'endorsed' or 'certified'.**
5. **DSWG quality assurance standard (i.e., professional association endorsement/certification) draft to be reviewed and discussed with TGA when finalised.**
6. **Future TGA documents refer to dental practitioners (instead of dental sub-divisions) and dental technicians unless the framework is specific to a sub-division of dental practitioners.**
7. **Discussion and clarification of a health practitioners' role in outsourcing to a dental laboratory and/or dental technician.**
8. **Discussion and clarification of a dental laboratory's role in employing a dental technician without a recognised qualification.**
9. **Clarification on how TGA proposes to monitor dental laboratories and dental technicians' compliance (e.g., qualifications and/or endorsement).**
10. **Further discussion with the DSWG on the exemption examples relating to dental technicians, dental laboratories and a health practitioners role within this proposed framework.**
11. **TGA to clarify reporting requirements for exempt medical devices.**
12. **Clarification on impact exemption has on advertising.**

ALTERNATIVE CONFORMITY ASSESSMENT PROCEDURES

The DSWG professions agree with the intent behind the alternative conformity assessment procedures and believe this may adequately negate the costs involved with thirty party conformity assessment under the current framework. We acknowledge TGA's work on this proposal and appreciate the solutions presented in the proposed refinements.

As highlighted in the previous section – exemption, there are a few areas we believe require refinement under the alternative conformity assessment procedures as follows:

- The alternative conformity assessment should be made available to all Class IIa dental devices manufactured in Australia by a registered dental practitioner, appropriately qualified dental technician or endorsed dental laboratory.
- The alternative conformity assessment procedure must not be available to outsourced medical devices manufactured overseas.
- References to the Oral Health Profession Association should be replaced with 'by the relevant professional association'.
- The term accreditation should be avoided unless relating directly to dental practice accreditation under the NSQHS.
- Refinements are required in the examples section relating to registered health practitioners, accredited dental laboratories and qualified dental technicians.
- The DSWG professions are working on a quality assurance standard for dental laboratories which will be made available when finalised for TGA's review and input.

RECOMMENDATIONS – ALTERNATIVE CONFORMITY ASSESSMENT PROCEDURES

1. **The alternative conformity assessment option should be made available to all Class IIa dental devices manufactured in Australia by a registered dental practitioner, appropriately qualified dental technician or endorsed dental laboratory.**
2. **Class IIa medical devices outsourced and manufactured overseas must not have access to the alternative conformity assessment option.**
3. **All references to the Oral Health Profession Association should be replaced with 'by the relevant professional association'.**
4. **Alternative wording used for describing accreditation – suggested terminology includes 'endorsed' or 'certified'.**
5. **DSWG quality assurance standard (i.e., professional association endorsement/certification) draft to be reviewed and discussed with TGA when finalised.**
6. **Refinement and discussion on alternative conformity assessment examples relating to registered health practitioners, dental technicians and dental laboratories.**

GENERAL

The DSWG professions concluding remarks for TGA's consideration are:

- The DSWG professions quality assurance standard will aim to incorporate existing processes such as practice accreditation documentation and standard operating procedures.
- Dental specific information and presentations on adverse events, the essential principles and post-market surveillance would greatly benefit the dental profession.
- Academic institutions must be engaged as part of the consultation process, the work of TGA and the DSWG must be reflected in course content.
- It is not enough to have a quality assurance standard; checklists in themselves are not sufficient - we believe documentation needs to be made available by manufacturers to health practitioners in asserting compliance. Implementation of this quality assurance standard is crucial and requires all peak professional associations involvement. We do not believe there is any requirement for third-party audits and/or inspections unless compliance cannot be demonstrated.
- The public (patients/consumers) must be aware of TGA's role and the fact that medical devices must comply with the essential principles. We suggest supporting material is made available to health practitioners to share with patients highlighting this fact.
- There must be a transitional process for new graduates to help ensure this framework works and is achievable to the incoming dental profession.

We reiterate our support of TGA's efforts in developing and implementing this framework and again appreciate TGA's acknowledgement of our concerns evident in the proposed refinements document. We also recognise the need to balance this framework with the regulatory burden and costs to dental professionals which will inevitably need to be passed on to consumers. To ensure the dental profession is prepared for and complies with these changes it is important for us to all work together. We believe the DSWG is a good start to this and look forward to meeting again soon.

We ask that you update the entire dental working group once further information on the DSWG professions recommendations, points of clarification and suggestions becomes available.

Yours sincerely,

Dr Mark Hutton
Federal President
Australian Dental Association

Nicole Storman
National President
Australian Dental & Oral Health Therapists' Association

Jenine Bradburn
National President
Australian Dental Prosthetists Association

Dr Howard Holmes
Federal President
Australian Society of Orthodontics

Cheryl Dey
National President
Dental Hygienists Association Australia

Richard Giddings
Owner
Absolute Orthodontic Services

Tony Minichilli
Owner
Bioart Dental

David Rodwell
Owner
Rodwell Orthodontic Laboratory

Enc.

DSWG PROFESSIONS RECOMMENDATIONS

EXCLUSIONS

1. **Teeth Whitening medicaments exclusion should be read in conjunction with the Poisons Standard with supporting documentation available to practitioners and consumers.**
2. **Retainers and aligners added to the list of exclusions.**
3. **Polymers, resins, denture repair kits and denture adhesives are removed from the exclusion list and continue to be regulated by TGA.**
4. **Clarification on whether the wording 'as part of physical impressions of a patient's anatomy and models cast from these' incorporates study models.**
5. **Future guidance and consultation documents to refer to dental practitioners and dental technicians rather than subdivisions within dentistry (e.g. dental prosthetists).**
6. **Further discussion required on excluded device advertising.**

EXEMPTIONS

1. **A blanket rule for all Class I non-sterile non-measuring medical devices manufactured in Australia by a registered dental practitioner, appropriately qualified dental technician or endorsed dental laboratory to be exempt from listing on the ARTG.**
2. **Class I non-sterile non-measuring medical devices outsourced and manufactured overseas must require listing on the ARTG.**
3. **All references to the Oral Health Profession Association should be replaced with 'by the relevant professional association'.**
4. **Alternative wording used for describing Accreditation – suggested terminology includes 'endorsed' or 'certified'.**
5. **DSWG quality assurance standard (i.e., professional association endorsement/certification) draft to be reviewed and discussed with TGA when finalised.**
6. **Future TGA documents should refer to dental practitioners (instead of dental sub-divisions) and dental technicians unless the framework is specific to a sub-division of dental practitioners.**
7. **Discussion and clarification of a health practitioners' role in outsourcing to a dental laboratory and/or dental technician.**
8. **Discussion and clarification of a dental laboratory's role in employing a dental technician without the recognised qualification.**
9. **Clarification on how TGA proposes to monitor dental laboratory's and dental technicians' compliance (e.g., qualifications and/or endorsement).**
10. **Further discussion with the DSWG on the exemption examples relating to dental technicians, dental laboratory's and a health practitioners role within this proposed framework.**

11. **TGA to clarify reporting requirements for exempt medical devices.**
12. **Clarification on impact exemption has on advertising.**

ALTERNATIVE CONFORMITY ASSESSMENT PROCEDURES

1. **The alternative conformity assessment option should be made available to all Class IIa dental devices manufactured in Australia by a registered dental practitioner, appropriately qualified dental technician or endorsed dental laboratory.**
2. **Class IIa medical devices outsourced and manufactured overseas must not have access to the alternative conformity assessment option.**
3. **All references to the Oral Health Profession Association should be replaced with 'by the relevant professional association'.**
4. **Alternative wording used for describing accreditation – suggested terminology includes 'endorsed' or 'certified'.**
5. **DSWG quality assurance standard (i.e., professional association endorsement/certification) draft to be reviewed and discussed with TGA when finalised.**
6. **Refinement and discussion on alternative conformity assessment examples relating to registered health practitioners, dental technicians and dental laboratories.**

APPENDIX ONE

The Dental Sector Working Group professions has collaborated on these definitions with a view to submit a request with the GMDN Agency for new or modifying existing listings.

It should be noted the “device name” essentially reflects “the kind” or purpose of the device.

PROSTHESIS FOR DENTAL RESTORATION - SELF REMOVABLE

DEVICE NAME (suitable for all Class I) Existing GMDN are similar but do not allow for versatility.

DEFINITION

A personalised prosthesis that is provided by a dental professional. The device is intended to artificially replace one or more teeth, bone and tissue within the oral cavity. The device is self-removable and will include a base or framework which is supported by surrounding soft and hard tissues and/or teeth within the oral cavity. The device may be retained using fixed devices or structures within the oral cavity. The device construction is versatile and will be suitable for single, partial or full reconstruction. The device can be made using a variety of materials including polymers, acrylics, ceramics, metals and alloys.

PROSTHESIS FOR DENTAL RESTORATION - FIXED OR BONDED

DEVICE NAME (suitable for all Class IIa) Existing GMDN are similar but do not allow for versatility.

DEFINITION

A personalised prosthesis that is provided by a dental professional. The device is intended to artificially replace one or more teeth, bone and tissue within the oral cavity. The device is fixed or bonded and may include a base or framework which is supported by teeth and/or other fixed device/s or structure/s within the oral cavity. The device construction is versatile and will be suitable for single, partial or full reconstruction. The device can be made using a variety of materials including polymers, acrylics, ceramics, metals and alloys.

APPLIANCE FOR CORRECTION AND/OR STABILISATION OF DENTAL ANATOMY - SELF REMOVABLE

DEVICE NAME (suitable for all Class I) Existing GMDN are similar but do not allow for versatility.

DEFINITION

A personalised device that is used during a course of treatment provided by a dental professional. The device is intended to influence or retain the shape and/or function of the stomatognathic system. The device is self-removable and has a versatile design that may be tooth borne or tooth and soft tissue borne. These devices may be used during treatment and/or management of; orthodontic tooth movement, dentofacial and jaw orthopaedic, temporomandibular joint dysfunction, oral parafunction (including bruxism and habit prevention), sleep disordered breathing/snoring or for splinting during oral and maxillofacial or orthognathic surgery. The device will include a framework that may include various components such as occlusal platforms, bite ramps, wires, clasps, hooks, orthodontic brackets, tubes, habit guards, springs and/or screws. The device can be made using a variety of materials including polymers, acrylic, ceramics, metals and alloys.

APPLIANCE FOR CORRECTION AND/OR STABILISATION OF DENTAL ANATOMY - FIXED OR BONDED

DEVICE NAME (Suitable for all Class IIa) Existing GMDN are similar but do not allow for versatility.

DEFINITION

A personalised device that is used during a course of treatment provided by a dental professional. The device is intended to influence or retain the shape and/or function of the stomatognathic system. The device has a versatile design that may be cemented to teeth and/or attached to other fixed structures within the oral cavity. These devices may be used during treatment and/or management of; orthodontic tooth movement, dentofacial and jaw orthopaedic, oral parafunction (including bruxism and habit prevention) or temporomandibular joint dysfunction. The device will include a framework that may include various components such as occlusal platforms, bite ramps, wires, clasps, hooks, orthodontic brackets/bands, tubes, habit guards, springs and/or screws. The device can be made using a variety of materials including polymers, acrylic, ceramics, metals and alloys.

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