Response ID ANON-3NHQ-DDKY-6

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-13 10:17:42

Introduction

1 What is your name?

Name:
[redacted]

2 What is your work title?

Work title:
[redacted]

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
Australia Dental Association (Queensland Branch)

5 What is your company/organisation address?

Please provide the business address of your company or organisation.:

24-28 Hamilton Place, Bowen Hills Qld 4006

6 Which industry do you work in, or represent?

Please state the industry that you work in, or are representing in your submission.:
Dentistry

7 Are you responding:

On behalf of an organisation

Exclusion

8 Do you agree with the rationale for the proposed exclusion of products?

Yes

If you answered 'no' to the above question, why do you disagree with the rationale for the proposed exclusion of the products listed?:

ADAQ agrees that dental-related patient-matched devices which are excluded from regulation should pose no or negligible risk to patients.

However, ADAQ does not agree with the rationale for the proposed exclusion of products as outlined in the consultation document as the premise of a blanket exclusion is a risk to patient and public safety. This seems to directly contradict the TGA's stated purpose on the need for regulatory change as outlined on page 6 of the consultation document; "Newer methods of manufacture such as 3D-printing allow more complex and, in some cases, higher risk medical devices to be personalized for an individual patient and supplied under the custom-made medical device exemption. For lower risk devices these advances resulted in new manufacturers, who are not always trained or accredited, entering the market."

ADAQ is of the view that the rationale for the proposed exclusion of products should be amended to include therapeutic products that pose no or negligible risk to patients. A requirement for the exclusion of these products should be that they are prescribed and manufactured by a health professional such as a dentist. An example of such a product is an occlusal splint used to treat teeth grinding. Any risk to the patient from these products can be managed as a dental practitioner has the skills and training to:
- Assess patient need
- Prescribe an appropriate product
- Ensure the product fits appropriately
- Provide continuity of care

ADAQ acknowledges that dental technicians and prosthetists have the appropriate training to produce these products, however they do so under instruction from registered dental practitioners and this clinical governance must be preserved to minimise risk to patients.

9 Are the risks posed by the products adequately managed if they are excluded from regulation by the TGA?

Yes

Please explain your response, including by providing examples that illustrate and/or support your position.:

Provided that the medical devices are supplied ONLY under the direction of a registered dental practitioner, thereby preserving the already existing model of clinical governance. An exclusion should NOT apply to the general public or any manufacturer who is not considered to be a registered dentist, or an appropriately trained dental technician or prosthetist.

10 Are there further products that meet the principles proposed for exclusion? What are they and why should they be excluded?

Ensure your answer directly addresses (1) why the products pose no, or insignificant, levels of risk or (2) why the product does not meet the definition of a medical device. :

ADAQ proposes the items below be excluded when prescribed and manufactured by a registered dental professional, technician, or prosthetist.
- Denture repair kits
- Study models
- Working models
- Orthodontic appliance positioning tray
- Mouthguards used as occlusal splints
- Bleaching trays

When prescribed and manufactured by a registered dental professional, technician or prosthetist, the risk to patients from these products will be nil or negligible. Otherwise, risks may include gum irritation or inappropriate use. Again, this risk can be managed through oversight by registered dental professionals through:
- Assessment of the patient
- Customisation of the tray for the patient
- Appropriate fitting of the device

ADAQ is of the view that where an occlusal splint is prescribed under the direction of a registered dental professional, it should be excluded from regulation, given its low risk profile.
Occlusal splints (commonly known as a night guard) are patient matched hard moulded appliances made from resin. These devices are designed to protect teeth from wear and cracking from clenching or grinding habits.
These devices are made with biocompatible materials and can be used for protection of the dentition and surrounding tissues, similar to sports mouthguards and dental whitening trays which are excluded from the TGA requirements.
The risks associated with occlusal splints are similar, if not the same, as the risks posed by mouthguards and whitening trays (which are excluded). These risks are gum irritation and the incorrect use of the device by the patient. Therefore, where occlusal splints are prescribed by a registered dental professional, the ADAQ's view is that these should be excluded from regulation.

Exemption

11 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 the consultation paper?

Yes

If you answered 'no' to the above question, please explain why it is that you disagree with the rationale for the proposed exemption of Class I non-sterile, non-measuring patient-matched medical devices?:

However ADAQ formally requests that the TGA explicitly recognise that registered dentists and dental specialists also have the skills and training to manufacture (in addition to prescribing) Class I patient-matched medical devices as it is within their scope of practice.
The Australian Health Practitioner Agency (Ahpra) defines dentistry as;
"Dentistry involves assessing, preventing, diagnosing, advising on, and treating any injuries, diseases, deficiencies, deformities or lesions on or of the human teeth, mouth or jaws or associated structures. It includes restricted dental acts (see section 121 of the National Law)."
Further, section 121(2)(a) of the National Law includes "…. fitting, inserting, adjusting, fixing, constructing, repairing or renewing artificial dentures or a restorative dental appliance".
Undergraduate dental science curricula in Australia provide the education and training required to manufacture Class I non-sterile non-measuring patient-matched medical devices. This is recognised by both the accrediting body (the Australian Dental Council) and regulator (Ahpra). ADAQ is concerned that the TGA proposal to exempt Class I patient-matched medical devices produced under certain circumstances does not recognise general dentists as manufacturers of these devices. Our firm position is that dental practitioners, including specialists, should be included as a profession that can manufacture the devices in the exempt (Class I) category

12 Can the risks posed by Class I non-sterile, non-measuring patient-matched medical devices when produced under the circumstances listed in the consultation paper be adequately managed if they are exempted from inclusion in the ARTG?

Yes

Please explain your response, including by providing examples that illustrate and/or support your position.:

Registered dental practitioners work in multidisciplinary teams to provide patient care and maximise patient outcomes. Inherent in this model of care is clinical governance supported by Ahpra registration standards including scope of practice, code of conduct, record keeping and continuing professional

development.
The risks to patients posed by Class I non-sterile patient-matched medical devices are:
a) Device failure causing harm
The risk of product failure causing harm in devices exempted from inclusion in the ARTG can be managed through:
i. Appropriate assessment of the patient by a registered dental professional
ii. Appropriate prescribing and manufacturing of the device, including record keeping (materials used, date of manufacture, treating dental practitioner)
iii. Appropriate fitting of the device; and
iv. Provision of appropriate instruction on use of the device to the patient.
ADAQ is, however, concerned that a blanket approach in granting Class I exemptions does not mitigate the risk associated with clear aligners where a member of the public takes their own impressions, and the device is prescribed and manufactured without a face-to-face assessment by a dental professional registered in Australia. This risk would be mitigated if the TGA amended their proposed criteria for exemption to ensure that all the steps in matching the patient to the device are undertaken by a registered health practitioner.
b) The standard of patient care provided
Patient care sits outside of the remit of the TGA and this is adequately mitigated by the existing regulatory framework.

13 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?

Ensure your answer directly addresses 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.:

Yes. The ADAQ is of the view, the list of items in this category should be expanded to include:
• Retainers. These devices are used after the completion of orthodontic treatment and are used to maintain the teeth alignment. These devices are removable and commonly worn at night.
• Essix Retainer with tooth/teeth replacement. These devices are used by patients to temporarily replace a missing tooth/teeth, whilst the patient is waiting for additional permanent treatment for the missing tooth/teeth.
• Any other orthodontic appliances (including twin blocks) as they are not intended to stay continuously in the mouth for more than 30 days.
• Oral sleep device. This is used to reduce snoring or assist with sleep apnoea. These devices are used at night and are removable.
The risks relating to the above devices is similar to the other dental devices referred to in this category and the ADAQ comments relating to the other devices for this category equally apply to the devices stated above.

Alternative conformity assessment procedures

14 Do you agree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched medical devices when produced under the circumstances listed in the consultation paper?

No

If you answered 'no' to the above question, please explain why you disagree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched medical devices?:

It is ADAQ's view that the dental devices identified for this category should be exempt, rather than subject to the alternative conformity assessment procedure.
ADAQ takes this view as there is no change in the risk profile between the devices proposed to be exempt and the devices proposed to be subject to the alterative conformity assessment procedure. The only difference between the items in the category is the longevity of the item in the oral cavity.
ADAQ is also of the view that the listing of these device on the ARTG is an unnecessary increased burden in regulation.
An example of this can be seen with the manufacture of indirect restorations such as crowns, where the devices used by registered dental professionals, dental specialists and technicians/prosthetists to mill patient-matched devices are already registered on the ARTG (for example the ARTG has registered the Sirona Cerec MCXL- CAD/CAM unit, dental, chairside which is approved for dental restorations chairside in the dental laboratory or office). Further, the material used to manufacture the device is also listed on the ARTG (for example Dental material kit, porcelain/ceramic restoration which is approved for use in the prefabrication and custom made dental restorations). As both the machine and the material used in the manufacture of the device are already listed on the ARTG, the ADAQ is of the view the additional regulation proposed is unnecessary where a registered dental professional or dental specialist assesses the patient, prescribes and/or manufactures and fits the device.
ADAQ acknowledges the concerns raised by the TGA in the consultation document with regards to the risks posed by Class IIa devices (to cause) significant harm. ADAQ holds the evidence based position that the risk of inherent material failure is very low.
A systematic review by Abduo and Sambrook (https://onlinelibrary.wiley.com/doi/full/10.1111/jerd.12384) found that "tooth preparation, tooth vitality and occlusal force…influence ceramic onlay survival" and that "different modern glass-ceramic materials, manufacturing techniques and cementation materials have minimal effect on glass ceramic onlay survival". This supports ADAQ's stance that the risks of harm posed by Class IIa devices are not due to inherent material failure, but rather treatment-related factors, which are not within the remit of TGA regulations.

In terms of risk of harm, this review found 2-5 year survival rates of 91-100%, which ADAQ would believe is a clear demonstration of the low overall risk that is posed by Class IIa devices.

In summary, the combination of:
1) The high success rates of Class IIa devices, and therefore the lower proportional risk of harm as demonstrated in systematic reviews; plus
2) the recognition that inherent material failures do not contribute to a significant proportion of the treatment failures; and
3) the existence of regulation around the materials and equipment used to manufacture Class IIa devices
strongly supports ADAQ's view that Class IIa devices should be regulated under the Exemption mechanisms.

Further, and in the alternative, if the alternative conformity assessment procedures are to remain for the Class IIa patient matched devices, then ADAQ requests the TGA explicitly recognise that registered general dental practitioners, in addition to dental specialists, have the requisite skills and training to both "prescribe" AND produce/manufacture Class IIa patient-matched medical devices within their scope of practice and therefore need to be included as a profession who is able to manufacture these devices in line with the proposed amendments.

15 Do you agree that the risks associated with the Class IIa patient-matched medical devices when produced under the circumstances listed in the consultation paper could be adequately managed through the proposed alternative conformity assessment procedure?

Yes

Please explain your response, including by providing examples that illustrate and/or support your position.:

However, ADAQ believes that Class IIa patient-matched devices could be managed in the same way as proposed for class 1a devices as they pose minimum risks to patients. Further, ADAQ believes strongly that the risk profile for these devices can be adequately managed by registered dental professionals, dental specialists and dental technicians/prosthetists and it should be noted these professionals are currently managing these risks to an adequate standard.
As outlined above in this submission, dentists study for a minimum of 5 years at university before allowing them to register as a dentist. Further, a number of dentists continue on with additional study in a specialist area for an additional 2 or 3 years. During this study, dentists are taught about all aspects of dentistry including material science and risks associated with the devices proposed to be regulated by the TGA. Through their training, accreditation and ongoing professional development, these health professionals are provided with the necessary skills which makes them capable of managing the risks of the manufacture of these devices. By way of example registered dental professionals and dental specialist as part of their role:
• Are required to understand and explain the risks of Class IIa devices to patients in order to obtain informed consent. This requirement is set out in section 3.5 of the Dental Board Code of Conduct.
• Provide options to patients regarding the material to be used for Class IIa devices. For example, they must understand and be able to explain to patients the different materials from which a crown is made, such as porcelain or ceramic.
• Are required to understand the specifications for the Class IIa device. As part of their role, they take impressions which are necessary to meet the requirements for the manufacture of these devices
• Are trained and must be compliant with infection control requirements. The infection control requirements are set out in the Dental Board of Australia "Infection Control Obligations of Dental Practitioners" and are required to be adhered to by all dentists and dental specialists. This is also a requirement under the Dental Board's Code of Conduct. Infection control training is also part of a dentist's CPD requirement.
• Are required as part of their continuity of care obligations in the Dental Board's Code of Conduct to ensure review of patients after a Class IIa device is inserted. This is usually organised by a follow up appointment.

16 Are there further circumstances where an alternative conformity assessment procedure for Class IIa patient-matched devices would be appropriate?

Please ensure that your answer directly addresses what measures are in place to manage the risks associated with the devices.:

Yes. ADAQ is of the view that the list of Class IIa items should encompass all fixed prosthodontic devices category especially:
• Onlays and inlays. These devices are similar to a crown but cover partial loss of the tooth structure. They are manufactured in a similar way to a crown and therefore, it would be appropriate to include these
• Fixed prothesis. These are implant retained bridge/denture and are manufactured in a similar way to a bridge
The risks relating to the above devices is similar to the other dental devices referred to in this category and the ADAQ comments relating to the other devices for this category equally apply to the devices stated above.

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

Please outline your reasoning.:

ADAQ would strongly advocate for all Class IIa dental devices to be subject to the Exemption mechanism as opposed to the Alternative Conformity Assessment for the reasons outlined in Question 14.

Alternative approaches we should consider

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

If applicable, please write your response in the text box below.:

Yes, the alternative mechanisms already exist in the TGA regulation of the materials and equipment used in the manufacturing of patient-matched devices. The proposed regulation of patient matched devices manufactured from the materials and equipment that are already regulated through their listing on the ARTG appears to provide unnecessary duplication. Considering the catalyst of the proposed regulatory changes appears to be the advent of 3D printing equipment and manufacturing of more complex patient matched devices, ADAQ is of the view that focusing on the regulation of the equipment and the materials would be most effective in enhancing patient safety and potentially reduce the regulatory burden for the TGA, as well as its stakeholders.
It is ADAQ's position that considering the above alternative mechanisms for regulation already available, and combined with the training, education and scope of practice of registered dental professionals (which includes detailed knowledge of material science, manufacturing of dental devices, anatomy of the jaw and oral cavity and requirement for ongoing scientific and evidence based continuing professional development), ALL patient-matched devices manufactured upon the assessment, prescription and fitting by a registered dental professionals within their scope of practice should be regulated under

the Exemption mechanism as the highest level of regulation. The current regulatory framework for health professionals through AHPRA will supplement TGA's efforts to enhance patient safety from the manufacturing of patient-matched medical devices.

Required final step - Publishing my response

19 Do you consent to the Department collecting the information requested in Citizen Space about you, including any sensitive information, for the purposes of this consultation?

I consent

20 I consent to the submission made by me being published on the Department's website, and accessible to the public, including persons overseas, in accordance with the following preference:

Publish response, without my name but including my organisation's name

21 If there are specific answers you have provided that you do not wish to be published, please indicate these below.

Please state below any specific questions that you do not wish to have your answers to published.:
No.

22 May we contact you for further information or to seek feedback about how the consultation was undertaken?

Yes

23 By making a submission, I acknowledge that:

I acknowledge the above