Response ID ANON-3NHQ-DDPY-B

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-06-17 01:17:28

Introduction

1 What is your name?

Name:
[redacted]

2 What is your work title?

Work title:
DOCTOR

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
[redacted]

5 What is your company/organisation address?

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

Dental Serenity

[redacted]

6 Which industry do you work in, or represent?

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

7 Are you responding:

As an individual

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?:

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.:

The examples given : mouth guards, whitening trays , have low risk , they are simple devices and as long as the materials used are on the tga, they will be hard to do harm. Anatomical models have been used for years and can be made of any material plaster, resin. It would be unlikely to have an adverse event with such a device. Whitening trays themselves are just a thermoplastic outline that holds material. The material used in it is more of a concern that the delivery system

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. :

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?:

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.:

They already are. Any risks created by dentures , splints , provisionals are worn by dental professionals as part of our duty of care and professional indemnity. If the materials used are biocompatible and non toxic, then the risks to patients are already handled by the skill of the operator/ diagnosis and treatment planning. Acrylic allergy is the most common material complication, with any other issue being bespoke design issues which won't be solved via legislation or accreditation. Patient management is the issue , not device structural issues. If materials used in construction are listed on tga, then the rest comes down to professional skill and training/ knowledge

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.:

Essentially most dental treatments and devices that are meeting class I , by short term use , or even long term intermittent use , handle the real risks purely by having the materials used as being tga listed . The constructions of devices themselves are skills provided by dental technicians training,dental degrees and post graduate courses and education . There is continual support and discussion about what materials work better, last longer and give better outcomes. The whole profession is geared towards seeking better patient outcomes. Ensuring that the materials we are using is safe and biocompatible will take care of toxicity and health issues. Leaving us unfettered to utilise these materials as tools, will allow creativity and professional growth to provide better patient outcomes.

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?:

I was concerned with your example of crowns and bridges construction resulting in recurrent caries / tooth fracture. Also the idea of reporting adverse outcomes for such devices would be laughable. There are a multitude of reasons a crown / bridge might fail and not all of them are related to device construction. Poor prep design, inadequate cleaning by the patient, difficult moisture control during cementation by the dentist inserting the device are just a couple of scenarios that would create an adverse reportable event. Is the tga really seeking to have dental material failures reported , because that essentially is a daily event in any dentsl office. The majority of dental care is managing failing dental devices after they have been in use in the oral environment. The current discussion creates an open door for what constitutes failure/ reportable events and who is responsible for device failure. The examples listed imply that any crown failure can be blamed on manufacturer of a crown. Hence I would suggest that class II devices made by dentists / dental technicians are better regulated by ahpra and professional bodies who can assess if they were made/ planned/ designed and executed appropriately. Class II naterials however should be evaluated and regulated by the tga to ensure there are no toxicity issues.

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.:

If you leave dentists and technicians to work to our professional obligations, then the risks are managed by ensuring we use tga approved materials. The devices themselves will be regulated by the professional bodies

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.:

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.:

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.

With improvements in technology, such as 3D printing / cad cam dentistry that are allowing dentists to reduce costs to patients and provide accurate and faster treatments. The issue is not about the machines that set the material , or the drills that cut them. But rather what resins are being used, what blocks are being turned into prosthesis.

simply give us TgA approved materials that are safe to use , we can then use these technologies to create solutions . These materials already exist, are being used and are being refined at a rapid rate. There is no epidemic of adverse health outcomes , in fact the opposite. More dentists are providing more accurate work with improvements in 3D scanning, rapid 3D printing of anatomical models and in house same day restorations minimising risks of exposed tissue, temporary provisional materials breaking and post operative pain.

The TGA doesn't need to regulate what we make from these machines because it will be a logistical nightmare in record keeping/ reporting and ultimately adverse outcomes are going to be managed by professional regulatory systems like ahpra and the dental board. Minor failures will have low biological issues and patient management strategies will deal with these. Ie replacement / repair or refund.

The TGA could simply regulate the materials we use , insist they are used by dental professionals or trained auxiliaries / dental technicians . This takes care of overseas labs using in appropriate materials. This takes care of regulating every possible iteration/ code / device name . There is no loop hole here because it doesn't matter what the device is called, it has to be made from approved safe substances.

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 or my organisation's name (anonymously)

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.:

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