Response ID ANON-3NHQ-DDKT-1

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-13 14:39:28

Introduction

1 What is your name?

Name:
[redacted]

2 What is your work title?

Work title:
dental prosthetist

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.:

[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 Prosthetics

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?:

Sorry I'm confused, are you now saying that dentures, whether it be full dentures and or partial dentures, mouthguards splints are now exempt?

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.:

All products used in the process of denture manufacture are purchased through recognised dental warehouses within Australia that already have to comply with TGA regulations. Cross infection guidelines are adhered to in this production. As I'm aware, all materials used in the production of dentures are registered in Australia for health and safety therefore if this is the case, why is there a proposal to tax or regulate the finished product. No doubt the warehouses pay a cost to register these products so imposing a cost at the end, to me, is nothing more than double dipping. My governing body is AHPRA they already control my ability to maintain a licence to fit and make dentures. Too many regulators is just prohibitive. I have to have the appropriate insurances in place. I cannot see the relevance of this additional tax/fee on products that I make.

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. :

Full upper, full lower or single dentures , part upper part lower either acrylic or chrome metal framework partial dentures , mouthguards invisalign splints ,are these things now exempt ?

I think all dentures, no matter what type or style should be exempt, If a prosthetic eyeball is exempt then please explain why a denture is not. In all my years of making and fitting dentures I have never seen an adverse reaction to a denture. Yes it does replace an anatomical structure but so does a dental filling. Why are dental fillings not include in your list, why are they not considered a medical device.

Why also are Dentists and therapists not included in having to comply with these regulations? They also manufacture and fit dental devices. Are they exempt from these new regulations?

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.:

We must already maintain appropriate training requirements, hold the appropriate governing body licences and hold the correct type of insurance to be able to practice.
I do believe that there should be heavy regulations on appliances and raw materials that are outsourced or directly importing from other countries where the health and safety regulations and guidelines are not adequate or on par with or bypassing those regulations in Australia.

No patient has to wear a denture 24 hours a day 7 days a week, they can be taken out of the mouth any time or even not wear them at all. In all my years of practice I have never had a patient harmed by one of my dentures, splints or mouthguards.

I also believe my profession is already at great risk of becoming obsolete, most prosthetist I know are approaching their retirement years, there are little to no new apprentices and this requirement to adhere to further regulations in an already heavy regulated industry will be the death nell to the remainder of the Prosthetists still trying to survive in the industry.

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.:

Se 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?:

As dental prosthetist I do not do any invasive procedures, that interfere with the integrity of mucosal membranes. The materials used by laboratories as long as they are used as the manufacturers specifications and are registered in Australia, there should not be an issue.
Has there been any issues in the past that have needed recalls by manufacturers or a ban from the use of particular products, I am not aware of any that effect my work. The end product have always been cleaned and disinfected before use and instructions on home care have always been provided. We are now in the dentist field and once the appliance reaches the dentist hands then they need responsability for the patients instruction, not the lab.

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 all of the parties in the manufacture of a dental products are Australian licenced and trained and are current.

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.:

I am not involved in the manufacturing of any Class IIa devices so I can not offer any opinion on this.

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.:

I am not involved in the manufacturing of any Class IIa devices so I can not offer any opinion on this.

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.:

No.

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.:
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