Response ID ANON-3NHQ-DDQ1-4

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-06-29 16:38:39

Introduction

1 What is your name?

Name:
[redacted]

2 What is your work title?

Work title:
Dental Technician

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.:
manufacture of patient-made dental prosthesis / appliances to specific details by dentists

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.:

I am a dental technician, graduated in [redacted]. Since 2000, I have been working at [redacted].
We have been making removable and fixed dental appliances prescribed by dentists - based on the impressions / records that the dentists supply to us steps by steps.
From the impressions supplied, we pour up to make working models, and work on these supplied models to produce the dental appliances as listed on TGA Consultation Document including bleaching trays, removable prosthesis such as full or partial dentures, occlusal splints, sport mouth-guards, fixed prosthesis such as crowns and bridges, orthodontic removable or fixed plates / retainers.
The materials that we use are sourced from well-known and registered dental suppliers, which all have their products are TGA approval before they can supply to dental laboratories.
The models we work on are supplied by our dentists - who are registered with AHPRA.
Our job is to make the prescribed dental prosthesis to fit on the supplied models by the dentists to their description - if not, the dentists will not accept the made dental prosthesis and we have to remake until the dentists are happy with.
As always, the dentists are the ones who do the insertion of the custom-made / patient-made dental appliances to their patients. The dentists are the ones who have training and are qualified with experience and knowledge to fit these removable / fixed dental prosthesis for their patients, are the ones who can adjust clinically to make the dental prosthesis specifically right for their patients if required. The dentists give patients the instructions to take

care of their dental appliances and follow-ups to look after their dental health to ensure the longevity of their dental prosthesis.
TGA mentioned about crown and bridges are fixed dental appliances - Level 2a classification. Again, it is the dentists to assess the their patients' dentition for the ordered dental prosthesis , to check the fit of the crowns and bridges, and the patients are the one who need to look after their teeth and their dental prosthesis .
If the dentist are qualified registered dental practitioners, the dentists can monitor and manage their patients' dental appliances without any risks.
We only work on the supplied models to produce the patient-made dental appliances.
Therefore, I do think that patient-customized dental prosthesis made by dental technicians should be excluded from regulation by TGA , and they would not pose any risk if the appliances are adequately managed by accredited dental health professionals (dentists, dental specialists).
Thank you for your time and attention.

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. :

not to my knowledge

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.:

There are no risks at all. if patient's appliance caused any discomfort, patient can remove it and see their health provider to have it adjust until they are fine with the appliance.

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.:

not to my knowledge

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?

Yes

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?:

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.:

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.:

not to my knowledge

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.:

not to my knowledge

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.:

Qualification of health professionals need to be regulated to ensure right products of patient-matched medical devices for patient health and safely.

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