Response ID ANON-3NHQ-DDDF-C

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-06-23 19:05:24

Introduction

1 What is your name?

Name:
[redacted]

2 What is your work title?

Work title:
Dental Technician / Laboratory Owners

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

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 risk factor for products used in dental technology are adequately managed as all products are of the name brand products that have been tested and recommended by the companies.
Through the availability of data sheets provided by the manufacturer all procedures and risk factors are outlined in accordance with the regulations.
Any adverse reaction to the use of the products is dealt with by consolation with dentists and medical practitioner's.

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.:

All dental laboratory Class 1 APPLIANCES are constructed with approved, name branded products purchased through dental suppliers within Australia. All products have the availability of a data sheet outlining any relevant information including any procedural requirements to risk management for the purpose of the manufacture's well being.
Correct handling and storage is also a factor to keeping the material adequately acceptable for use.
All appliances are made with consultation with dentists, and only should be manufactured by qualified trained technicians.

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.:

All dental Class 1 non- sterile, non- measuring patient - matched devices should only be manufactured by qualified trained personnel holding at least the diploma of dental technology or equivalent .

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?:

Crown and Bridge and dental implants are fabricated by qualified dental technicians in full consultation with Dentists. All materials should be purchased with dental suppliers within Australia, that are within the TGA regulations.

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.:

Only if the appliances are being made in overseas laboratories then all these appliances should have all materials used listed and the patient should be aware that the appliance has been made overseas.

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.:

Ultimately the most dangerous aspect of this regulatory burden is the fact that dental prosthesis are being manufactured overseas. Mainly within China.
This factor is not regulated, it reduces employment within Australia, it poses a massive risk with patient health and safety.
There is no guarantee that the materials being used are legitimate.
The items are manufactured overseas so there is no legal ramifications for any problems that will arise.
Also as the devices are made overseas there is no certainty that the devices are being manufactured by qualified personal who hold the same or better qualification that are required within Australia.
THE PATIENTS ARE NOT TOLD THAT THE PROSTHEIS IS BEING MANUFACTURED IN CHINA AND ARE NOT GIVEN A CHOICE.
THEREFORE THIS COMPROMISES FREEDOM OF CHOICE AND THE POTENTIAL HEALTH AND SAFETY OF THE PATIENTS.

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