Response ID ANON-3NHQ-DDSY-E

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-14 13:22:13

Introduction

1 What is your name?

Name:
Confidential - i am making this submission as a whistleblower

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:
Confidential - i am making this submission as a whistleblower

5 What is your company/organisation address?

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

Confidential - i am making this submission as a whistleblower

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?

No

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

My industry body has not consulted with members.

Their ask is designed to assist their big corporate members with 3d printers not aolw traders like me.

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

No

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

I have been making dentures by had for decades, but this is a dying art.

The big corporate players in my industry body are moving to 3d printers.

This proposal is designed to crush the little guys like me and give a select group a free kick.

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. :

no

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?

No

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?:

This proposal is designed to benefit a select few members of the ADPA and ADIA with a special carve out to avoid compliance so they can mass manufacture using 3D printers.

Neither the ADPA nor the ADIA have consulted their membership.

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?

No

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

No. Inclusion on the ARTG is not an overly rigorous process if you are following the rules.

If they really wanted to help sole traders like me making stuff by hand they would have framed their ask explicitly to do this.

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.:

No. Number one priority should be patient safety

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?:

The ADPA and ADIA are in no way capable of providing independent conformity assessment procedures.

They will milk little guys like me in "compulsory professional development" fees and charges to qualify for their alternative conformity assessment pathway and give a green light to the big corporates to 3d print unregulated 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?

No

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

The ADPA and ADIA are in no way capable of providing independent conformity assessment pathways or procedures.

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.:

No

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.:

No Class IIa patient-matched medical devices should be subject to an alternative conformity assessment procedure.

If there is an alternative conformity assessment procedure it should be run by somebody other than the ADPA or the ADIA.

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.:

Either leave things as they are right now or bring in a process to just help little hand-made guys like me. Either way I will always comply with the law.

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 the ADIA and ADPA should be asked to show if they really consulted with their members on this

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