Response ID ANON-3NHQ-DDDQ-Q

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-06-18 13:57:35

Introduction

1 What is your name?

Name:
[redacted]

2 What is your work title?

Work title:
Dentist

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.:

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?

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.:

By ensuring the exempt devices are appropriately labelled and instructions given to patients, particularly in respect to caring for their devices, we can make sure that patients are better educated about their composition and use. However, as registered dental practitioners, we have been using some of these devices for a hundred years and not had significant adverse outcomes. With new technology penetrating the industry, I understand the rationale for modifying some rules and regulation, however, if anything, this is making us all safer, not less safe. For example, there is less risk of cross contamination and infection transfer in our practices when we use scanners, versus analogue impressions. There is less need for decontamination of these impressions and transfer from a dirty to clean area (surgery to lab), pouring up models with stone (fine particles) and grinding models (sharp stones) which can present additional hazards to us and our staff. For the patient, using TGA approved materials in TGA approved machines to mill and produce the devices such as crowns, aligners, models, means the process is a lot more precise, there is an opportunity to communicate risks and benefits with patients more clearly as they can usually visualise final outcomes. As the process is quick and streamlined, we are less inclined to compromise on fit and quality of work than if we used externally produced work. For example, if a crown milled in house doesn't appear to be of the best esthetic quality, we can easily change it on the spot and give the patient a higher quality product on the spot. The patient doesn't have to return to the practice multiple times and has a chance to give their input. If we use a lab externally, we would need to return the work to the lab, take an additional scan or impression, attempt to communicate with the technician what the patient doesn't like and then postpone the visit with the patient, hoping that the following reiteration of the crown is a better one. There is so much room for error in this process.

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.:

Dental crowns, veneers and bridges. Please reconsider and include these devices in exempt group of devices. Dentists have been making in-house crowns with TGA approved materials, in TGA approved machines for over 30 years. There has been no need to recall anything. Why now? We have already invested so much in buying this superior technology to give a superior product to our patients and ensure their satisfaction. I feel the TGA is punishing us, more forward thinking dentists for being 'forward' instead of doing things the same old, outdated and flawed way (as expressed above). Besides, our standards are regulated by our registering body and we are trained in the use of all our technology. We practice in our scope. If we don't we get deregistered. I feel the TGA is completely ignoring this and making our professional AHPRA registration meaningless. Not to mention financial and bureaucratic burden. Most dental practices are already drowning in regulation and compliance, This proposed change and heavy hand of TGA will be destructive to our industry. It will add to our costs of running our businesses, increasing the cost to the consumer! Dentistry is already out of reach for about 60% of Australians. This will just make it more so! Please reconsider and consider exemptions on all dental devices which are able to be produced in dental practices. None of them are new, we have been doing this, within our scope and training for many years without endangering the public.

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?:

This does not remove the burden of compliance and bureaucracy for us.

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.:

I believe there is no need for alternative conformity assessment at all.

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.:

Crowns and bridges as previously noted, I feel they should be in the exempt category.

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.:

Please consider backing out of dentistry all together and making our industry exempt from these changes. We are not funded by any government funding, we struggle to provide affordable services to our patients with a lot of added compliance burden over the years. We invest in technology and are the most enthusiastic early adopters of life-changing technology and processes that would give our patients the highest quality, safest products, services and experiences. From infection control processes and technology to digital scanning and CAD CAM processes. I feel that the most forward thinking ones in the industry are being punished. The dentists who outsource everything will not be affected at all, but you should understand that they are the ones who are the most outdated. If you feel we are doing something wrong, be transparent, let us know what problem you are actually trying to solve. I still don't understand what that is. Your premise is wrong. This process has wrecked the mental health of many of my colleagues and the fact that you are adding compliance cost to each dentist, not the practice, is even worse. It costs us $10K per year to remain registered and you want to make this worse! You should seek to better understand what is happening at the forefront of our industry rather than seek to draw financial reward from us. More cost to us, means less affordable care for over 60% of Australians already left behind and the number will increase. Just leave this industry alone, please.

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.:
nil

22 May we contact you for further information or to seek feedback about how the consultation was undertaken?

No

23 By making a submission, I acknowledge that:

I acknowledge the above