Response ID ANON-3NHQ-DDQX-B

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-06-25 15:54:35

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.:
Dental Manufacturing of Orthodontic Medical Devices

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?:

Yes, I absolutely agree with the rationale for the proposed exclusion of products.

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 risks are adequately managed by being manufactured by a certified and qualified Dental Technician and a registered Dental Lab, demonstrating that the Essential Principles have been followed, meeting packaging and labelling requirements, maintaining physical and electronically stored documents including lab sheet instructions, invoice and statement to DHP declaring material information and medical device characteristics and it's intended use.

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. :

All low risk removable orthodontic medical devices that should be excluded would be essix removable retainers, mouthguards, bleaching trays, study models. These medical devices are basic in nature in terms of function and do not pose a significant health risk to the patient.

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?:

Yes, I absolutely agree with the rationale for the proposed exemption of products.

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.:

The risks are adequately managed by being manufactured by a certified and qualified Dental Technician and a registered Dental Lab, demonstrating that the Essential Principles have been followed, meeting packaging and labelling requirements, maintaining physical and electronically stored documents including lab sheet instructions, invoice and statement to DHP declaring material information and medical device characteristics and it's intended use.

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 low risk removable orthodontic medical devices that should be excluded would be all other orthodontic removable medical devices including URA's, aligners and occlusal splints. The risks are adequately managed by being manufactured by a certified and qualified Dental Technician and a registered Dental Lab, demonstrating that the Essential Principles have been followed, maintaining physical and electronically stored documents including lab sheet instructions, invoice and statement to DHP declaring material information and medical device characteristics and it's intended use.

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?:

Yes I do believe that an alternative conformity assessment procedure needs to be put in place. The current regulatory burden on the types of Class IIa medical devices must be alleviated to allow legitimate Dental Labs to continue manufacturing these devices without the need to put a QMS in place and the costs associated with it. Without this change, small Businesses such as myself will be forced to cease manufacturing Class IIa medical devices and will have to reassess and restructure their Business model to manufacturing only Class I 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.:

Conformity certificates and assessments should be replaced by close monitoring of a Class IIa medical device between the patient and DHP for any adverse effects, reactions or damage to a fixed medical device during the course of treatment. Regular interaction and follow up checks with the patient by the DHP to whom the medical device was fitted is imperative and should be mandatory as an essential protocol. Under the current TGA rules and regulations, there is a lot of emphasis and responsibility placed on the manufacturer of medical devices but it's important to note that we as Dental Technicians act under instruction from the DHP. In this instance, it should be understood that any manufactured medical device is by PRESCRIPTION ONLY by a DHP and that risks of the medical device can therefore be adequately mitigated. There are also other factors that can compromise the safety and integrity of the medical device when supplied to the DHP so it also bears the question of exactly who is responsible for the safety, efficacy, durability and performance of the medical device should an issue or adverse effect arise? This can include how it's fitted and inserted into the patients mouth, the type of bonding agents the DHP uses to secure fixed appliances, suitability and any other reactions that can occur in the mouth due to certain plastics or metals that the patient may be sensitive to which the DHP needs to assess. Furthermore, any additional instructions by the DHP to the patient such as medical device activation, any use of cleaning solutions to maintain medical device, patient care and compliance, eating certain sticky foods that can damage, fracture or dislodge the medical device can all impact the safety, durability, efficacy and performance of the manufactured medical device. If an issue were to arise, the event should be carefully assessed and investigated to appropriately determine responsibility.

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.:

As a manufacturer, if quality materials are being sourced and purchased from a Dental Sales Company by a Dental Lab combined with the knowledge, expertise and experience of a trained and qualified Dental Technician as well as complying with the Essential Principles, then this should be satisfactory that a medical device will be constructed to an acceptable and safe standard by the manufacturer without the need for further conformity certificates and/or assessments.

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 do believe that special rules should apply for different “kinds of medical devices” such as those that are “fixed” in the mouth which should be given exemptions as the actual risks they pose are not as dangerous or harmful as perceived. Examples of these type of fixed orthodontic medical devices include, bonded retainers, fixed expanders and fixed space maintainers. The exemptions should be judged and based on statistical evidence that historically compares recorded adverse events of the fixed medical device versus the success rate of the fixed medical device without any adverse effects to the patient. It would be important to analyse this type of statistical information and understand the function of these fixed medical devices before imposing such extreme regulatory measures on these type of medical devices.

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.:

Yes, obtaining Product Liability Insurance cover may also present as additional assurance for public confidence and to the DHP knowing that the medical device has been constructed by a manufacturer who is legally covered for any faults of a medical device.

Also, any Dental Lab that operates as a manufacturer and registers themselves with the TGA must NOT operate unless they have or employ at least ONE certified and qualified Dental Technician who must then take responsibility for:
1. any manufactured medical device by his/her team,
2. demonstrate they meet the Essential Principles.

In regards to the implementation of advanced medical technology such as 3D printing, I also believe this should be a completely separate regulatory framework than the traditional processes Dental Labs are following. The manufacturing processes involved are different when making models out of gypsum /plaster versus making models in plastic via electronic means which may affect the outcome of a fully finished product namingly it’s fit and retention. I believe any establishment involved in operating this type of technology should be regulated differently and therefore provide evidence that the appropriate level of training has been conducted to ensure it’s correct use.

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.:
all answers can be 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