Response ID ANON-3NHQ-DDCN-K

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-04 11:22:06

Introduction

1 What is your name?

Name:
Nikhil Dutt

2 What is your work title?

Work title:
Dentist

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
Saints Dental

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.:
Dentistry

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.:

An example of such device is snap on smile which can be bought online as well under different brand names and needs to be adapted to ones teeth by putting it in hot water which a random person won't be able to do .
Even mouthguards/occlusal splints which are available in chemist shops need to be adapted to the teeth by heating and should cover/protect the teeth and soft tissues which if not done by a trained dental professional , won't serve the intended purpose .
All dental devices worn inside the mouth whether for cosmetic or physiological purposes, should be brought under the TGA framework and fitted personally by a dental professional .

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. :

Nothing should be excluded from the framework but regulation should be simplified and wherever possible a self declaration should be sufficient with registration of registered dental professionals fabrication/sponsoring such devices .

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?:

The devices are manufactured by trained dental professionals only whether manufactured by dental technicians/prosthetists in Australia or overseas .
The latest equipments and materials are supplied by the same manufacturers whether in Australia or overseas and are not available for purchase by anyone else except by dental professionals in their individual capacity or sponsored by a corporate entity .
For example all denture making materials are predominantly supplied by Dentsply or Ivoclar Vivadent all over the world while Heraes Kulzer is a vendor dealing in denture teeth in addition to the above .
These manufacturers already have CE/US FDA certifications and the denture or other dental devices if fabricated of a certified material , will be considered safe for the intended use by the public if inserted personally by a registered dental professional .
The device if being manufactured locally isn't any safer than being made overseas with standard/similar procedures using standard/certified materials .

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.:

I would like Dentists to be added to the list of professionals under whose instructions the devices are being manufactured whether locally or overseas and the dentist will be solely responsible for the device to fulfil all the regulatory /TGA requirements .

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.:

The devices should only be exempted if being personally fitted by a registered dental professional and no online sale should be allowed with personal examination of the person intending to purchase the device .
No device should be exempted which is going to be sold solely online as there won't be personal monitoring by a trained and registered dental professional .

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?:

Dentists should be added to the list and section 1 should be modified to :
1.the device is manufactured by/under instructions of a trained , accredited dental professional ; or

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.:

Registered Dentists should be allowed to import them while undertaking full responsibility for the devices and undertake and fulfil everything mentioned under sections (a),(b)&(c).
Sample device/documentation can be supplied with self declaration.
Section (c) is already completed for all patients who visit the practice regularly while it cannot be reinforced as there is a cost involved with regular dental visits .
Any problems associated are corrected at no cost which even includes replacement .

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.:

All sponsors should be given a registration number on providing a self declaration and should be given an option of supplying all technical documentation /certification in advance along with a sample device .
There should be a single registration for all devices to simplify the process and remove unnecessary regulatory burden as there are already too many regulations in place .

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

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.:

Self regulation by getting registered with TGA online and supplying all types of Class I & IIa devices being imported and providing all technical information/documentation/certification/sample devices with the registration and providing declaration that all regulations will be followed pending regular checks/audits by TGA .

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, including both my name and organisation's name

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