Response ID ANON-3NHQ-DDPW-9

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-06-17 09:52:41

Introduction

1 What is your name?

Name:
Frank Farrelly

2 What is your work title?

Work title:
Dentist

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
Darlinghurst 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.:
Dental

7 Are you responding:

On behalf of an organisation

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?:

For the most part, yes. Any device that is to be regulated should list what risk is to be mitigated by the regulation. Otherwise, the regulation is a burden without a clear benefit. If each type of product is to be included or excluded, the risks associated as the reason for inclusion is not overburdensome to list, so compliance can address that.

Specifying that they should be fitted by a healthcare practitioner is not the same as saying they should be manufactured based on their prescription. In this case, perhaps clarifying that would help too.
eg aligners made by a technician without a prescription from a dentist or orthodontist should not be fitted by an oral health therapist at a facility. Fitting them is within their scope of practice, prescribing them is not.

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 of professionally made appliances under prescription by a registered practitioner are already compliant. The compliance and professional expertise already makes them expensive.

Adding additional compliance requirements will overwhelm smaller operators without an increase in safety. This will increase cost, likely leading to increased use of unregulated products by consumers without professional oversight.

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. :

Temporary crowns (currently usually made chairside, but technology allows CAD/CAM manufacture)
Removable (or fixed) orthodontic appliances - similar rationale and treatment effect to aligners, just different production and placement
Orthodontic Retainers

Exclusion should be based on training, not just job title. For instance, dentists are trained to make some of these items too and may have in house labs. Some practitioners are dual trained or registered. It should be based on scope of training and practice, not title.

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?:

se answers re: exemption

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.:

Materials are already required to be biocompatible and adequate training is required to treat the patient directly.

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.:

From a logistic side, manufacture of a dental crown is different from a filling as it is constructed from a different material, extraorally.

However, placing a filling, intraorally is actually the same thing in a smaller environment with a lower range of materials available due to the limitations of intraoral work. Extraoral work allows the use of more favourable materials, so increasing regulation of that, while accepting the same practitioner can use more limited materials in a more difficult environment is illogical.

The materials available to be used are already regulated for TGA approval. Clear manufacturing standards should exist, but regulation of existing production systems that are designed for intraoral use needs to show a benefit. Already, practitioners are held responsible for their work and required to use appropriate materials. For most CADCAM dentistry, the manufacturer already has guidelines on the correct, safe use of the material. Usually the material is a single product (single block of porcelain, or single resin). The production is around changing the shape to match the patient, not changing its properties to match the patient.

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?:

Certification on a per manufacturer basis should not be required. Certification of a defined process could apply to all manufacturers of that product and manufacturers could self certify that they follow that, or register any deviation from that.

Also, certication of equipment used for manufacture (systems) could be certifed by TGA to cover all users of that machine that manufactures medical devices. I know this i proposed already. It seems illogical to have temporary measures that are ignoring this. It seems the regulation has started before

the regulation is ready.

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 agree with the lack of certification.

However, the devices should not be suitable for a patient to simply be a patient of a healthcare facility, it should be under prescription of the treating provider.
As it is written, if a patient has a regular dentist, a technician associated with that facility could produce a device without prescription. EG a non-orthodontically trained technician can make aligners for a patient, if they are a patient of the practice. This is outside their scope of treatment for diagnosis and prescription. It should be clear that it is only within their scope of practice, or on prescription from someone who has that scope.

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.:

For manufacturing systems (eg CAD/CAM systems) certification of each component of the system. This should allow open systems. Currently if only a start to finish system is allowed, the market variability of different scanner systems, different mills, different furnaces etc, also allowing for upgrades of components as the technology improves.

If the system is start to finish only, few systems will comply and patients/providers will have less choice.

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.:

Devices made without assessment of the patient by a trained practitioner. eg SmileDirectClub makes aligners for patients who have not seen a registered practitioner. Some labs will make occlusal splints or custom mouthguards (which would otherwise be exempt from Class 1 or Class2a)

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.:

Approval of trusted materials, perhaps with manufacturer consultation.
eg Emax CADCAM blocks have been used safely for over a decade. Certifying their use in accordance with manufacture guidance (or similar from competitors) for the construction of devices. Rather than certifying the manufacturing process, it is the end product.

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.:

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