Response ID ANON-3NHQ-DDKB-F

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-14 14:15:41

Introduction

1 What is your name?

Name:
Patrick Gregson

2 What is your work title?

Work title:
Regulatory Affairs Associate

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
3M Australia Pty Ltd

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.:
Manufacturing - Medical devices

7 Are you responding:

On behalf of an organisation

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?:

In principle 3M does agree with the rationale behind the exclusion of certain class I low risk medical devices.

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.:

For certain types of low risk devices, we do believe the risks associated with the proposed products and devices can be adequately managed if they are excluded from regulation by the TGA.

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 comment.

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?:

3M does not agree with the rationale for exempting the proposed list of products from regulation.

In particular, 3M does not agree with the classification of aligners as class I.
Some Aligners have been classified as class I, we believe, for the following reason:
• Classification rule 1.1(b) – the individual aligner is replaced with a new one within 30 days and therefore they are technically for short term use.

3M believes that aligners should be class IIa for the following reasons:
• The full treatment course, which consists of the same material which is in contact within the oral cavity month by month (the aligners are adjusted and replaced), should be taken into account with regards to the risk posed to the patient - and the risk of serious adverse clinical events. Aligners are, from a biocompatibility and risk perspective, for long term use – classification rule 1.1(c).
• They are classed as Device Class II in the by the US FDA and Device class 2 by Health Canada.

3M believes that the classification rules for aligners needs to be addressed by the TGA. If the proposed class I exemptions are put in place, aligners currently classified as class I could be exempted. However, these devices should be considered class IIa and exempting these devices would pose unacceptable safety risks to patients.

Additionally, to amend the regulatory regime such that these devices are exempted from inclusion in the formal register, means Australia would have weaker regulation than in comparable markets, including the USA, Canada and Europe.

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.:

3M does not think all Class I devices should be exempt. The proposed exemptions outlined in this consultation leave the risk assessment and conformity assessment of the proposed devices to clinicians and other third-party bodies. These entities are not appropriately qualified to handle the responsibility as Manufacturer, do not have the technical capabilities nor the expertise to assess the safety, efficacy and conformity of medical devices, and continuously regulate and monitor their use in the Australian market. It is unclear who will oversee the qualification of these entities and ensure they keep it up to date with the design profile of the product. Furthermore, HCPs better serve the patient within their profession as a dentist/clinician rather than as a manufacturer as well.

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 comment.

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?:

3M does not agree with rationale of using alternative conformity assessment procedures. We believe this will lead to an uneven playing field, discrepancies in regulation adherence, confusion and a non-cohesive framework . The TGA should remain the only regulator of these products to ensure patient safety is consistent for these product types.

Additionally, when reading through the new PMD guidelines, 3M does not agree with the exclusion of certain class IIa products that are now considered raw materials used in the manufacture of a medical device. For example, zirconia ceramic blocks and disc products are the critical material in the production of dental crowns and bridges. Currently, these products are included in the ARTG as class IIa devices. This risk classification is due to the possibility of serious patient complications in the event that the crown or bridge fails. The new TGA exclusion criteria propose that these products will be excluded from TGA regulation because they are raw materials instead of medical devices. The TGA has indicated that in the upcoming MDPS regulations, that neither the finished crown or bridge product or the zirconia ceramic material will be regulated by the TGA. Instead the MDPS itself will be regulated

by the TGA, which requires an in-depth oversight of the raw material suppliers.

This would mean that the responsibility for the zirconia materials falls on the MDPS manufacturer rather than the current manufacturer of the zirconia material. This would negate the significant investments made by the current legal manufacturer to ensure the safety and efficacy of zirconia through conformity assessment and it is not clear how the MDPS regulations are going to account for this – how will the safety and efficacy of the zirconia material be ensured without conformity assessment and ARTG inclusion? Suppliers of zirconia, for instance, would not want to disclose confidential technical product information such as specifications and biocompatibility information to MDPS manufacturer.

Lastly, an approach of considering products such as Zirconia ceramic blocks being used to manufacture crowns and bridges to generally become raw materials instead would represent a different approach than the approach just recently confirmed again in the European Union: Per "MDCG 2021-3 Questions and Answers on Custom-Made Devices & Considerations on Adaptable Medical Devices and Patient-Matched Medical Devices - March 2021", products such as Zirconia ceramic blocks can continue to be classified as medical devices by their legal manufacturers, and be placed onto the EU market by them as such.

Whilst the TGA have introduced the concept of an MDPS in the new framework and consultation, there are no specific MDPS questions in this consultation. 3M would like there to be further consultations and responses on this matter.

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.:

3M does not 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. These are complex products which need consistent regulation from an expert authority not a variety of organizations. Introducing a number of different organisations to oversee the regulation will lead to inconsistencies and therefore mixed risks to patient safety.

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. This is because a Class IIa device is a device where the risks associated with the manufacture and use of the device cannot be adequately self-assessed and managed.

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 comment.

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.:

No comment.

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