Response ID ANON-3NHQ-DDSQ-6

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-14 11:39:20

Introduction

1 What is your name?

Name:
[redacted]

2 What is your work title?

Work title:
[redacted]

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.:
Health

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?:

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.:

These are very low risk products and Australian regulatory requirements will remain in place.

Items are supplied within an accredited National Safety and Quality Health Service (NSQHS), and by trained professionals who are already monitored by their professional bodies, and also via systems such as IMS+.

Products are also adapted at point of service for use with patients in accordance with the manufacturers instructions.

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. :

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.:

These very low risk devices are produced within an accredited NSQHS Health Service and by trained and accredited professionals who are regulated by professional bodies. The clinical staff work within their scope of practice and within the confines of our Policies and Procedures. The products are also provided by manufacturers with specific instructions on use for patients. Product production is recorded and any incidents included in IMS+ for investigation.

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.:

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?

Not Answered

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?:

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?

Not Answered

Please explain your response, including by providing examples that illustrate and/or support your position.:

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.:

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.:

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.:

Splints/braces/casts should be excluded from the requirement to register on the ARTG as they are created from products already on the ARTG and adapted at point of service for use with patients according to manufacturers instructions. The regulatory burden for such products would be unreasonable as the devices are created within NSQHS accredited facilities by trained professionals who are already monitored by professional bodies, work within CCLHD/NSW Health Policies and Procedures, and report through IMS+.
It is also requested that a change to the wording on page 12 be attended where it states "By an orthotist or prosthetist who is a full member of the Australian Orthotic and Prosthetic Association" to "By an orthotist or prosthetist who is eligible to be a full member of the Australian Orthotic and

Prosthetic Association". AOPA membership is not mandated in order to be fully qualified and accredited, and practice in [redacted]

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.:
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