Response ID ANON-3NHQ-DDCQ-P

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-08 16:55:47

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.:
Medicine

7 Are you responding:

On behalf of an organisation

Exclusion

8 Do you agree with the rationale for the proposed exclusion of products?

Not Answered

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?

Not Answered

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

None of our devices come under the proposed Excluded criteria

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.:

Our Class 1 patient matched devices are used only within our healthcare facility which is accredited for [redacted] standards. Our devices are designed and made for their purpose by trained Health professionals either registered with [redacted] (Radiation Therapists) or with the Australian professional college (Medical Physicists accredited via [redacted] Note that [redacted] is in the process of registering with APHRA). All Medical procedures are prescribed by Radiation Oncologists who are also accredited and registered with [redacted]

All Radiation Therapists are trained in-house in making the devices (eg patient specific lead shielding and bolus) to Department protocols. The devices are designed in consultation with Medical Physicists to be suitable for purpose (eg shielding or shaping radiation dose). QA of each device is commensurate with the associated risk. Most boluses are included in the patient planning CT scan which allows robust QA of device suitability ie shape, position, density. Daily imaging is also used to verify the bolus position/size. Shielding devices and simple bolus devices undergo QA checks prior to use by accredited Radiation Therapists or Medical Physicists.

All our patient matched devices are only used within the Radiation Oncology Department at the time of Patient Treatment or Planning scans. The devices are placed in position by trained Radiation Therapists and removed at the end of the session. The devices are stored in the department when not in use. Devices are not for sale.

It is my belief, as an [redacted] accredited Medical Physicist, that the Radiation Oncology professional training/accreditation, in-house processes and safety culture across the industry are suitable to manage the risks involved and TGA oversight would not add anything significant wrt the devices in question.

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.:

Our devices are not listed among the examples on page 12 but meet the criteria listed on page 11. All staff involved in prescribing, making or performing QA on devices are professionally trained and accredited medical Professionals. Radiation Therapists and Radiation Oncologists are [redacted] registered. Medical Physicists are not [redacted] registered but the [redacted] college is in the process of organising [redacted] registration for the Medical Physics profession. Medical Physicists are accredited via the [redacted] college following an internationally recognised 4year professional training program and final examination process.

All the examples given are for devices that are fitted to the patient by a medical professional and the client/patient will wear the device outside the clinic. By contrast in Radiation Oncology, the devices are ONLY used within the Radiation Oncology Department, fitted by Radiation Therapists and worn under circumstances where they are under direct supervision of the Radiation Therapist during their planning or therapy session.

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?:

Our devices do not come under this category and I am not familiar with any suitable examples.

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.:

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.:

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