Response ID ANON-3NHQ-DDQV-9

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-06-30 17:54:56

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?

[redacted]

5 What is your company/organisation address?

Please provide the business address of your company or organisation.:

Department of Radiation Oncology, Cancer Care Services,
[redacted]

6 Which industry do you work in, or represent?

Please state the industry that you work in, or are representing in your submission.:
Healthcare

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.:

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. :

Physical impressions of anatomy, as listed in consultation document examples. NOT necessarily medical devices made from these impressions.

Phantoms used for imaging or radiation dosimetry quality assurance testing. Commercially available solutions are listed on the ARTG, but they don't really satisfy 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?

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 quality management standards employed by trained, accredited professionals may not always meet a standard commensurate with the risk posed by the medical device, and the TGA is better placed to assess this for medical devices than professional or registration bodies. The advent of 3D printing has allowed more complex (arguably "riskier") patient-matched devices to be produced at point-of-care with less training than could be achieved in the past. For professionals who have appropriately considered conformity with essential principles and who have developed a QMS commensurate with the risks posed by manufactured devices, I don't believe that the requirements for ARTG listing represent a meaningful additional burden.

In the future, I believe MDPSs will alleviate regulatory burden on point-of-care medical device production (and reduce risk in departments where professionals perceive current requirements as excessively burdensome). I think that manufacturers wanting to explore non-MDPS solutions for patient-matched medical devices should be subject to degree of oversight that exists in current regulatory framework.

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.:

It is unclear what exemption from ARTG means in terms of declarations made to the TGA. Would manufacturers be required to provide notification of manufacturing of exempted patient-matched devices (akin to custom-made device requirements in current framework)? I believe it is important that a notification be made to the TGA, if ARTG listing is made unnecessary. If no notification or registration of a device exists, how would medical devices that have been manufactured without conforming to essential principles be identified by regulators?

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.:

Simple radiotherapy treatment equipment, produced using (old) well-established safe materials, such as wax, jelly, bags of rice and plaster-of-paris.

NOT 3D-printed radiotherapy treatment equipment (e.g. bolus, shielding, brachytherapy applicators), unless health professionals training adequately covers the risks associated with these devices in a way commensurate with risk posed.

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?

Yes

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?

Yes

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.:

Anatomical models (include in consultation document) are appropriate.

Patient matched brachytherapy moulds, applicators and/or templates (e.g. vaginal brachy moulds based on medical images or conventional moulding materials).

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.:

The availability of MDPSs will help with this.

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