Response ID ANON-3NHQ-DDSW-C

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-14 13:53:26

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:
Health Technology Management Unit, East Metropolitan Health Service

5 What is your company/organisation address?

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

Health Technology Management Unit
East Metropolitan Health Service
Royal Perth Hospital
Level 1, North Block
Wellington Street, PERTH, WA, 6000
Box X2213, GPO Perth, WA, 6847

6 Which industry do you work in, or represent?

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

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.:

Yes the risks are adequately managed. The supplier/manufacturer will still have to adhere to the mandatory standards and product safety requirements laid out by the Australian Consumer Law and to report any adverse events when the product is being used as per the intended purpose.

For example: wheelchair trays that are attached to the wheelchair to assist in feeding.

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. :

The TGA has previously consulted on “Products used for and by people with disabilities”:

https://www.tga.gov.au/sites/default/files/consultation-products-used-and-people-disabilities.pdf

Appendix A of that consultation lists products which may be considered for exclusion.

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.:

Yes, the risks can be managed as manufacturers will still have to comply with the essential principles and apply the relevant conformity assessment practices.

For example, Biomedical Engineers who design and oversee the manufacturing of Class I non-sterile, non-measuring patient-matched medical devices carry out the risk assessments as per ISO 14971, AS 3551 within a hospital setting and also complete the relevant essential principles and conformity assessments. This is the process currently used for these devices in our facility under the previous regulations for custom-made medical devices and we have a long and demonstrated history of successfully managing these risks for these devices.

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.:

There needs to be more investigation before exempting Class I non-sterile, non-measuring patient-matched medical devices from registration based on where they are being manufactured, which accredited professional manufactures it and what third party mechanisms of oversight could be used.

For example, it is currently not within the NDISQSC scope of practice to assess a provider’s ability to manufacture medical device as part of their audit and we are unsure if it falls under NSQHS scope of work to assess this.

Also, significant care needs to be taken by TGA when selecting an accrediting body which entitles registered professionals of this body to exemption. For example, choosing Australian Orthotists and Prosthetics Association (AOPA) as an accrediting body appears to raise restraint of trade issues, as there are many qualified and practicing orthotists and prosthetists who are not members of AOPA and may not wish to join this trade association. A Registration body should not require membership of a particular professional association. Both the ACPSEM Register and the National Engineers Register referenced below offer registrations to anyone with suitable qualifications, without requiring membership of APCSEM or Engineers Australia.

Using APHRA accreditation on the other hand would not raise these problems, as it legislated by Federal law and it is not a professional body.

Other suggested criteria that could be included are:

* Manufactured by an Engineer on the National Engineers Register (NER) with the Biomedical Engineering Area of Practise. Note that the nomenclature around Engineering Registration may change as a result of recent State Engineers Registration acts in Victoria and NSW.

* Manufactured by a Medical Physicist on the ACPSEM Register of Qualified Medical Physics Specialists and Radiopharmaceutical Scientists

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.:

Yes, the risks can be managed when manufactured under the circumstanced listed in the consultation paper. These circumstances describe how Class IIa, IIb and III devices, classified as custom-made medical devices under the previous regulations, are currently manufactured in our facility. Our facility (a tertiary hospital) has a National Safety and Quality Health Service (NSQHS) Standards accreditation. Our manufacturing is undertaken by suitably qualified professionals, including biomedical engineers, rehabilitation engineers, orthotists and prosthetists. Additionally, we have an ISO9001 Quality Management System whose scope includes "The design, development, manufacture…of medical equipment and medical devices". For each device type, we address the essential principles and conduct appropriate risk analyses. Under these circumstances, approximately 1500 Class IIa, Class IIb and Class III custom-made medical devices have been safely supplied over a period of 35 years.

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.:

As above, other suggested criteria that could be included are:

Manufactured by an Engineer on the National Engineers Register (NER) with the Biomedical Engineering Area of Practise.

Manufactured by a Medical Physicist on the ACPSEM Register of Qualified Medical Physics Specialists and Radiopharmaceutical Scientists

We further recommend mandating an ISO9001 or ISO13485 Quality Management System (or equivalent) to permit the manufacture of Class IIa or higher devices under this alternative conformity assessment procedure.

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.:

All Class IIa patient-matched devices which can be manufactured under the circumstances described in the paper should be allowed to undergo alternative conformity assessment procedure.

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.:

We strongly recommend extending the alternative conformity assessment procedure to Class IIb and Class III patient-matched medical devices. The manufacturing of these devices, previously regulated under the former regulations for custom-made medical devices, has been conducted safely in our facility for 35 years.

Additionally, provision of Class III patient-matched medical devices routinely occurs in the operating theatre where it is unregulated by the TGA (e.g. surgeons modifying fixation devices on the table beyond their original purpose). This is a common practice in operating theatres around Australia. By allowing alternative conformity assessment procedures for Class III devices such as these, this practice could be brought out of the operating theatre (where it is unregulated) and allow the TGA to become aware of and properly regulate this manufacturing activity. This will most likely lead to better patient outcomes as (for example), the in-theatre device modification could be undertaken prior to surgery by Biomedical Engineers in the hospital using a controlled manufacturing process, reported to the TGA and then supplied as a Class III patient-matched medical device.

Stringent criteria, beyond those required for Class IIa patient-matched medical devices, would be appropriate. For example, for Class III patient-matched medical devices to be eligible for alternative conformity assessment, it may be limited to manufacturing in a National Safety and Quality Health Service (NSQHS) facility AND be conducted by appropriately qualified personnel AND the manufacturing process be controlled by an appropriate Quality Management System.

Failure to have an alternative conformity assessment procedure for Class III patient-matched devices will mean that our facility may have to cease providing these devices to our patients when the transition period ends in 2024. For many of these devices, there is no alternate product on the market and it will result in a lesser standard of care for these patients. The loss of this advanced manufacturing capability in a hospital environment will also lead to a de-skilling of advanced manufacturing and lessen Australia's international competitiveness.

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 but including my 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.:
You may publish all of the answers I provided.

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