Response ID ANON-3NHQ-DDSU-A

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-14 10:36:25

Introduction

1 What is your name?

Name:
Peter Slattery

2 What is your work title?

Work title:
Director, STARS Rehabilitation Engineering (Metro North Hospital and Healthcare Service)

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
Surgical Treatment and Rehabilitation Services Hospital

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.:
Assistive Technology Provision

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.:

Yes, particularly for low risk, relatively high-volume items like spectacles etc, the Australian Consumer laws offer adequate protection

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. :

As per discussion in on of the forums, materials that are used to make medical devices should not be included on the ARTG for at least Class 1 devices. The manufacturer is responsible for assessing the suitability of the materials for the purpose and declaring that in documentation related to their device. ARTG for the materials is a doubling of the regulation.

Devices like exercise bikes are also sold broadly as a consumer product. ARTG registration has been used as a market point by some companies while their devices do not offer any specific therapeutic claim over other consumer models but are priced much higher. This should be discouraged.

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, we agree with this proposal. There are several pre-existing regulatory protections for these services as outlined in the consultation paper. For services liked to public hospitals, there are strong legal requirements to report and manage adverse clinical events; significant general safety and quality governance requirements to comply with the National Safety and Quality standards. They include strong legal requirements for suitable recruitment and monitoring of workforce capability as well as processes for handling of adverse events.

Rehabilitation Engineering in Metro North Hospital and Healthcare Service falls under three difference level of safety and quality governance:
• National safety and Quality Health Services (NSQHS)
• National Disability Insurance Scheme Quality and Safeguards Commission (NDISQSC)
• Board of Professional Engineers Queensland in accordance with the Professional Engineers Act 2002 (Qld)

These governance structures have many aspects that are directly related to aspects required by the Medical Device Regulations including:
• Recruitment of suitably qualified staff
• Ongoing monitoring of mandatory training and CPD requirements
• Risk management frameworks including reporting, investigation, and management of adverse events
A key point of difference in this scenario compared with direct sale of medical devices is that a health service is being provided rather than just a sale transaction. Care is provided as part of a multi-disciplinary care model ensuring that ensures that the devices provided are fit for purpose. There is a chain of care from referral to discharge. This is required by both the NSQHS and the NDISQSC.

Example: - Wheelchair user with newly acquired pressure wound related to seating unable to find a commercial solution who is referred for custom seating by treating health care professional.
• Case triaged on information provided by treating healthcare professional and person themselves.
• All parties involved in assessment
• Process of trial and review until clear that device is meeting need
• Discharge of care back to treating team
• Review available at request
• Repeat prescriptions still assessed by trained professional
Notes on all patient treatment and care are recorded as per the requirements of the NSQHS and the NDISSQSC and are audited for compliance.

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.:

Not at the moment but we are working with Engineers Australia to enhance governance of rehabilitation engineering to assist with service that are provided in the NGO or commercial sector that may not have the governance framework of the hospitals or NDIS.

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?:

Consideration should be given to dealing with osseointegrated prosthetics in two separate parts. The implanted components are of a much higher risk than the components fitted externally to the abutment.

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.:

As per response above, the implanted component of osseointegrated is a much higher risk and the decisions about what to use and how they are implanted are generally directed by surgeons. The components fitted externally are generally managed by prosthetists and these could be covered under the previously mentioned Class I exemption.

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

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

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 Australian consumer laws are relatively strong and well known in Australia. This should be used instead of the MDR's for the low risk and high consumer volume items as has already been mentioned.

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.:
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