Response ID ANON-3NHQ-DDKW-4

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-13 14:20:24

Introduction

1 What is your name?

Name:
Chris McCann

2 What is your work title?

Work title:
Clinical Lead Orthotist/Prosthetist

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
Orthotics/Prosthetics ServicesFlinders & Upper North North

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.:
Orthotics and Prosthetics - Allied 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.:

A minimum of 90% of medical devices used by this health service have already been approved by the TGA and have been purchased through SA Health Purchasing . Before becoming an approved provider. Those few one off products that are not on the approved list are selected by a trained AHP and are fitted and reviewed for effectiveness by the treating clinician. all O/P products that are purchased and fitted or used to manufacture patient matched devices are classed as class 1 low risk devices with the exception of 2 products which are class 11a (electronic prosthetic knee units) which are classed as 11a because they have battery power. All other products are considered to be within the lowest risk class 1 as all are considered non-invasive. Additionally all devices are manufactured and fitted by certified practitioners (AHP's or AHA's). This service already has an adverse reporting system (SLS). We are a registered provider with the NDIS and as such are required to meet all the safety and quality requirements of that organisation. I agree there needs to be some sort of registration faulty parts recall system.

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. :

All products classed as class 1 and are non-invasive .

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.:

The vast majority of products and componentry fitted at this facility have already been
through a TGA approval process instigated by the suppliers and are purchased through SA Health.
Theses patient matched devices should be exempt if they meet the following criteria They should be exempt if:
- When fitted by a trained and certified health practitioner eg AHP, AHA, Nurse.
- the product is provided with adequate wear and care instructions and
if deemed necessary by the treating practitioner, a follow up appointments provided.

-There is a recall system in place in case of fault products

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.:

As above

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.:

Where the Orthotist /Prosthetist and other AHP/ Health practitioner is qualified and trained and certified to meet manufacture and fit and provide follow up on the specific device.

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.:

Not sure we do not fit many class 11a devices.
As per above for the devices we fit

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.:

All class 1 patient matched devices should need to go through TGA before being made available for sale.

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.:
None

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