Response ID ANON-3NHQ-DDG7-Z

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-14 23:33:55

Introduction

1 What is your name?

Name:
[redacted]

2 What is your work title?

Work title:
Pedorthist

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.:
Pedorthics (orthopaedic footwear, orthotics, ankle foot orthotics)

7 Are you responding:

As an individual

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.:

Australian pedorthists only manufacture and supply low risk assistive technology (AT), falling into the TGA Class 1 non-sterile, non-measuring patient matched medical devices. The AT is used/worn on the exterior of the lower limb, and are designed to improve function, mobilisation, and quality of life for the end user.

Pedorthists conduct comprehensive assessments and develop treatment plans, and provide instructions and safety procedures for the patient/user. This also involves keeping clinical records of all patients.

Pedorthists are recognised by and provide services under other health and government bodies, with the NDIS, DVA, EnableNSW, and ACTES being some examples within my own practice.

On page 11 of the "Proposed refinements to the regulation of personalised medical devices", TGA has outlined a potential exemption for Prosthetists and

Orthotists as supplying non-invasive ankle-foot orthotis, orthopaedic shoes, and orthotics. Pedorthists are also qualified to manufacture and supply these devices, and should be classified and made exempt alongside P&Os.

It is important to note that the NDIS registers pedorthists under the custom prosthetics service delivery, with our manufactured devices classed as low risk assistive technology.

The Pedorthic Assocation of Australian and Australian Orthotic and Prosthetic Association developed a joint "Orthotic, Prosthetic, and Pedorthic Services Schedule" endorsed by Private Healthcare Australia.

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.:

In order to become a certified pedorthist, you must undergo training and accreditation, and pass a panel with the Australian Pedorthists Registration Board (APRB). The APRB has annual auditing requirements, with registrants submitting CPD and Case Work logs in order to retain certification. The APRB has complaints policy and processes in place, and disciplinary procedures for pedorthists on their register.

Pedorthists working with the NDIS must register with the NDIS Safety and Quality Safeguards Commission, with 3-yearly verification auditing requirements. The audit includes a minimum criteria for Risk Management procedures that must be met.

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