Response ID ANON-3NHQ-DDKJ-Q

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-14 21:10:51

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:
[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.:
[redacted]

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?:

As the owner of a small business ([redacted] providing foot orthotics to the podiatry profession, exclusion seems the best option. Our orthotics are manufactured in accordance with instructions provided by qualified AHPRA registered practitioners. These products fit the new TGA definition of patient matched under the low risk class 1 classification. The manufacture of foot orthotics requires no formal qualifications. It is a small industry with no standards or governing body. It has always existed under the guidance of biomechanically trained podiatrists.

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.:

Our orthotic device manufacturer is informed by a process of prescription from a qualified podiatrist. The podiatrist prescribes, modifies and dispenses the device. podiatrist prescribed foot orthotics are considered a low risk conservative treatment for biomechanical problems. Any problems that arise with fitting and dispensing these devices is dealt with by the podiatrist in relationship with their patient.
Foot orthotics are are devices that fit into a shoe to assist with foot function. Patients are informed at the time of fitting to stop using the orthotic if pain arises. It is usual for a podiatrist to follow up with a patient 4 to 6 weeks after fitting to check for any issues or modifications required.
In addition, patients using foot orthotics prescribed by AHPRA registered podiatrists are covered under mandatory insurance standard to the industry.
Podiatrists are also university trained , with the application of use of orthotic therapy being part of their biomechanical training.
Podiatrists, like all health professionals are subject to ongoing professional development requirements to maintain registration.

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. :

Scanning systems applied to the of mapping or measuring foot shape for the purposes of manufacturing a prescribed foot orthotic.
These devices represent an insignificant level of risk to both operator and patient during the scanning process for the manufacture of a low risk product.
No performance standard for accuracy or otherwise actually exists within the industry to adequately exclude different brands or models. Products already comply to Australian standards for electrical safety.

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.:

Risk associated with the manufacture of orthoses is managed by the prescribing podiatrist. They are responsible for the prescription, modification and dispensing process.
If an orthotic does not meet the prescription requirements it will not be dispensed to the patient.
See question 9 for clarification.

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.:

Prescription-based foot orthotics prescribed by and dispensed only to AHPRA registered podiatrists should be exempt. This addresses the need for a system that allows control of product safety and suitability as provided under the current system and insurance structure.
Importantly, orthotics are fundamentally simple devices of either shaped rigid plastics or mouldable foams of varying density designed by prescription from the practitioner, not set by the manufacturer. also, the orthoses may be drastically changed by the practitioner to address individual patient needs at the time of fitting or during the life of the product. This processes can include processes such as grinding, re-moulding using heat to change shape, adding wedges and padding and recovering. At this point the end product may vary considerably from its manufactured state.
The manufacturer has no control over modifications done to the product which in turn makes regulation of the product manufacturer questionable as it relates to public safety since the manufacturer cannot be responsible for changes done to the device by third parties.

This current system is also reflected in the liability insurance of manufactures which currently puts the responsibility with the prescribing practitioner for the design of and protection against inappropriate prescription. This has been the status quo for decades within the podiatry profession for the use of orthoses as a treatment modality.
Clarity is required to gauge effect TGA registration of such manufacturers would achieve.

Potentially negative outcomes of TGA registration are;
1. Potential closure of small businesses run by skilled craftsmen due to enforcement of costly ISO certification.

2. Difficulty gaining product liability insurance if the manufacturer is forced to take full responsibility for the product design (even though the manufacturer has no contact with or control of the patient of product once dispensed)

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?

Not Answered

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?:

Not Applicable

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?

Not Answered

Please explain your response, including by providing examples that illustrate and/or support your position.:

Not Aplicable

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 Aplicable

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.:

Not Applicable

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.:

• Exempt TGA registration for products sold from one AHPRA registered podiatrist to another AHPRA registered podiatrist even if they are not of the same business. This will relieve those manufactures with formal qualifications from doubling up on existing regulation.

• A simplified process , making it easier to understand.It seems that ISO certification is simply not needed for such simple products. Many traditional manufacturing techniques are used, including hand shaping and hand grinding.

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