Response ID ANON-3NHQ-DDK8-5

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-13 15:22:38

Introduction

1 What is your name?

Name:
Wendy Rowland

2 What is your work title?

Work title:
Chief Executive Officer

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
Australian Hand Therapy Association

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.:
Hand Therapy

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.:

The products would be fabricated and supplied by an AHPRA registered Occupational Therapist or Physiotherapist, or by a qualified therapy assistant under the direction of an AHPRA registered health professional.

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. :

Commonly available household items/appliances/tools used in a rehabilitation process should remain excluded from registration by the TGA. These represent a very low risk to the patient and can be easily discontinued by the patient should concerns arise.

They are often items that a patient is already familiar with that may be used if cost or availability prohibits access to a medical device specifically to meet the same objective. For example, the use of a household hammer as a strengthening aid when a purpose-built one-sided weight is unavailable, or the use

of a towel to aid upper limb stretches where therapy band or theratube is unavailable.

Risks for these items can be managed via the existing feedback and complaint processes through AHPRA, as well as the ability for patients to lodge concerns directly with the healthcare facility. Where the provider is a NSQHS healthcare facility internal risk management processes would be sufficient to address any reported issues or concerns.

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?:

We agree with the rationale and have answered 'yes' to this question, but wish to make the additional points below:

• the professions linked to the examples of non-invasive orthoses and prostheses needs to be updated to include Occupational Therapist/Physiotherapists

• the final provider of the device may be directly overseen by an AHPRA registered health professional - there may be instances where a therapy assistant (non-APHRA registered), under the guidance of a registered professional, physically fits or provides a device.

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.:

Hand therapy practitioners in Australia are AHPRA registered Occupational Therapists and Physiotherapists ensuring a minimum standard of education, continuing professional development and regulatory mechanisms are in place to provide assurance and protection for the public. Significant on-the-job training and professional supervision are the norm in this specialty area of practice, with the Australian Hand Therapy Association offering opportunities for further skill development and recognition of advanced skills, knowledge and experience.

The most common patient issues related to splint/orthosis/garment provision include skin irritation, oedema, general discomfort and/or altered sensation which are temporary and generally fully resolve once addressed. These short-term symptoms that can be resolved successfully by the therapist through adjustments to the splint/orthosis/garment. Adhering with the TGA Essential Principles and requirements for instructions for use to be provided with splints/orthoses/garments the patient will be advised of the potential for these minor complications and to contact the therapist/clinic should concerns arise. This provides a feedback mechanism for patients to have common issues addressed and resolved at a clinic or facility level. Improved technology, such as telehealth and email allow patients to send photographs directly to the clinic if concerns arise, and aids consumer feedback, allowing potential issues to recognised and addressed quickly.

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.:

The general scope of practice for Occupational Therapists and Physiotherapists specialising in hand therapy in Australia includes the fabrication of custom-made upper limb splints/orthoses/garments using materials that include, but are not limited to, Lycra, neoprene, thermoplastic and Velcro. Hand therapy practitioners may be specifically requested to fabricate splints/orthosis/garments beyond the upper limb (for example foot/lower limb) using splint/orthosis/garment fabrication principles. Other examples may include oedema or scar management of other body parts, where there is no other appropriately trained health professional available. These requests are generally from a referring surgeon in circumstances where standard pre-fabricated devices are unsuitable or insufficient. The same common issues and risk mitigation strategies used for upper limb splints/orthoses/garments apply to those items fabricated by hand therapy practitioners for the lower limb.

Of note, the current proposed exemptions lists Orthotists and Prosthetists as professions linked to non-invasive orthoses and prostheses including hand splints (with or without outrigger) and ankle-foot orthosis. This section should also include Occupational Therapists and Physiotherapists based on the rationale within this submission.

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?:

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.:

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.:

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.:

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.:

It is a requirement for Occupational Therapists and Physiotherapists to document the provision of a device to a patient. Therefore, if there were any specific concerns that individual's details could be easily identified and collected without consulting an additional log recording each patient matched device provided to every patient attending the clinic.

If additional record keeping is required, consider decreasing the requirements for exempt patient-matched devices (for example those fabricated by hand therapy practitioners) to recording those for whom an issue/complication arises (eg skin or nerve irritation) that does not fully resolve after a defined period (for example 7 days). This will decrease the record keeping requirement which currently appears to require every patient-matched splint/orthosis/garment provided to a patient be recorded. One therapist could potentially fabricate 10 or more patient-matched devices each day (more than 2,000 devices per year). As most patients do not experience any issues with their splint/orthosis/ garment this is a significant decrease in regulatory burden that will have no impact on patient health and safety.

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.:

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