APA submission to proposed refinements to the regulation of personalised medical devices

(Template of online survey used on the submission)

Introduction

1 What is your name?

Name:
Dan Miles

2 What is your work title?

Work title:
Deputy General Manager – Policy and Government Relations

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
Australian Physiotherapy 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.
Physiotherapy

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 Physiotherapist.

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 amedical device. :

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

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 toaddress 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 whenproduced 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 listedin 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:

Physiotherapists in Australia are AHPRA registered 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 Physiotherapy Association offering opportunities for further skill development and recognition of advanced skills, knowledge and experience.

Some of 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 physiotherapist through adjustments to the splint/orthosis/garment. This would occur as part of their scope of practice as is highlighted through the safety and quality mechanisms that already exist for AHPRA registered healthcare providers.

13 Are there further circumstances where Class I non-sterile, non-measuring patient-matched devices could be exempt? If so, what measuresare 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 thatthe risks associated with the manufacture of the devices have been managed and the Australian regulatory requirements for medical devices have beenmet before they are supplied:

The scope of practice for Physiotherapists in Australia includes the fabrication of custom-made upper and lower limb splints/orthoses/garments using materials that include, but are not limited to, Lycra, neoprene, thermoplastic and Velcro.

Alternative conformity assessment procedures

14 Do you agree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched medicaldevices 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 assessmentprocedures 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 listedin 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 beappropriate?

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 compromisingpatient 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 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 handtherapy 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 personsoverseas, 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