Response ID ANON-3NHQ-DDSD-S

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-14 13:47:45

Introduction

1 What is your name?

Name:
Natasha Korbut

2 What is your work title?

Work title:
Advocacy and Policy Officer

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
The Australian Orthotic Prosthetic 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.:
orthotics/prosthetics

7 Are you responding:

On behalf of an organisation

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?:

Yes, AOPA agree with the rationale for the proposed exemption ruling for Class 1 patient-matched orthoses and prostheses.

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 risks posed by Class 1 patient-matched orthoses and prostheses can be adequately managed if they are exempted from inclusion in the ARTG. We provide an explanation for this response, including illustrative examples relating to the risk profile of the medical devices and existing regulatory mechanisms.

Class 1 patient-matched orthoses and prostheses are medical devices that pose extremely low risk to consumer safety. They are manufactured by trained and certified professionals, and also receive regulatory oversight by numerous other third-parties. This additional regulatory oversight reduces the residual risk of these low risk medical devices and therefore demonstrates adequate risk management if exempted from inclusion in the ARTG.

Low-risk medical devices

All patient-matched orthoses and prostheses that are prescribed, designed, manufactured and fitted to the consumer by trained and certified orthotist/prosthetists are Class 1 medical devices. Class 1 medical devices are defined by the TGA as low-risk. AOPA believe that this low-risk classification is entirely appropriate for patient-matched orthoses and prostheses given that to our knowledge there have been:
• No breaches of the TGA Essential Principles,
• No breaches of TGA conformity assessment procedures, and
• No ombudsman complaints at the state/territory level

AOPA also functions as the complaint processing body for the orthotic/prosthetic profession. When reviewing our complaint history over the past five years, we also note that only one complaint in relation to orthosis/prosthesis manufacture for a Class 1 patient-matched device, has been made.

The lack of TGA breaches and low number of complaints exemplify that risk related to the manufacture of Class 1 patient-matched orthoses and prostheses, is extremely low.
Patient-matched orthoses and prostheses are manufactured by trained and certified professionals.

Appropriately trained and certified orthotist/prosthetists oversee all stages of device manufacture and supply of Class 1 patient-matched orthoses and prostheses. Each stage provides an opportunity for the orthotist/prosthetist to ensure the device meets the consumer's needs, is safely manufactured, and minimises risk to the consumer.
AOPA is a Full member of the National Alliance of Self-Regulating Health Professions (NASRHP), and therefore, AOPA-certified orthotist/prosthetists meet the same standards to practice as other allied health professionals including speech pathologists, audiologists, occupational therapists, podiatrists and physiotherapists, as examples. A breach in any standard or code may result in the complaints procedure being activated and loss of certification.

By way of summary, the standards required to practice include:
• The Minimum Tertiary Standards to practice in Australia, including an AQF level 7-equivalent qualification,
• Entry-Level Competency Standards,
• Personal scope of practice,
• Ethical Principles and Code of Professional Conduct,
• Continuing Professional Development,
• Recency of Practice.

Given that appropriately trained and certified orthotist/prosthetists oversee the prescription, manufacture and supply of Class 1A patient-matched orthoses and prostheses, the risk associated with these devices is very low.

Third-party regulations result in a low residual risk.

In addition to the low risk profile and practitioner certification requirements, there are a number of existing third-party regulations that result in very low residual risk for Class 1A patient-matched orthoses and prostheses. While these medical devices pose low risk to consumers, AOPA acknowledge that an exemption to inclusion on the ARTG will leave a small remaining risk. AOPA believe that existing third-party regulations governing device manufacture, practitioner certification and consumer rights, more than adequately mitigate this remaining risk, particularly when complemented by the TGA exemption requirements (i.e., meeting the Essential Principles).

Existing third-party regulations and the TGA exemption requirements are captured in the table in our pdf submission. Note that each regulation captures different aspects of device manufacture and supply. Together, these regulations provide cohesive risk mitigation for patient-matched Class 1A orthoses and prostheses, resulting in a very low residual risk and making these devices suitable for exemption from inclusion on the ARTG.

Unnecessary burden if exemption is denied

Without the proposed exemption AOPA expect the administrative and financial burden of compliance with medical device regulations to be excessive.

Beyond the considerable administrative time cost, the financial cost of compliance with the proposed regulation is extremely prohibitive for small private practices.

Manufacturers must pay to register each Class 1A patient-matched orthosis or prosthesis on the ARTG and pay an annual maintenance fee thereafter. The average orthotic or prosthetic practice will need to register between 6 and 12 devices, which will cost an estimated $3,300 to $6,600 upfront and $540 to $1,080 annually. We anticipate the total first year cost to the industry to be in excess of $900,000 in fees alone, for a profession of less than 600 practitioners. This is an unnecessary financial burden given the risk profile and existing risk mitigation strategies and regulations for Class 1A orthoses and prostheses.

Excessive regulatory costs will reduce access to orthotic/prosthetic services for Australian consumers through:
• Increased costs for orthotic/prosthetic service,
• Practitioners offering fewer types of orthotic and prosthetic services (and thereby avoid ARTG listings),
• Financial and administrative requirements acting as a barrier to new orthotic/prosthetic practitioners entering the market.

This is a significant concern for our small workforce, given our low orthotist/prosthetist practitioner prevalence (i.e., number of practitioners per 100 000 population) and low number of service providers (i.e., estimated number of 150) particularly in non-metropolitan areas.

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.:

AOPA appreciates the medical device industry is large and diverse. AOPA recognise the scope of each allied health professional to be different, although overlap between professions is expected. It is vital for the TGA to engage with each peak-body individually to obtain a clear understanding of the regulatory oversight provided by each peak body, and the scope of practice for each profession.

We therefore defer to the expertise of other professional bodies, regarding medical devices manufactured and supplied by the relevant professionals, including but not limited to:
• Australian Podiatry Association,
• Occupational Therapy Australia,
• Speech Pathology Australia,
• Audiology Australia,
• Australian Pedorthic Association,
• Australian Physiotherapy Association,
• Osteopathy Australia.

We expect the majority of these peak bodies to have a similar regulatory oversight to AOPA, and their certified practitioners would be subject to similar standards and codes as seen in Table 1 in our pdf submission.

We note on page 12 of the consultation paper that Osteopaths have been listed to manufacture plagiocephaly helmets. AOPA raises this listing as an error and advises the TGA to seek consultation with Osteopathy Australia, given our recent advice that osteopaths do not manufacture plagiocephaly helmets.

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?:

The proposed alternative conformity assessment procedures relate to Class 2A medical devices. AOPA are not aware of any patient-matched medical devices in this category, that are manufactured by orthotist/prosthetists.

AOPA would like to provide some clarification regarding the statement on page 13 of the consultation paper:
“Examples of Class 2A patient-matched devices include: orthoses that are intended to penetrate the skin and be anchored within the body”

AOPA is not aware of any patient-matched medical devices manufactured by orthotist/prosthetists that meet the above description.

Almost all patient-matched medical devices manufactured by orthotist/prosthetist are classified Class 1A. To our knowledge, there is currently one exception: the Halo-thoracic orthosis. Halo-thoracic orthoses are devices that immobilize the spine after significant trauma. The device comprises of a ring (or halo) that is attached to the skull via four pins. The halo is then connected to a vest via metal struts. Halo-thoracic orthoses penetrate the skin of the head and are anchored within the body - however, they are Class 2B adaptable medical devices.

Class 2A orthoses that penetrate the skin are worn for 30 days or less. Class 2B orthoses, including Halo-thoracic orthoses, are worn for 6-12 weeks. The classification of Halos was clarified directly with TGA representatives.

Therefore, the proposed conformity assessment procedures should not extend to any devices manufactured by certified orthotist/prosthetists.

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.:

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