Response ID ANON-3NHQ-DDKK-R

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-13 08:23:17

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:
Directors of Physiotherapy Services QLD, QLD Health.

5 What is your company/organisation address?

Please provide the business address of your company or organisation.:

QEII Jubilee Hospital, Brisbane, QLD

6 Which industry do you work in, or represent?

Please state the industry that you work in, or are representing in your submission.:
Public Physiotherapy, Allied Health

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?:

Devices utilised by public Physiotherapists do not fall under the ‘excluded’ category therefore no impact on Physiotherapy for this category.

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.:

Devices utilised by public Physiotherapists do not fall under the ‘excluded’ category therefore no impact on public Physiotherapy for this category.

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. :

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, if Physiotherapy is added as a profession rather than the current list of just orthotists & prosthetics then exemptions for devices manufactured as per the points below will encompass the devices utilised by public Physiotherapists and avoid duplication of regulation.

- Within a healthcare facility accredited against the National Safety and Quality Health Service (NSQHS) Standards by a body recognised by the Australian Commission on Safety and Quality in Health Care (ASCQHC).

 - By a health professional registered with the Australian Health Practitioner Regulation Agency (AHPRA) under the Health Practitioner Regulation National Law Act 2009, and whose scope of practice encompasses production of the patient-matched medical devices that they are producing; and
The devices they produce are intended to be used by a patient of the healthcare facility, registered provider or AHPRA-registered health professional.

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.:

Yes, the following mechanisms allow for adequate monitoring and reporting of manufacturers in this field and ensure that class I non-sterile, non-measuring patient-matched medical devices can be adequately managed should they be exempt from inclusion.
1. AHPRA registration: all Practicing QLD Health Physiotherapists must be AHPRA registered and as such have oversight of minimum standard of education, continuing professional development and regulating standards.
2. QLD health employees work within the NSQHS standards as an accredited organisation and Queensland Health is regularly audited according to these standards.
3. QLD health employees work within a supervision framework that enables professional and clinical support appropriate to level of expertise.
4. RiskMan reporting is available across QHealth sites and provides a single state-wide integrated information system to collect, integrate, manage and report clinical incidents, workplace incidents, consumer feedback and risk.
5. Policies, Procedures and Work Unit Guidelines exist across QHealth Physiotherapy Departments to ensure safe and consistent clinical practice.
6. Onsite competency training and supervision.
7. QHealth mentorship and support through following state-wide groups i.e. Queensland Hand therapy Network (QHTN), and the State-wide Lymphoedema Network.

Patient risk from the suggested examples of exempt medical devices that Physiotherapy manufacture i.e.
• Hand splints (with or without outrigger)
• Shoulder orthosis
• Ankle-foot orthosis
• Orthopaedic shoes
• Orthotics
Most commonly relate to skin issues ie skin irritation, minor pressure areas, general discomfort, localised oedema and/or altered sensation and are generally temporary in nature.
These risks are outlined in instruction handouts provided at point of care and patients/carer are encouraged to contact their therapist immediately if they occur for adjustment and further prevention.
RiskMans are completed for actual and “near miss” incidents.

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.:

Yes

All splinting of the body (non-invasive) abides by the same principles outlined above and as such, these should also be exempt. I.e. knee splinting to protect muscle flap, neck splinting for burns contracture prevention etc.

Scar management can be a significant area of practice for Physiotherapists and as part of this, a combination on ARTG manufactured devices e.g. cica care silicone and Ottoform are used along with patient-matched splinting, massage and interim compression devices to secure in place and provide external pressure to physiologically change the scar process. As Physiotherapists, we are trained in tissue healing and management and principles of oedema management and compression. We attain the splinting and compression skill development in our training and again in on the job training and attendance at special interest groups, conference and workshops and membership of national bodies. Where able, devices registered on the ARTG are utilised in this space however where not available or the patient needs are not standard, devices are manufactured.
As above, main risks reported are skin irritation, minor pressure areas or oedema. These are registered on RiskMan and Patient information is provided at point of care on monitoring for these issues.

Compression management

Whilst we rely on external agencies to manufacture high grade compression that is listed on the ARTG, patients often require interim garments, pressure inserts or low-level compression over wound dressings and for initial wound, scar and oedema management. These are manufactured according to core oedema management principles taught at university and a combination of on the job training, workplace competencies, courses and conferences.
As these provide low level compression, risk is low and reported via RiskMan. Patient information is provided at point of care to monitor for these issues.

Positioning Devices
Similarly to splinting, Physiotherapists use splinting and foam etc to provide optimal positioning to help align posture and prevent pressure/pain to areas i.e. foot drop splints for the lower limb to prevent shortening of the achilles tendon. The same principles apply to splinting and pressure care and Patient information is provided at point of care and any risks reported.
Please note this is just a summary of the areas in which Physiotherapists work and manufacture. Our profession and training provide us with the clinical reasoning to help people with different needs adapt to standard environments and our work may involve modifying standard pieces of equipment to allow access and use. All the examples of items we manufacture have been deemed class I low risk and with the outlined risk management strategies in place are well regulated.
- The risk of patient harm associated with lack of regulation versus the loss of professional artistry and patient access to customised care needs to be considered.

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?

Yes

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?:

There are not any Physiotherapy devices used in the public service that are considered Class IIa.

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, without my name but including my 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