Response ID ANON-3NHQ-DDGA-A

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-14 21:05:17

Introduction

1 What is your name?

Name:
Ian Starkey

2 What is your work title?

Work title:
Chair – NSW Physiotherapy Advisory Network & Physiotherapy Head of Department Blacktown & Mt Druitt Hospitals

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
NSW Physiotherapy Advisory Network & WSLHD

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 – NSW Physiotherapy Advisory Network

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.:

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. :

Physiotherapists working in public health facilities across NSW are regularly involved in the production of upper limb and lower limb casts and splints/orthoses for the management of a wide range of diagnoses and conditions. For example, the majority of NSW Public Health facilities employ Physiotherapists who produce multiple casts and splints/orthoses daily as part of their patient management. These casts and splints/orthoses are “one-off” devices, made for individual patients using adaptable products that are already included on the ARTG (where required). Following thorough assessment by trained, accredited and registered Physiotherapists these casts and splints/orthoses are adapted to patients’ specific needs at the point of care, for the sole use of the individual patient.

These casts and splints/orthoses are created from padding materials, casting/plastering tapes/bandages (including Plaster of Paris and synthetic casting tapes) thermoplastic, fixing straps (usually Velcro), and other splinting materials which are all mass-produced materials intended to be assembled,

adapted or modified according to the manufacturer's instructions. These materials are used as intended by the manufacturer, to address anatomical, physiological or pathological features of a particular patient. The suppliers of such materials have already registered the materials for inclusion in the ARTG where they meet the criteria for registration.

We therefore propose that Physiotherapists are not involved in manufacturing per se. Casts and splints/orthoses produced using these materials are adaptable medical devices and do not need to be registered for inclusion in the ARTG as patient-matched medical devices. If this is not supported please see further submissions under the proposed exemptions section.

Physiotherapists are health professionals registered with the Australian Health Practitioners Regulation Agency (AHPRA) under the Health Practitioner Regulation National Law Act 2009. The production of casts and splints/orthoses is within the scope of practice of Physiotherapists. Competency assessment and continuing professional development related to this scope of practice is expected through Health Facility Physiotherapy Departments, cross boundary clinical networks and the Australian Hand Therapy Association. NSW healthcare facilities are accredited against the National Safety and Quality Health Service (NSQHS) Standards by bodies recognised by the Australian Commission on Safety and Quality in Health Care (ASCQHC).

Casts and splints/orthoses are provided as part of a comprehensive treatment program and are reviewed and reassessed throughout the course of treatment at follow-up appointments. Patients are provided with instruction on how to care for and manage the device according to their needs, including advice on avoiding adverse outcomes and appropriate action in the event of an adverse outcome. Physiotherapists are trained to understand patient pathology (such as physical, neurological or cognitive factors) which may increase their risk of an adverse response to cast splint/orthosis application. Any adverse events such as infrequently occurring skin irritation and pressure areas, are addressed by the Physiotherapist by adapting the device or by changing the management approach. Adverse event are documented in the patient medical record, reported according to the NSW Health Incident Management Policy Directive 2020_047 in the NSW Health Incident Management System (IMS+) and overseen by NSW Local Health District Patient Safety Teams.

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.:

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.:

Casts and Splints/Orthoses:
The current proposed refinements paper does not include Physiotherapists and their role in producing splints/orthoses. Splints/orthoses produced by Physiotherapists should be included in the exemptions (if not considered for exclusion based on the above rationale).

Also, the proposed refinements paper does not specifically mention casts which are also currently widely produced/applied by Physiotherapists across NSW. Casts applied by Physiotherapists should also be included in the exemptions (if not considered for exclusion based on the above rationale).

Physiotherapists working in public health facilities across NSW are regularly involved in the production of upper limb and lower limb casts and splints/orthoses for the management of a wide range of diagnoses and conditions. For example, the majority of NSW Public Health facilities employ physiotherapists who produce multiple casts and/or orthoses daily as part of their patient management. These casts and orthoses are "one-off" devices, manufactured for individual patients, according to their specific disease, disorder or disability requirements, by trained, accredited and registered health professionals, following thorough assessment and diagnosis, for the sole use of the individual patient.

These casts and orthoses are created from materials which are all mass-produced and intended to be assembled, adapted or otherwise modified according to the manufacturer's instructions. These materials are used as intended by the manufacturer, to address either or both of the anatomical & physiological features of a particular individual or address a pathological condition of an individual.

Physiotherapists are health professionals registered with the Australian Health Practitioners Regulation Agency (AHPRA) under the Health Practitioner Regulation National Law Act 2009. The production of casts and splints is within the scope of practice of physiotherapists. Competency assessment and continuing professional development related to this scope of practice is available through Health Facility Physiotherapy Departments, cross boundary clinical networks and the Australian Hand Therapy Association. NSW healthcare facilities are accredited against the National Safety and Quality Health Service (NSQHS) Standards by bodies recognised by the Australian Commission on Safety and Quality in Health Care (ASCQHC).

Casts and orthoses are almost always provided as part of a more comprehensive treatment program and are reviewed and reassessed throughout the course of treatment at follow-up appointments. Patients are provided with instruction on how to care for and manage the device catered to individual circumstances, including advice on avoiding adverse outcomes and appropriate action in the event of an adverse outcome. Physiotherapists are trained to understand patient pathology which may increase the risk of an adverse response to cast and splint application (such as physical, neurological or cognitive factors). Any adverse events (infrequently occurring skin irritation and pressure areas, being the most usual) are addressed through adaptation or change in management approach, are documented in the patient medical record and reported via the IMS+ incident management system overseen by Clinical Governance Units at respective Districts/Networks.

Therapist made Positive Expiratory Pressure (PEP) devices:
Another group of devices what are produced by physiotherapists working in NSW public health facilities are Positive Expiratory Pressure (PEP) devices, including therapist-made Bubble-PEP and PEP constructed from TGA approved componentry. PEP is a commonly used approach to assist patients with chronic respiratory to improve secretion clearance and improve lung ventilation.

The therapist-made bubble-PEP device is constructed from inexpensive and easily attainable materials such as a clean container/bottle filled with water, with a tube inserted into the bottle 1-3. The resistance caused by blowing through the tube into the water generates positive pressure and oscillations in the airways of the lungs2-4 which assists with 1) improving secretion/airway clearance (in patients who have respiratory impairments due to excess secretions and/or difficult clearing secretions) 5, 6, and 2) improving lung ventilation (in patients who have respiratory impairments after surgery) 6, 7. The therapist-made bubble-PEP device is prescribed, constructed and provided on an individual basis when a clinical need for the device is indicated (i.e. to improve secretion clearance and/or ventilation), and after a risk assessment has been performed by the treating physiotherapist. Only patients assessed as safe and appropriate would be provided and taught how to use the therapist-made bubble-PEP device as part of a respiratory physiotherapy program to treat their respiratory impairments. The therapist-made bubble-PEP device is for short-term use under the supervision and guidance of a physiotherapist, and the device is cleaned following infection control guidelines.

An additional PEP option that is utilised within the Acute Physiotherapy workforce are devices created from TGA approved componentry - predominantly ventilator circuit components. The benefit of this form of PEP is it enables appropriate PEP device resistors to be utilised with cheaper mouthpiece connections already supplied in hospitals for short term use with patients. Formal PEP systems are single patient use only and often the cost is prohibitive for some of our population to purchase as a trial. The assembled PEP units allow Physiotherapists to trial PEP therapy with patients to assess efficacy prior to the patient investing in a longer-term PEP therapy system. This type of device also allows expiratory pressures to be measured in line with evidence based recommendations. As stated in Physiotherapy for Cystic Fibrosis in Australia: A Consensus Statement, endorsed by the Thoracic Society of Australia and New Zealand8, PEP therapy consists of pressures maintained within the range 10-20cmH2O. These assembled PEP devices allow the pressures to be safely monitored with a manometer, ensuring evidence based, safe treatments for our sputum producing population. All treatments are provided by university trained and AHPRA registered professionals within their scope of practice. As above, these PEP devices are prescribed, constructed and provided on an individual basis when a clinical need for the device is indicated (i.e. to improve secretion clearance and/or ventilation), and after a risk assessment has been performed by the treating physiotherapist. Infection control and patient supervision and education are as stated above for the Bubble PEP.

Similar to the case for casts and splints, there are multiple levels of governance in place to safeguard patient safety. Physiotherapists are registered with AHPRA and prescription of PEP devices as a therapy falls within the scope of practice for physiotherapists. Also, professional development and competency assessments related to this skill set are available through physiotherapy departments and clinical networks. The PEP devices are prescribed in facilities accredited against the NSQHS standards and physiotherapists supervise the use of PEP devices in these facilities as part of a respiratory physiotherapy program, therefore allowing opportunity to reassess risk should the patient's condition change. We acknowledge that there are commercial PEP and Bubble-PEP devices available on the market that are TGA approved, however, these devices may not be easily available or accessible1,6, especially in remote or regional areas. As described above the therapist made alternatives provide an excellent, evidenced based alternative to trial such devices with patients prior to investment in a commercial device by either the patient or the health service.

References:
1Santos MD, Milross MA, Alison JA (2016) Therapist-made bubble-positive expiratory pressure: a survey of physiotherapists in Australia. Cardiopulmonary Physical Therapy Journal; 27: 3-10.

2Santos MD, Milross MA, Eisenhuth JP, Alison JA (2018) Tubing internal diameter affects the pressures and oscillation frequencies generated by the therapist-made bubble-positive expiratory pressure device. Physiotherapy Theory and Practice; DOI: 10.1080/09593985.2018.1485067.

3Santos MD, Milross MA, Eisenhuth JP, Alison JA (2017) Pressure and oscillation frequencies generated by bubble-positive expiratory pressure devices. Respiratory Care; doi: 10.4187/respcare.05164.

4Sehlin M, Ohberg F, Johansson G, Winso O (2007) Physiological responses to positive expiratory pressure breathing: a comparison of the PEP bottle and the PEP mask. Respiratory Care 52(8): 1000-5.

5Santos MD, Milross MA, McKenzie D, Alison JA (2020) Bubble-positive expiratory pressure device and sputum clearance in bronchiectasis: a randomised cross-over study. Physiotherapy Research International; doi: 10.1002/pri.1836.

6Liverani B, Nava S, Polastri M (2019) An integrative review on the positive expiratory pressure (PEP)-bottle therapy for patients with pulmonary diseases. Physiotherapy Research International; https://doi.org/10.1002/pri.1823.

7Westerdahl E, Lindmark B, Eriksson T, Friberg O, Hedenstierna G, Tenling A (2005) Deep-breathing exercises reduce atelectasis and improve pulmonary function after coronary artery bypass surgery. Chest 128: 3482-88.

8The Thoracic Society of Australia and New Zealand (2015) Physiotherapy for Cystic Fibrosis in Australia: A Consensus Statement. Available from

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.:

As above for Class I non-sterile, non-measuring

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