Response ID ANON-3NHQ-DDS7-C

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-14 10:55:14

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:
[redacted]

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

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?:

In general yes, although we would like the TGA to consider extending this provision to allow for certain medical high priority situations to be excluded as set out below in question 3.

9 Are the risks posed by the products adequately managed if they are excluded from regulation by the TGA?

Not Answered

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. :

We propose that the principle of exclusion might be extended to apply to situations in which a unique custom-made medical device is a medical-requirement-at-short-notice for patients in hospital either to address an urgent medical condition or to facilitate a patient's discharge from hospital. We feel this exclusion would apply to non-standard devices (custom-made) if a suitably qualified person manufactures the device within their

scope of practice, the device has been requested by a health professional and the outcome assessed by a health professional.

The idea behind this consideration is to allow health professionals to respond to high priority medical needs without delay or burden associated with TGA compliance concerns.

We provide explanation by way of a recent example:

A patient has tetraplegia from a historical spinal cord injury. Due to the high level damage to the spinal cord the patient uses a mechanical ventilator with a trachea tube to breath as part of his daily life. The patient was admitted to an acute spinal ward to address a variety of medical issues. The medical team discover an air leak where the ventilator tube enters the patient's neck. This means the ventilator is not working efficiently also the sound of the air leak causes the patient distress. A medical specialist decides that surgical correction is not a preferred option; nurses apply special dressings to reduce the air leak without complete success. The medical team calls upon a qualified Orthotist to help. The Orthotist manufactures a silicon disc that goes around the ventilation tube and over the dressing. This device applies a gentle pressure on the dressing to reduce an air leaks allowing the patient to breathe comfortably.
The effectiveness and safety of the device is monitored by a team of health professionals (orthotist, nurse, medical specialist). Once this is proven to the satisfaction of the patient and the team the patient is one step closer to discharge from hospital.
The silicon disc is a low risk, non-invasive device manufactured by a qualified health professional in a hospital setting.
Because the device is required at short notice the health professional does not have time to complete an audit of its design against all the TGA essential principles such as standards of manufacture, ISO standards, risk analyses, material testing or other evidence. There may not be enough time to develop a complete set of instructions to supply with the device.
Because of this situation the health professional cannot supply a compliance statement with the custom-made medical device because he or she is not in a position to prove compliance with the regulatory framework at the time of provision.
This example illustrates how an orthotist or other health professional may be called upon to create a high priority medical device at short notice for the benefit of patients in hospital. While this example is a simple device, anything might be asked for in a hospital setting at some point in the future. It is not possible to predict in advance the requirement or the complexity.
We feel this kind of situation should not be encumbered with TGA regulatory constraints associated with providing a custom-made medical device because such considerations may hamper or discourage the efforts of the medical team to respond to high priority needs.

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?:

In principle yes we agree, however, point 1 'the device is manufactured by a trained, accredited professional', may better read as: '1. the device is manufactured by an accredited professional who is trained to manufacture that kind of device and the device is within their scope of professional practice.'

We note the examples provided for Orthotists appear to be limited to upper limb and below the knee. We don't know if this is intentional to suggest that only some types of orthoses are exempt. To clarify, Orthotists provide a broad range of external medical devices encompassing most of the body including AFOs, KAFOs, helmets and spinal braces. We would submit that, provided appropriate local quality controls are in place, all might be exempt.

We note there are no examples for the prosthetist included for external devices such as prosthetic limbs, this may have been an oversight.

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.:

In principle we agree with the proposed management of risks. For example public healthcare facilities have robust clinical governance procedures in place and they employ recognised health professionals.

We agree with the inclusion of orthotist or prosthetist who is a full member of the Australian Orthotic Prosthetic Association (AOPA); our profession is specifically skilled in the manufacture of medical devices. Members of AOPA are already required to comply with AOPA competency standards and continued professional development.

Eligibility for full membership of AOPA is a common employment requirement but actual membership is not compulsory. In the case where a facility employs a suitably qualified orthotist/prosthetist but does not employ a member of AOPA then the TGA may require the facility to adopt compliance to standards similar to AOPA in order to qualify for the exemption.

We agree in principle with NDIS registered providers so long as the registration requirements provide sufficient oversight, standards of practice and providers work within their training and professional scope of practice.

We agree in general terms with recognising AHPRA providers but have concerns as follows:

Some but not all AHPRA practitioners are trained in medical device manufacturing as a core element of their professional qualification. Additionally, those professions who are trained to manufacture devices have a limited scope. For example, exclusions should include:

• Orthotists providing orthotic devices
• Prosthetists providing prosthetic devices
• Orthoptists providing corrective eyewear
• Dental prosthetists supplying dental prostheses etc

In summary we believe the exemptions from inclusion in the ARTG should only apply in cases where the health professional manufactures a medical device within the scope of their professional training to manufacture such a device.

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.:

• Class I non-sterile, non-measuring patient-matched devices may also be manufactured by a technician who has been trained and or supervised within a health care facility by a qualified Orthotist or Prosthetist.

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?:

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?

Yes

Please explain your response, including by providing examples that illustrate and/or support your position.:

we would raise the same concerns that we have raised for class I devices as detailed in our answer to question 5; that health professions need to be specifically trained in the manufacture of the kind medical device and operating within scope of professional practice.

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.:

See response to q.5 specifically:

For example, exclusions should include:

• Orthotists providing orthotic devices
• Prosthetists providing prosthetic devices
• Orthoptists providing corrective eyewear
• Dental prosthetists supplying dental prostheses etc

In summary we believe the exemptions from inclusion in the ARTG should only apply in cases where the health professional manufactures a medical

device within the scope of their professional training to manufacture such a device.

Manufacturers/ providers who fall outside of specifically regulated professions for provision of that device as part of their profession should be required to comply with the requirements of the TGA and demonstrate adherence to the essential principles.

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 or my organisation's name (anonymously)

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.:
I would like to clarify I am submitting this response on behalf of [redacted], not on behalf of those organisations and not individually

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