Response ID ANON-3NHQ-DDGS-V

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-14 16:34:03

Introduction

1 What is your name?

Name:
Alanna Grover

2 What is your work title?

Work title:
Advanced Clinical Lead Physiotherapist

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
RSS: Allied Health, on behalf of RLHN Physiotherapy

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.:
Public 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?:

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.:

1. Yes we agree with the rationale for the exclusion of the products as stated based on a no harm principle.
2. Yes The products are low risk and represent ‘over the counter products’ such as ‘bunion pads’ which may be dispensed to a client in a healthcare setting that are freely available to purchase in a retail setting pose little or no risk to the consumer. Materials and components which will be incorporated into a patient matched device and are therefore regulated as part of that device and as such can be excluded in their own right

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. :

All non-invasive class 1 devices.

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 it is reasonable to exclude patient matched devices of Class 1 non-sterile non Measuring if they are produced in a NSQHS accredited organisation.
We are assuming that exempt devices will still need to meet the other regulatory requirements / essential principles.
We seek further clarification on the points below'
• For those devices that are manufactured on site for the accredited health service and not manufactured by an AHPRA registered health Professional i.e. an allied health assistant what constitutes 'trained'?
• In this scenario what would the mechanisms of oversight need to be demonstrated?
• For those devices that are manufactured off site from the accredited health service and not manufactured by an AHPRA registered health Professional i.e. an orthotic Lab technician what constitutes 'trained'?
• In this scenario what would the mechanisms of oversight need to be demonstrated?
• Packaging and labelling requirements for items e.g. Foot orthotics. Nil information evident on the TGA website as to what these requirements are.
• Clarification of the information that is supplied to the patient is it purely a product data sheet or is there a requirement for clinical application information in addition to the device data sheet.
• Record keeping and whether current documentation in medical records as part of daily clinical practice is sufficient to meet TGA needs? A challenge for SA Health would be the ability to easily pull this information from existing medical record systems especially for remote sites that are paper based.
• Whether SA Health internal system for adverse event reporting would be sufficient to satisfy TGA requirements or if an alert is required to be embedded in our Safety Learning System reporting to include TGA notification for any adverse events relating to 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.:

Yes the risks can be managed within an accredited NSQHS organisation.
The RLHNS are supporting that all items created by OT,O&P,PT,&PODs working under SA Health are considered for exemption for the following reasons:
• These Class I non-sterile devices are produced within a health care facility that is accredited against NSQHS standards
• All OT,O&P,PT,&PODs working in SA Health hold a current registration with AHPRA
• OT,O&P,PT,&PODs are working within their scope of practice and clinical training when producing these devices.
• Clinical governance provided through a supervision framework ensures allied health staff are trained and competent in creating these devices.
• The devices are intended to be used by a patient of an SA Health care facility
• SA Health have an internal safety reporting system that enable staff to report any adverse events

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 class 1 devices that are made up of individually exempt parts or components that are already TGA compliant e.g. lower limb prosthesis that are manufactured by Certified Othrotists.
RSS is suggesting as SA Health meets the requirements by TGA in : ensuring the devices are produced by OT,O&P,PT,&PODs who are registered with a accrediting body working within scope of practice in a governance structure that mitigates risks and has documentation structure and a reporting system for any adverse events ; that SA health OT,O&P,PT,&PODs devices be considered for an alternative conformity assessment which would allow items to not require certification for inclusion in the ARTG. Refer to pg 9 and pg 13

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?:

This section is not relevant for RLHN OT,O&P,PT,&PODs as currently noone utilises Class 11a and above 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.:

n/a

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.:

n/a

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.:

n/a

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.:

 Clarification on packaging and labelling requirement
 Clarification for LHNs as to the due diligence required to demonstrate suppliers are TGA registered/compliant.
 Clarification on the scope of patient information to be supplied with a device and the recording of the information given to a client.
 Details to be included in records of supply
 Updated safety reporting system within SA Health that could allow ease of data retrieval for any adverse event due to a medical device to be pulled and sent to TGA rather than a duplication of reporting.
 Nil requirement of conformity assessment for each LHN, site or therapist rather one application is required through SA Health

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.:
none

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