Response ID ANON-3NHQ-DDS2-7

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-14 11:32:38

Introduction

1 What is your name?

Name:
[redacted]

2 What is your work title?

Work title:
Podiatrist

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.:
Health

7 Are you responding:

As an individual

Exclusion

8 Do you agree with the rationale for the proposed exclusion of products?

No

If you answered 'no' to the above question, why do you disagree with the rationale for the proposed exclusion of the products listed?:

I am not sure how you are applying this rationale to orthotic/insole/ offloading pads/toe props or braces that are manufactured by and issued by Podiatrists to their own patients/clients...
Do you mean that if we manufacture and supply a class1 , non-sterile orthotic device for a patient we are able to self regulate because of our university training, clinical experience and ongoing professional development that we can be trusted to do the right thing, choose quality/safe products/materials to use inn what would have to be regarded as a low risk end product/device to the patient.. and hence we are exempted... ok.

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.:

I will need an extension of time to be able to put together a more meaningful response to all this... I have just discovered your email today..

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. :

I will need an extension of time to be able to put together a more meaningful response to all this... I have just discovered your email today..

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.:

"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."

I agree with this if you apply it to the Podiatry profession. We are university trained, have ongoing professional development, have clinical experience in the prescription and manufacture of orthotic and similar devices. We are in a position to properly fit, asssess and monitor such devices and are hence being held accountable by the patient in providing safe and effective outcomes.

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.:

I would think that the above should be adequate to ensure safe products being supplied to our patients. Further professional development course/updating skills could be advantageous.

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?:

This is beyond my scope of practice and I have no opinion

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.:

This is beyond my scope of practice and I have no opinion

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.:

This is beyond my scope of practice and I have no opinion

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.:

This is beyond my scope of practice and I have no opinion

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.:

I was disappointed to find that Podiatry has not been included in the blurb so far provided in your discussion papers... it is hard to forecast what your expectations are for our profession specifically when the examples that have been thus far provided are not particularly relevant.

It would be helpful if the TGA could address how we will be affected directly... the manufacture and supply of orthotics, padding, toe props and splints etc are a large and important part on how we manage our patient's issues... it will be devastating to find that we are unable to have the freedom to prescribe and individually modify/manufacture items to match our patient's needs, and have to rely on a reduced range of prefab products that have managed to go through the expense and time etc of gaining TGA approval due to the economies of scale for mass produced items.... I am concerned that the appoval process for all the various materials we may utilise becomes to onerous and we are then unable to utilise various top cover materials, padding materials etc.. we will not be able to properly service our patients..

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.:
nil

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