Response ID ANON-3NHQ-DDGM-P

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-14 17:12:46

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:
Sydney Local Health District

5 What is your company/organisation address?

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

SLHD, King George V Building, 83 – 117 Missenden Road, Camperdown NSW 2050

6 Which industry do you work in, or represent?

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

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?:

Yes, products which do not pose a significant risk to patient safety should be excluded from the TGA's regulatory purview.
Additional non-statutory guidance would ensure the overarching aims of the regulatory framework are extended to this class of product, including that that products are to be provided by a suitably qualified clinician/technician working within their scope of practice.
SLHD also recognises that providing consumer information about products in this category which are supplied to them as part of their clinical care is optimal, but that this should be provided as outside the regulatory framework in line with the requirements of the National Safety and Quality Health Service (NSQHS) Standards Partnering with Consumers Standard.

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.:

Yes, products are still covered by Australian Consumer Law provided by relevant state and territory legislation.

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. As outlined in the proposal, as long as the level of risk posed by the device is considered to be very low.

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. As outlined in the proposal, devices manufactured by appropriately trained and/or registered practitioners should be exempted from inclusion in the ARTG.
The current proposal also ensures patient/public safety through requiring meeting of the Essential Principles, evidence of conformity assessment and the reporting of adverse effects. These requirements will assist manufactures in ensuring patient safety.

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.:

No

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?:

- As outlined in the proposal, it must be demonstrated that the risks associated with the manufacture and use of the device can be adequately managed.
- In relation to the requirement that the device is manufactured by a trained, accredited professional, this may require further definition to ensure the level of oversight is appropriate and should be undertaken with the relevant professional groups, i.e. AHPRA etc.

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.:

Yes, the risks associated with the proposed Class IIa patient-matched devices, produced under the circumstances listed in the consultation paper could be adequately managed through the proposed alternative conformity assessment procedure.
The current proposal also ensures patient/public safety through requiring meeting of the Essential Principles, as well as the other regulatory requirements listed in the proposal.
Products will remain under the regulation and statutory frameworks such as through Australian Consumer Law, and professional activities surrounding the provision of products, such as the design and manufacture of dental devices, will be covered by the National Law which regulates the professional activities of dentists.
In the oral health domain, it is also important to note, that the risks associated with secondary caries related to crown and bridge prostheses are more likely to be related to failures in the cementation of these devices by dentists, rather than failures within the manufacture process. The practice of dentists is regulated adequately by the provisions of the National Law.

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.:

The proposed conformity assessment procedures outlined adequately cover, for example, the practice of dentistry by prosthetists and dentists and the manufacture of devices by trained dental technicians.

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.:

As a significant innovator in medical devices and technology, SLHD request consideration be given to how best to support innovation and research, for example, within the rigorous framework of an approved clinical trial, that costs for registration be reduced or waived, particularly when the purpose of the trial is to increase access and reduce the cost of innovative clinical interventions. The cost burden of conformity assessments should consider alternative models which enable innovation outside of a commercial space to flourish, and moreover, for those innovations to be shared with others in the public health system.
The model should also consider how larger LHDs may support through outreach and manufacturing support rural and regional locations which do not have the capacity to establish themselves as manufacturers. Costs associated with the regulatory model should be therefore be imposed centrally rather than at a service level to ensure equitable distribution of regulatory cost impacts across the system.

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.:

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