Response ID ANON-3NHQ-DDSZ-F

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-13 18:10:03

Introduction

1 What is your name?

Name:
[redacted]

2 What is your work title?

Work title:

3 What is your email address?

Email:

4 What is your company/organisation?

Organisation:

5 What is your company/organisation address?

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

6 Which industry do you work in, or represent?

Please state the industry that you work in, or are representing in your submission.:
Member of the public

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 don't think you should be including anything about individual patients without their consent, especially if you're including personally identifiable information such as names, initials or birthdates, and transmitting that information electronically. I read through the linked legislation, and I noticed that multiple times it allowed for information to be transmitted electronically without having to seek patient consent? You should always be asking for patient consent for ehealth.

Can you please think through the harm that ehealth is having on patients feeling comfortable seeing a doctor, and can you also please consider the sensitivity of some of the health information you're talking about here. Your discussion paper only mentions specialists such as dentists, audiologists, hand therapists etc, but this would also apply to other specialists such as urologists too. Some of the health information you're talking about would be quite sensitive, and you need, need, need to get patient consent before you collect that data, and especially before you share it over the internet. Otherwise, you are putting their data at risk of hacking, and worse, putting them in a position where they might not access treatment. That's the harm that ehealth does.

Could I suggest consulting with some urologists, gynaecologists, gastroenterologists, plastic surgeons etc, to see exactly what patient-matched devices would be covered by this change? You need to think beyond dentists and think to other specialists who deal with more sensitive health issues. Because too much data sharing, too much removal of patient privacy, can and does have a negative effect on patients seeking treatment.

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. :

No patient-matched devices should be registered at all unless you have that patient's consent. Can you ease up on all the data sharing please? It is doing harm. I can't see a doctor now without worrying how many other people are going to be reading my medical records, or if my health information is going to be transmitted online despite me opting out of ehealth. Why am I not in control of that as the patient?

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?

No

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?:

Your proposal doesn't include patient consent. If you are sharing the health information of identifiable patients, you need their consent for that, especially if you're planning on sharing it electronically. That includes the risk of re-identifiability from a combination of initials and birthdates, as allowed for in the current regulations. You need consent.

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.:

You should not be collecting any health information about specific patients without their consent. That matters moreso for the highly sensitive health information you would get from specialists such as urologists, gynaecologists etc. Have you consulted with them on what patient-matched devices they would use?

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?

No

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?:

Can you please consider how sensitive some of the health information you're dealing with would be? You've focused on dentists and orthodontists, have you consulted with gynaecologists, urologists and plastic surgeons? What information would be sent to the TGA about women having breast implants or reconstructive surgery after breast cancer? You're talking about anatomical models and photos, have you forgotten the negative reaction when breast cancer survivors found out that photos of their breasts were being sent to Medicare? And how many more have avoided getting reconstructive surgery because of that?

You need patient consent if the data relates to specific patients.

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.:

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.:

Anything where the data sharing would lead to a patient refusing treatment. You need to make exceptions for when patient consent can't be obtained, for when that data sharing is an impediment to treatment. That especially applies to electronic data sharing, because ehealth is a very definite impediment to treatment-seeking.

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.:

Patient consent.

It's not only about regulatory burden, it's also about patient privacy if you're collecting any amount of identifiable patient health information, and especially if you're transmitting that data electronically. You need patient consent for ehealth, it can do so, so, so much harm if it is forced. Why is it not up to us as patients to decide if we trust ehealth or not? Because we are the ones who are having our trust in doctors compromised, we are the ones who are having our lives put at risk because of that. You need patient consent to transmit data electronically.

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.:

22 May we contact you for further information or to seek feedback about how the consultation was undertaken?

No

23 By making a submission, I acknowledge that:

I acknowledge the above