Response ID ANON-3NHQ-DDC2-Q

Submitted to **Proposed refinements to the regulation of personalised medical devices**
Submitted on **2021-07-06 12:56:08**

Introduction

1 What is your name?

Name:
Juanita Fernando

2 What is your work title?

Work title:
Adjunct Research Fellow

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
Medical Education Research & Quality (MERQ)unit. School of Public Health &Preventive Medicine. Mon U

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.:

Digital Health research and application- Education **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 do agree reviewing the rationale for the proposed exclusion of listed products, but maintain that all PMDs must be made subject to relevant, prescriptive regulation by the TGA. My view is informed by empirical evidence, rather than rational; e.g., on another matter- adverse events, even deaths, are linked to the application of Electronic Medical Records (EMRs) for health care, but these adverse events are not presently recorded by the TGA (1-3). It seems that the risk of adverse health events were not originally envisaged when EMRs , which can be beneficial, were first registered with the TGA . But empirical evidence indicates that EMR's can, and do, represent fundamental risks to patients, where end-user error working with an EMR/EHR can foster unintended, real life, consequences. Technological advances, such as 3D printing for complex and potentially higher risk PMDs and where manufacturers are not always suitably trained or accredited can enter the market, are of concern. And the pace of technological change will accelerate in the future. The TGA rationale is logical given the current state of knowledge, but excludes the benefit of empirical evidence and future-proofing PMD technological development.

1. Victorian Coroners Court of Victoria at Me bourne. Finding Into Death Without Inquest, Coroner Caitlin English, Deputy State Coroner. COR 2019 6921., pp. 6-13. https://www.coronerscourt.vic.gov.au/sites/default/files/2021-03/IanFraser_692119.pdf
2. Kim, Mi & Coiera, Enrico & Magrabi, Farah. (2016). Problems with health information technology and their effects on care delivery and patient outcomes: Asystematic review. Journal of the American Medical Informatics Association : JAMIA. 24. 10.1093/jamia/ocw154. https://www.researchgate.net/publication/311898687_Problems_with_health_information_technology_and_their_effects_on_care_delivery_and_patient_outcomes_A_syste
3. Office of the Australian Information Commissioner. (July 2019) Australian Privacy Principle guidelines.https://www.oaic.gov.au/privacy/australian-privacy-principles-guidelines/?start=0&tags=87

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

No

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

See comment above

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. :

See response to Q 8.

Exemption

11 Do you agree with the rationale for the proposed exemption of Class I non-sterile, non-measuring patient-matched devices whenproduced under the circumstances listed in the consultation paper?

Not Answered

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 circumstanceslisted in the consultation paper be adequately managed if they are exempted from inclusion in the ARTG?

Not Answered

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, whatmeasures 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.:

Please refer to my response to Q8.

Alternative conformity assessment procedures

14 Do you agree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched medicaldevices 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 circumstanceslisted in the consultation paper could be adequately managed through the proposed alternative conformity assessment procedure?

No

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

Possibly, but proposed alternative conformity assessment procedures must strive to exclude legal loopholes, such as currently occurs with the Australian PHN's (Personal Health Network's) whole of citizenry data collection, which is linked to the Department of Health (DoH). The PHNs guarantee the community that general practices supply them with de-identified, individual patient's health information. The information is stored by the PHNs and supplied to the Australian Institute of Health and Welfare and other, authorized, researchers to enable public health research. However, due to a "legal loophole", the PHNs harvest PBS and MBS numbers, which in conjunction with other patient information collected during data collection, ensures the information is completely identifiable. (1,2)

1. APF. Submission in response to the National Health Privacy Rules (2018) Review. 20 June 2021.
https://privacy.org.au/wp-content/uploads/2021/06/OAIC-NatHlthPRules-210604.pdf
2. Dunlevy, S. Privacy experts alarmed medical data is collected without consent. 11 June 2021. https://www.dailytelegraph.com.au/news/national/privacy-experts-alarmed-medical-data-is-collected-without-consent/news-story/7e2d7e8a224bdf3fe02f45e6bd8ec8a8

16 Are there further circumstances where an alternative conformity assessment procedure for Class IIa patient-matched devices would beappropriate?

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.:

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 personsoverseas, 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.:

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