Response ID ANON-3NHQ-DDK5-2

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-14 12:06:16

Introduction

1 What is your name?

Name:
Margaret Noonan

2 What is your work title?

Work title:
Senior Policy Officer

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
Assistive Technology Suppliers Australia

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.:
Assistive Technology Suppliers

7 Are you responding:

On behalf of an organisation

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?:

ATSA does not support the proposed rationale.
All Assistive Technology under the current responsibility of the TGA would not be suitable for exclusion as ATSA does not support the thinking that a medical device can never pose a risk. In our view, the Therapeutic Goods Act 1989 provides a definition of a medical device, and if a device fits within that definition it is the responsibility of the TGA to provide regulatory oversight of the device. Any form of exclusion should only be considered if there is doubt it is a medical device.

AT is evolving rapidly and there needs to be oversight by the TGA of new products coming into the Australian market (Reference: WIPO Technology Trends 2021 Assistive Technology). The effective role of the premarket TGA ARTG framework regulates safety and performance for medical devices, and if a device is excluded it is outside the TGA's jurisdiction meaning there will not even be post-market monitoring by the TGA. This is of great concern.

The rationale requires further clarification on what items would be Excluded rather than what items will not be Excluded.

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.:

Through the ARTG the TGA holds the current and historical data of the suppliers and manufacturers. To remove the listing from the ARTG, any future product recalls will be difficult to perform and dependent upon on the urgency of the situation, time lost in accessing data could greatly impact the

circumstance.

Allied health professionals who script Assistive Technology rely on the equipment meeting the minimum standard through the self-declaration framework set by the TGA. If a particular AT device is Excluded from the ARTG, the liability shifts more towards allied health professionals who are not trained or equipped for such oversight as they lose the TGA framework for checking the AT credentials.

There is currently a shortage of experienced prescribers of AT in rural and regional areas which has resulted in the delay of existing orders for AT leaving patients/clients who are without the necessary AT. The indications are that if allied health professionals are expected to accept a higher liability through product being Excluded, there is a risk that this already limited resource, will reduce further.

It is ATSA's view that the TGA provides the right balance of regulation for Class 1 medical devices as it is a central body equipped with sufficient powers controlling the product regulation, recall and minimum quality standards, that has a pre-sales control.

Example 1:
A walking stick could be considered as a low-risk device, however if the wall thickness is not to standard and fails, it could result in a catastrophic outcome. By having this registered on the ARTG, then if the source of the problem is track to a particular factory, all importers who use that factory can be notified of the issue, or recall. It would not be practical due to the time and complexity to track down all importers who use an affected factory if the item was an Exempt item.

Example 2
If an importer of a low-risk Exempt AT item ceased its operations, and a year later there was an identified issue with the AT device that required urgent recall. The ability to track down the details of suppliers and end users would be costly and slow as there would be no base records available.

Example 3
Prior to the inclusion of AT onto the ARTG in 2020 there were many examples of persons/business who sold AT to the open market, and once the shipment was sold, they shut up shop, and disappeared. You could argue that can still happen, however the need to pre-register AT as a medical device, adds a level of complexity, responsibility and accountability prior to selling devices that the most vulnerable persons in society purchase.

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. :

ATSA supports the approach that if a medical device falls within the definition contained within the Therapeutic Goods Act 1989, the TGA needs to provide regulatory framework. Excluding a device from the jurisdiction of the Act in our view dilutes the required protections for the user of the medical device which should have oversight.

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?:

Excluding or exempting medical devices from entry on the ARTG removes the ability to track and trace medical devices effectively and timely when a risk to the user is identified. The current ARTG framework is fit for purpose, therefore why remove an effective safeguard of medical devices.

Also the annual reporting requirement for custom made devices is at odds with the nil annual reporting and registration requirement for mainstream devices.....what makes custom made different? To remain consistent, the current requirements of registration should be maintained for both custom made and mainstream 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?

No

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

Allied health professionals who script Assistive Technology rely on the equipment meeting the minimum standard and self-declaration set by the TGA. If AT assessed as low or high risk is Exempt from the ARTG, the liability shifts more towards allied health professionals who are not trained or equipped for such oversight.
Product recall will be less efficient and timely if moved away from the responsibility of the TGA. The TGA's database of suppliers and their source manufacturers for AT supports suppliers, allied health professionals and patients/clients if the recall is required. An efficient and effective product recall process is also a safeguard for the AT supplier's business and reputation. This process has most recently been applied to the manufacturer of a particular wheelchair with multiple distributors/suppliers in Australia.

In the event of an AT device failing repeatedly, the likelihood of the failure may be rare or low, but the consequences could be extreme making the overall

risk “High to Very High”. For example, a failure in a hoist, standing wheelchair or walking frame can result in serious injury or death. (Reference for risk rating: Australian Commission on Safety and Quality in Health Care, Risk Management Approach).

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 further circumstances recommended.

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.:

No alternative mechanisms advised . ATSA supports the current centralised regulation of quality and safeguards for AT in Australia.

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.:

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