Response ID ANON-3NHQ-DDK9-6

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-12 17:17:47

Introduction

1 What is your name?

Name:
Kym De Britt

2 What is your work title?

Work title:
Chief Executive Officer

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
ADIA

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.:
Dental Manufacturers Sector

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?:

ADIA supports a lighter regulatory touch for low-risk medical devices, so supports excluding a range of products that do not meet the new definition of a medical device, or if they do meet the definition have shown to have a very low risk profile.

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.:

ADIA supports a comprehensive assessment of very low risk products with the broadest possible group being declared to be excluded goods.

TGA can exclude goods that do not meet the definition of a medical device, and low risk product types as specified goods.

For those products where in some uses the goods may need to be regulated as medical devices, TGA could exclude the goods when used, advertised, or presented for supply in a particular way.

This is consistent with how TGA currently expresses the regulatory control of borderline products in the Excluded Goods Determination 2018, Schedule 2.

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. :

TGA has deemed that raw materials used in manufacture of personalised medical devices no longer meet the definition of a medical device so should be excluded. TGA is no longer accepting applications for inclusion of these products onto the ARTG, and actively working to have existing products removed from the ARTG.

This is consistent with the EU's proposed regulatory approach for these products. It should also be noted that Notified Bodies continue to consider these to be medical devices.

ADIA proposes to TGA that rather than have these components outside the regulatory framework thereby placing the onus of responsibility for the quality of these materials on the manufacturer, there should be an option for these goods to be included in the TGA regulatory framework where circumstances deem this to be suitable.

By adopting a framework with the option to register a raw material on the ARTG this would resolve problems where an item certified under MDSAP as a medical product will still be allowed to be imported into Australia. If there are no provisions for importers to list the raw materials on the ARTG this will create extra paperwork and "red tape" or perhaps even exclude products from being imported or exported.

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?

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted].

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.:

The ADIA has no confidence that the proposed exemption criteria can guarantee compliance with the Essential Principles. The existing regulatory framework that is based on manufacturing quality standards achieves this.

ADIA strongly supports the introduction of Conformity Assessment templates to assist small to medium business with meeting the required and appropriate quality standards in a low-cost manner.

The ADIA does not agree that a professional registration, historical qualification, or participation in an accreditation process that has no ongoing quality assurance measurements will equate to quality manufacturing standards that are reproducible and consistent.

As discussed in the previous question the ADIA would seek clarification on:
• Who will audit and regulate that the qualification of a manufacturer is deemed adequate?
• How will TGA check to ensure compliance & consistency?
• How will audits to ensure manufacturing quality standard of devices are consistent with devices manufactured under existing Conformity Assessment criteria be conducted?

Self-declaration for existing Class I medical devices was found to be unsuccessful with a level of non-compliance that resulted in TGA implementing a change that now requires the Declaration of Conformity to be supplied with a Class I application. TGA undertakes a limited review of each application.

The ADIA is unclear, when self-regulation previously failed, how this version of self-regulation will not be an issue for this group of Class I devices.

This group of Class I devices had limited regulatory oversight under the previous regulatory framework. This proposal to exempt from the framework is effectively reverting to the previous arrangements of no regulatory oversight.

The introduction of proposed alternative arrangements will create an uneven regulatory environment for medical devices manufactured overseas. It also creates the potential for locally manufactured medical devices to not be accepted by overseas regulatory requirements.

The ADIA feels that these changes would see Australia as setting the bar too low when Australia has previously been seen as one of the leaders in the quality and safety of goods manufactured or provided.

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.:

The ADIA agrees that there may be some professionals whose AHPRA registration and training is intrinsically involved in the manufacture of medical devices, such a prosthetists and podiatrists, but this would need to be specifically articulated in the scope of the AHPRA registration.

This, however, again raises the issues of auditing the process and qualifications so that it is fair and transparent for all applicants.

• How will the approval process be implemented?
• Will the TGA now be the regulator of qualifications rather than devices?
• How will the TGA monitor ongoing professional development to ensure current qualifications keep up with the changes in technology?

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?:

The ADIA believes that a Class IIa patient-matched medical device is a Class IIa medical device.

If the device has a lower risk to the patient than other Class IIa medical devices, then the device should be classified as a Class 1 Medical Device. All Class IIa medical devices should be treated equally.

As previously stated, the proposed alternative of individual professional qualifications or laboratory OHPA membership do not directly correlate to manufacturing quality standards, therefore there is no confidence that the alternate CA procedure provides appropriate levels of risk mitigation associated with medical devices manufacture.

There has been no evidence presented to date that demonstrates that holding a professional qualification or laboratory membership is sufficient to produce medical devices that meet appropriate quality standards.

If alternate CA procedures are to be allowed for patient matched Class IIa Medical Devices the alternate CA options should be accessible to all Class IIa Medical Devices.

If the alternate CA procedures are not allowed for all Class IIa devices the proposed refinements create a two-tier regulatory system that imposes a higher regulatory burden on Class IIa medical devices that do not meet the patient-matched medical device criteria, but which may have a lower level of risk to patients. This again creates inequity in the administration of the Class IIa medical devices.

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?

No

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

The ADIA believe that all Class IIA should be equally regulated. If the device is judged to be of such low risk, then it should be reclassified as a Class 1 medical device.

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 ADIA believe that all Class IIA should be equally regulated. If the device is judged to be of such low risk, then it should be reclassified as a Class 1 medical device.

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.:

The ADIA believe that all Class IIA medical devices should be equally regulated. If the device is judged to be of such low risk, then it should be reclassified as a Class 1 medical device.

All medical devices should meet a standard conformity assessment.

TGA are the regulator of devices in Australia and should remain the regulator of devices, not the regulator of qualifications. AHPRA is the regulator for the scope of practice of oral health workers and should not by default become the regulator of medical device manufacturing processes.

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.:

The ADIA would recommend a review of the classification rules as they apply to the oral cavity.

A full review of the definition would enable a large range of low-risk Class IIa medical devices to be reclassified to Class I medical devices. This would reduce the regulatory burden of third-party Conformity Assessment.

The ADIA would further recommend and support the introduction of a templated system for self- assessment for Conformity Assessment.

Before recommending any refinements or changes to the legislation the ADIA would recommend that the TGA conduct a review to assess the level of Class 1 and low risk Class 11a devices that are currently being manufactured by the various stakeholders.

Once this is established the TGA can assess the level of templated CA assessment that would be required for most of these low-risk devices. This would also identify the time and cost for the various stakeholders to implement.

This would alleviate some of the current concerns around having to pay exorbitant costs to have low risk devices approved.

The ADIA believes that the combination of a:
1. Review of the classification rules.
2. Reclassification of low-risk devices.
3. A consolidation of GMDN codes to reduce the number of devices required to be registered.
4. Review and implementation of a cost-efficient templated conformity assessment.

Would achieve:
1. A level playing field for most stakeholders.
2. A cost-effective CA for most low-risk devices.
3. A consistent standard in the quality of products produced.
4. Raising the standard across the industry.
5. A classification procedure that is within the TGA's current scope.
6. The removal of the requirement for TGA to assess/regulate qualifications.
7. The removal of the administrative requirements required for the TGA to implement the suggested alternate conformity assessment in a clear and transparent manner.

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.:

[redacted]

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