Response ID ANON-CBS3-RZB6-F

Submitted to Consultation: Proposed changes to the IVD medical device classifications and definitions
Submitted on 2025-05-08 17:54:06

Introduction

What is your name?

Name:
[redacted]

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
[redacted]

Responding to this Consultation

Question 1(a): Do you agree with the proposals to change the Australian classification rules and principles that have an impact on approved products (as specified in the first Section of the paper), noting the changes are reflective of the regulatory scrutiny based on the associated health risks?

Respond to the question 1a:

As a state health pathology service, a reduction in risk is certainly a focus for us. We support rewriting the IVD classification to match wording in EU as this broadens the ability to capture emerging diseases. We hope that the proposed changes to classification rules will have the outcome of improved clarity and transparency. We also agree with the need for global standardisation and a health risk driven classification of IVD devices, however, the implications for pathology laboratories and their quality management systems are large and involved. Therefore, there is hesitation with agreeing to proposals without disclosure of the complete scope/specific changes and the practical consequences on these in the laboratory setting.

Question 1(b): If no, which of the proposed changes do you not agree with? Please provide your reasons.

Respond to the question 1b:

There is concern around changes to classification of IVD devices and a possible “reclassification” of devices or products already in use. This remains the most practical consideration for us as a pathology service. We note that typically, if the legislation changes, it will detail actions required by affected products (whether further validation/verification is required or not), however this is a significant body of work for laboratories to take on. Especially if validated products or instruments are already in use, there is no real change to the product and yet there is pressure to re-verify & update methodology/reporting formats etc. Conversely, it is possible that products may no longer meet the particular IVD classification that they were previously marketed with, a change in IFU will also force validation and verification. If the retrospective body of work sufficient, in this case, to warrant use. We anticipate that there will additionally be flow-on effects on audit scope, re-certification/accreditation, pricing, procurement considerations and import conditions, to mention a few.

Resourcing in place to help us, as end users of IVDs, with any additional administrative burden when the changes to rules and classifications are made, would be essential and hugely helpful.

Question 1(c): Are there any other classification rules and principles, relating to the IVD medical devices, that need to be considered as part of this proposal?

Respond to the question 1c:

No

Question 2(a): Do you agree with the proposals to adopt certain terminology in the Australian classification rules that have no impact on approved products (as specified in Appendix A of the paper), noting the changes are to improve clarity?

Respond to the question 2a:

Yes, agree with this proposal.

Question 2(b): If no, which of the proposed changes do you not agree with? Please provide your reasons.

Respond to the question 2b:

Question 2(c): Do you agree the proposed changes in Appendix A of the paper, would not result in any impact on existing ARTG entries of IVD medical devices?

Respond to the question 2c:

We have questions around impact of these proposed changes. For example:

Replacing ‘with a risk of limited propagation’ with ‘without a high or suspected high risk of propagation’ seems minor but what are the implications for risk assessment?

Re: proposed change - "A life threatening situation, imminent or not imminent, poses a high personal health risk and is considered appropriate to be classified as a Class 3 device." Would removal of ‘imminent’ from the Australian classification rule affect classification/Severity assessment codes for clinical incidents. Would they default to a higher severity as a result of this?

Re: proposed change - "The statement ‘for the selection of patients’ currently applies to devices used for selective therapy and management, disease staging, and cancer diagnosis. Selection of patients already implies that devices are used for selective therapy. Devices for disease staging and cancer diagnosis Therapeutic Goods Administration Proposed changes to IVD medical device classifications and definitions V1.0, March 2025 Page 20 of 27 European IVD Regulation 2017/746 (Annex VIII) Current Australian regulation Proposed amendments are not used for selection of patients. The statement is ambiguous and hence, is proposed to be removed." Would removing the statement ‘the selection of patients:’ affect instruments/devices used as screening tools that might result in “selection of patients” with regards to infection control measures?

Appreciate the explanatory note with "Replace ‘specific characteristics’ with ‘no critical characteristics’. The term ‘no critical characteristics’ is in line with the Australian risk-based framework." However this change is open to interpretation, is confusing to the end user of a product and is perhaps of limited value.

Question 2(d): Are there any other classification rules, relating to the IVD medical devices, that need to be considered as part of this proposal?

Respond to the question 2d:

No

Question 3(a): Do you agree with the proposal to amend the Australian definitions as specified in Appendix B of the paper?

Respond to the question 3a:

Yes with some questions around inclusion of Control material.

Question 3(b): If no, which of the proposed changes do you not agree with? Please provide your reasons.

Respond to the question 3b:

Control materials - Again, will reclassification of a class 2 IVD to class 3 or 4 result in change to use of control material and audit scope at the user end?

Question 3(c): Are there any other definitions, relating to the IVD medical devices, that need to be considered as part of this proposal?

Respond to the question 3c:

No

Question 4(a): Do you agree with the proposal to apply a 6-month transition period after the EU IVDR transition timelines for the proposed Australian amendments to take effect?

Respond to the question 4a:

No

Question 4(b): Provide reasons for your position.

Respond to the question 4b:

If validation and verifications are to be repeated even for a few variables often require careful planning and reprioritising. This effort often takes longer than 6 months to achieve.

Question 5: Do you consent to your response being made publicly available on the TGA’s Consultation Hub website? Please indicate your publishing preferences.

I consent to my submission being published anonymously (without my name or my organisation’s name)

Question 6: If you consent to your submission being published, are there parts that you do not want published? Please specify which part(s). Please note – your contact email address and/or phone number will not be published with your submission.

Respond to the question 6: