Response ID ANON-CBS3-RZBK-4

Submitted to Consultation: Proposed changes to the IVD medical device classifications and definitions
Submitted on 2025-05-23 16:58:56

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:

We commend the TGA's ongoing efforts to align (wherever possible) the Australian regulatory framework with the European Union. With the implementation of the IVDR, European IVD requirements have become more closely aligned with Australia's Essential Principles and the Therapeutic Goods (Medical Devices) Regulations. We believe this presents an ideal opportunity to identify and leverage synergies between the two regulatory systems.

We support, in principle, the proposals outlined in the consultation to change the Australian classification rules that have an impact on approved products in Australia. Where we hold specific concerns, these have been addressed in the relevant sections of our submission.

While we agree that the proposed amendments will enhance clarity and transparency, we do not anticipate a corresponding reduction in the public health and safety risks associated with IVD medical devices supplied in Australia. The current Australian IVD regulatory framework is robust, with devices required to comply with the Essential Principles for quality, safety, and performance. In addition, the mandatory obligations and ongoing responsibilities placed on manufacturers and sponsors ensure continued compliance with regulatory requirements.

We note that, under the proposed changes, many manufacturers and sponsors may be required to up-classify their devices. This is expected to lead to new ARTG inclusions, along with associated submission and annual fees. However, it is unclear how such reclassification will lead to a meaningful improvement in device safety, particularly given that IVD test results are typically interpreted in conjunction with the broader clinical context and are rarely used as the sole basis for treatment decisions or diagnosis.

A. Cancer tests
We agree to the proposed amendment to the classification rules making it clear that all IVD medical devices used for cancer, screening, staging and diagnosis are Class 3 IVDs.

B. Preliminary testing and monitoring devices
We agree to the proposed amendment to remove the note relating to Rule 1.3 (f). Whilst this removal will result in up-classification of many devices from Class 2 to Class 3, it removes the current ambiguity in the classification rules.

C. Devices used to manage life-threatening conditions
We agree to the proposed amendment relating to Rule 1.3 (i).

D. Newborn screening devices
We agree to the introduction of a new rule for classification of IVD medical devices used for newborn screening.

E. Control materials
We agree to the proposed amendments.

F. Instruments
We agree with the proposed amendments to re-classify instruments with an independent measuring function, that do not use reagents with critical characteristics to achieve their intended purpose, based on the risks they pose. We note that clear guidance is needed to assist manufacturers and

sponsors in classifying their devices correctly.

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

Respond to the question 1b:

G. Software
We support the proposed amendment to Regulation 3.3(5); however, we find the explanation provided in the consultation paper lacks sufficient clarity and detail.

We encourage the TGA to consider the current European guidance issued by the Medical Device Coordination Group (MDCG), particularly MDCG 2019-11: Guidance on Qualification and Classification of Software in Regulation (EU). This guidance offers clear explanations, practical examples, and user-friendly flowcharts that greatly assist in interpretation. A comparable resource would be highly beneficial for manufacturers and sponsors in Australia. Notably, the existing TGA guidance, Understanding regulation of software as in-vitro diagnostic medical devices (IVDs), has not had a significant update since its initial publication in 2013. Additionally, providing clearer language regarding the consideration of a software device's overall intended purpose would help resolve ongoing uncertainty around the classification of stand-alone software as either a Medical Device or an IVD.

We have provided the TGA with examples highlighting existing discrepancies in the classification of standalone software between Australia and the EU. Despite the proposed changes, we believe such inconsistencies may continue. We look forward to further guidance from the TGA on this matter.

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, we agree with the proposals to adopt certain terminology from the EU classification rules.

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

Respond to the question 2b:

N/A

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 don't foresee any impact on existing ARTG entries due to the proposed changes outlined in Appendix A.

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:

We are broadly supportive of the proposed changes to IVD definitions and consider that the proposed additions and revisions will enhance clarity for both manufacturers and sponsors. We have included a suggestion regarding the current definition of Point of Care testing in section 3(b).

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

Respond to the question 3b:

Near-Patient Testing and Point of Care Testing - the term Near-Patient Testing is well established in the European context and in other parts of the world. We recommend that consideration be given to incorporating this terminology into the definition of Point of Care Testing; for example, Point-of-Care Testing (Near-Patient Testing). We also support the inclusion of the phrase "not intended for self-testing," as it adds valuable clarity to the definition.

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:

N/A

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:

We do not agree with the proposed six month transition period for the reasons outlined below.

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

Respond to the question 4b:

We recommend a transition period of two years following the respective EU IVDR transition deadlines for each product class. While we acknowledge the TGA's rationale for proposing a six-month deadline after the EU IVDR transition dates, this timeline would place a considerable burden on both manufacturers and sponsors. Manufacturers may be required to implement significant updates to their Quality Management System processes, procedures and technical documentation. At the same time, sponsors, especially those with extensive product portfolios, are likely to encounter considerable workload challenges in reclassifying and resubmitting products for ARTG inclusion.

Furthermore, discrepancies between the Australian and EU classification rules are expected to persist in some cases. Where such misalignment occurs, manufacturers may be required to develop additional technical documentation to satisfy Australian regulatory requirements. In certain instances, this may result in products being withdrawn from the Australian market.

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: