PATHOLOGY
TECHNOLOGY
AUSTRALIA

Pathology Technology Australia

Response to TGA Consultation "Consultation: Proposed changes to IVD medical device classifications and definitions"

23 May 2025

The members of Pathology Technology Australia (PTA) welcome the opportunity to comment on the TGA's Consultation "Proposed changes to IVD medical device classifications and definitions" and are supportive of TGA's publication of this consultation to provide more clarity on the impact to sponsors on the proposals for reclassification and changes to definitions in the current regulations, to align Australia's regulatory framework with the European Union.

Question 1: Proposed changes to classification rules and principles that have an impact on approved products

(a) **Do you agree with the proposals to change the Australian classification rules and principles as specified in Section A, noting the changes are reflective of the regulatory scrutiny based on the associated health risks?**

(A) Agree the update of cancer tests. There has been much discussion in Industry regarding the screening and staging of Cancer and the applicable tests. Many discussions centering on the interpretation, certain products could be both Class 2 or Class 3. Therefore, this alignment with the European regulation removing ambiguity and reclassifying as Class 3 is acceptable.

(B) Agree to remove the Preliminary testing and monitoring devices 'Note for paragraph (f) Rule 1.3. This note, also led to some ambiguity for certain sponsors as can be evidenced from approved ARTG records, with some Class 3 cell markers and some Class 2 cell markers. Industry will appreciate the clarity and support the change.

For points D) and E)* we agree to the proposed amendments, however it must be noted that the cost and audit time that may ensue in relation to an up classification. This will likely result in new ARTGS and therefore, an increase in annual fees. As Australia's regulatory framework has been well established and world class for some time, it is not evident how these amendments will substantially increase patient safety. None of the proposed amendments have been supported with post market evidence presenting a trend towards increased

adverse events. That is primarily due to the existing essential principles requirements under the current Australian regulatory framework, that Class 2 and 3 IVD devices encompass (a) the same performance dataset of validation tests and (b) are rarely the only deciding factor in patient treatment, rather they are part of the clinical management of a patient by a HCP who considers all clinical signs, symptoms and test results to determine a definitive diagnosis.

*An additional member comment on E) control materials - while agreeing in principle – had additional commentary that is also pertinent to the proposed change; when a user assigns values to Class 2 IVD unassigned controls they should then be reclassified to Class 3 in-house and Class 4 in-house IVD medical devices. The rationale would be the same as the TGA's for assigned value controls. That is, controls where values are assigned by a user may be intended for one specific analyte or multiple analytes. Since they are used to monitor performance of devices of various classes, they should be classified in the same class as the device.

F) Instruments – we agree with the amendment to align with the EU wording; however, we believe instruments themselves as a base functional machine should remain Class 1, inclusive of those with software aligned with published assays that drive and influence the instrument to complete the assay per its instructions for use. For instruments with an independent measuring function, that may require reclassification, this too will need further clarity and guidance from TGA to ensure manufacturers fully understand the additional requirements that this reclassification will require, especially for manufacturers who do not currently supply into the European market.

If no, which of the proposed changes do you not agree with? Please provide your reasons.

C)SARS-CoV-2 in-house IVD medical devices are classified as Class 3 In-house IVDs. Since the TGA does not undertake a full desktop evaluation of in-house tests supplied in Australia equivalent to a design examination, and is not proposing to do so via application audits, in-house IVD tests for detection of COVID-19 (SARS-CoV-2) should be reclassified to Class 4 IVD Medical Devices in Australia. In-house manufacturer's also have no post-market obligations to monitor the performance of their devices against the circulating and emerging variants of concern and no obligation to notify the TGA accordingly to ensure the associated risks are mitigated. Therefore, there is currently a benefit to up classifying these in-house tests to Class 4 in-house IVDs in Australia.

C) Devices to manage life-threatening conditions (and infectious agents) - If this aligned well with the European IVDR, and the interpretation of what might be life threatening is the same, then this would be acceptable. However, it is already clear that the Australian definition of life-threatening in a clinical sense differs from that in Europe. Alignment would be required to ensure that the current data available to support the claims for the products that meet the criteria of testing for life-threatening conditions- will continue to be acceptable.

G) We have concerns regarding the software classification rule. PTA proposes that in this in case, TGA fully adopt the EU definition. However, members have found the explanation in the consultation paper to be ambiguous and requiring further clarity on its intent. This is evident in the number of questions and follow up meetings this section of the consultation document has resulted in, both with TGA and within the PTA TARSC group itself. We urge the TGA to look at the current European guidance endorsed by the Medical Device Coordination Group (MDCG), in particular MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU). This guidance presents clear explanations and examples along with easy-to-understand flowcharts. A similar guidance would be helpful for manufacturers and sponsors in Australia. Additionally, clear wording around consideration of the overall intended purpose of a software device would eliminate confusion around classifying stand-alone software as either a Medical Device or IVD.

In meetings between TGA and PTA member, prompted by the initial release of this consultation, we have presented some examples to TGA of instances where there are already discrepancies in the classification of standalone software between Australian regulations and the EU. Considering the changes proposed by this consultation, we believe these discrepancies may persist. We await further guidance from TGA moving forward on this still unclear area.

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?

Yes, we agree with the proposals to adopt certain terminology from the EU classification rules on the understanding that as per the intent of this consultation there will be no impact on currently approved IVD's.

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

We do not have any changes that we disagree with for this section of the consultation.

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?

Members have not voiced specific concerns regarding their existing ARTG's, and the amendments proposed.

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?

No

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

PTA members agree with the majority of amendments to Australian definitions, with one exception outlined in response 3(b) below.

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

The term 'Near patient testing' should be incorporated into the PoCT definition because the intended use of an IVDR compliant IVD Medical Device will state 'for near patient testing' not for PoCT. If not incorporated into the PoC definition, there is a risk of non-compliant labeling. Any changes to the intended use in the Instructions for Use (IFU) to be compliant to the AUS regulations would have cost impacts (new SKU) and IVDR impacts. Possible removal of the CE mark for the AUS SKU.

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

Members have not indicated any other definitions that need to be considered.

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?

PTA do not agree to a 6-month transition period after the EU IVDR transition timelines.

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

Members have clearly indicated that this will not be enough time for many manufacturers to update the Australian specific documentation that they manage under their QMS. Although, many of the technical documents for products that are transition to IVDR will be common for the EU and Australia, manufacturers may have additional requirements or SOPS under their QMS which document the current classification rules for Australian products, their relevant GMDNs and the preparation of the Australian DOC, etc. These supporting documents would require significant updates through the manufacturers change control process.

Sponsors will also need to update their internal compliance documentation, in addition to new ARTG submissions. For sponsors with a large volume of impacted products, this will also prove a timely exercise**.**

Additional consideration must be given to Manufacturers of non-EU supplied products, they will not have been subject to update to IVDR and so will need to update their QMS specifically to meet the Australian requirements. An appropriate period of time will be needed for both EU and non EU manufacturers to implement these changes.

PTA would propose a transition time of 3 years post IVDR implementation.

While there is not complete alignment with all amendments and proposals, there are many changes PTA do align with. PTA recognise all the work the TGA have contributed to this consultation and as always are appreciative of the opportunity to provide feedback and comments on behalf of the IVD Industry.

Aileen O' Connor

Aileen O' Connor

Chair of PTA TARSC