Response ID ANON-CBS3-RZTV-1

Submitted to Consultation: Proposed changes to the IVD medical device classifications and definitions
Submitted on 2025-04-02 15:37:13

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:

I am unsure how this change in classification reform would reduce the regulatory burden? Could the TGA please release the evidence that they have collected to indicate that adopting these proposed changes will improve the clarity, transparency and increase consumer confidence.

A) Cancer tests

Why would FOB Tests be included within Cancer tests, as majority of the screening tests do not detect cancer and only detect analytes that may be a symptom (i.e., Hb in stool). However, having Hb in stool is also a sign of non-life-threatening diseases/illnesses that do not necessarily indicate that cancer is present.

Could TGA please explain their reasoning for why companies would have to make submissions are the change in classifications?
Would these Required submissions lead to TGA audits, either desktop or onsite?

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

Respond to the question 1b:

please see answer to question 1(a).

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:

As stated in your consultation paper, I believe that the regulations surrounding "at-home" tests should be reviewed.
The COVID pandemic allowed the Australian public to become aware (if not already aware) of how to read a test result from a Rapid antigen test.
This has proved that Australians are able to understand results and interrupt them.
The IVD world is moving towards Rapid Antigen Tests, so TGA should be reviewing the regulations to develop, allow and foster growth in this area of the IVD industry.

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, I agree with the proposed terminology changes to provide more detailed information to the readers.

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:

It depends if TGA is going to audit IVD manufacturers with this terminology in mind.

There may be some companies in Australia, where this change in terminology has affected their thought process on what evidence is required.

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:

IVD Self-tests should be considered for review.

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:

Definition of "point of Care testing" -
To clarify this definition further can the TGA please provide an example of who a "laboratory personnel" is, as this definition is confusing.
Does "trained Laboratory Personnel" mean an individual who has been trained how to process the IVD test at the designed site of processing/manufacturing the IVD medical devices?
Does this definition mean that Doctors are not considered "trained laboratory personnel?

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

Respond to the question 3b:

Please see answer to 3(a).

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:

Further clarification on in-house IVD should be considered by the TGA, considering the land-mark case that has just occurred in USA involving FDA.

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:

Yes, as long as the TGA can stick to their timelines for reviewing applications and provide outcomes within the timeframes and KPI's that are listed on TGA's website.

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

Respond to the question 4b:

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: