Response ID ANON-CBS3-RZB8-H

Submitted to Consultation: Proposed changes to the IVD medical device classifications and definitions
Submitted on 2025-05-23 16:28:04

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:

[redacted] supports the proposed changes in principle but has significant concerns about there being potential impact on laboratories using IVDs. We anticipate increased costs for purchasing affected IVDs, performing tests, and manufacturing therapeutic goods. In the worst-case scenario, these changes could lead to the discontinuation of some IVDs in the Australian market, making certain tests unavailable to the public.

Australia's small market size has led to the discontinuation of IVD supplies over the years. Recently, new IVD regulations in Europe have further limited the availability of IVDs for certain tests, sometimes leaving only one option. This can pose significant problems during shortages or product issues.

The proposed changes will reclassify some in-house IVDs, such as control materials, to class 3 or 4. This could place a significant burden on laboratories, which may lack the resources to register these materials as class 4 IVDs. While laboratories might initially implement class 4 tests using commercial options, commercial control materials may not always be available for these assays.

We urge the TGA to consider the impact on laboratories using IVDs and the Australian public, who rely on these tests.

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

Respond to the question 1b:

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:

Refer to response to Q. 1(a).

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:

Refer to response to Q. 1(a).

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:

Refer to response to Q. 1(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:

Refer to response to Q. 1(a).

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:

Refer to response to Q. 1(a).

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

Respond to the question 3b:

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:

Refer to response to Q. 1(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:

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:

Please remove my name and contact details and my organisation's name. Thanks.