Response ID ANON-CBS3-RZBA-T

Submitted to Consultation: Proposed changes to the IVD medical device classifications and definitions
Submitted on 2025-05-23 16:20:02

Introduction

What is your name?

Name:
[redacted]

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Health Equity Matters

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:

NA

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

Respond to the question 1b:

NA

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:

NA

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:

NA

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

Respond to the question 2b:

NA

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:

NA

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:

NA

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 do not agree with one of the proposed amendments, which would have a significant impact on the ability to use approved products.

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

Respond to the question 3b:

My comment relates to the amendments related to near-patient testing (EU) / point of care testing (Aus).

We are concerned about the proposed inclusion of the phrase 'not for self-testing' and the accompanying description ', i.e. the user of the device should not be a lay person who does not have formal education in a relevant field of healthcare or medical discipline.'

There is ambiguity in this example that we believe may present a risk for the ongoing use of PoCT for HIV by trained peer workers and volunteers.

Over the last decade, new models of HIV testing have been implemented to increase HIV testing rates for those most at risk. One of the most important of these models has been peer-led HIV and sexual health testing services utilising PoCT. There are different models in operation across the country, but all promote a strong partnership between peer expertise and clinical expertise to seek the best outcomes for individuals and for public health. The peers are trained and operate under a quality assurance framework.

These models have coupled the use of a device that provides an immediate result, with the ability for appropriately trained peers to undertake the testing, providing sexual health testing in a highly supportive environment. Outside of publicly funded sexual health services and GP clinics that see a large proportion of gay, bisexual and other men who have sex with men, many services that have the potential to offer HIV testing may not do so in a way that respects that individual and their sexual lives, which is why many people may seek peer-led services. Having trained peer staff members as part of the testing process has been particularly important for the high proportion of newly arrived migrants who are using these services.

The a[TEST] service, run by ACON Health and Sydney Sexual Health Centre, is one example of how peer-based PoCT can have a positive individual and public health benefit. Between 2015 and 2019, it undertook 1.3% of HIV tests, yet accounted for 13.4% of diagnoses among men who have sex with men. It was also estimated to account for 19.9% of HIV diagnoses in NSW among overseas-born MSM, and 19.6% of Asian-born MSM. This impact has continued in the years since that evaluation report was released. It is the intersection of the peer-led model, and the access to PoCT that drives these results.

We acknowledge the importance of training for PoCT operators, however, it would be a perverse outcome if we restricted the use of HIV PoCT testing so that peers could not undertake them, while similar devices are available for purchase as HIV self-tests.

The TGA must ensure that the proposed amendment still allows for appropriately trained peers to conduct HIV PoCT.

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:

The change may not specifically change the ARTG entries, but the change could prevent the majority of use of some of the devices by stopping the primary workforce from using them.

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:

NA

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

Respond to the question 4b:

NA

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, without my name but including 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:

NA