Response ID ANON-CBS3-RZBR-B

Submitted to Consultation: Proposed changes to the IVD medical device classifications and definitions
Submitted on 2025-05-23 15:11:34

Introduction

What is your name?

Name:
[redacted]

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
The Kirby Institute, UNSW

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:

No comment

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

Respond to the question 1b:

No comment

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 comment

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:

No comment

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

Respond to the question 2b:

No comment

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:

No comment

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 comment

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:

No, we do not agree with all proposed amendments.

Specifically the proposed change - "Point-of-care testing (POCT) is a well-established term for these types of devices rather than near patient testing. For this reason, the TGA proposes not to adopt the EU definition. However, it is proposed that the wording “not intended for self-testing” be included into the Australian definition of point-of-care testing to provide greater clarity regarding the intended use and setting, 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." Appendix B, page 23.

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

Respond to the question 3b:

The Therapeutic Goods Administration’s (TGA) proposed amendment to the definition of point-of-care (POC) testing raises concerns. By proposing that , the wording “not intended for self-testing” be included into the Australian definition of point-of-care testing 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, this amendment excludes essential members of the current workforce, including Aboriginal and Torres Strait Islander Health Workers and trained lay or peer workers. This in turn has significant potential to decrease the positive impact that POC testing can bring to addressing the health inequity in vulnerable communities in rural and remote Australia.

Aboriginal Health Workers play a key role in existing POC testing programs. These workers are often local, deeply connected to the communities/people they serve, and are key to ensuring cultural safety and trust in healthcare delivery. Their exclusion from POC testing due to their absence from the Health Practitioner Regulation National Law would undermine successful, community-embedded programs. Moreover, recent studies have highlighted the severity of staff turnover in many remote health services. For example, the average annual staff turnover rate for Aboriginal health services in regional and remote NT and WA is 151%. Notably, turnover rates were significantly lower for Aboriginal staff (81%) compared to non-Indigenous staff (162%), suggesting that empowering Aboriginal staff is also key in stabilising the workforce. Under the proposed changes, Aboriginal Health Workers would be excluded from preforming POC testing.

Equally concerning is the proposed exclusion of trained laypersons from performing POC testing. Peer-based models are globally recognised for their effectiveness in engaging hard to reach populations, particularly in the context of HIV and HCV. Peer workers, who often have lived experience of these conditions, play a critical role in increasing testing uptake, reducing stigma, and improving treatment adherence among vulnerable populations. The reality is that restrictive professional requirements for POC testing will worsen existing workforce shortages and inequities in access to care. Task-shifting has been endorsed by the World Health Organization as a strategy to improve health system efficiency and access. In Australia, where many remote communities face severe health workforce constraints, task-shifting is not only practical but essential.

The National Pathology Accreditation Advisory Council (NPAAC) provides guidance on POC testing, stating that operators must be “appropriately trained” and competent. The NPAAC does not specify that individuals must hold formal qualifications or be registered under national health practitioner laws. This flexible and evidence-based approach enables the inclusion of diverse, trained personnel. This guidance is consistent with other national policies, including the National HIV testing policy, yet the proposed restrictions to limit POC testing to ‘health professional’ would be contradictory.

For these reasons, we do not agree with the proposed change - "Point-of-care testing (POCT) is a well-established term for these types of devices rather than near patient testing. For this reason, the TGA proposes not to adopt the EU definition. However, it is proposed that the wording “not intended for self-testing” be included into the Australian definition of point-of-care testing to provide greater clarity regarding the intended use and setting, 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." Appendix B, page 23.

We urge the TGA to reconsider the proposed amendment to allow trained non-registered personnel, including Aboriginal and Torres Strait Islander Health Workers, peer workers and any other persons who has completed appropriate training, to conduct POC testing. Ensuring the regulatory framework supports alternate workforce models is critical to sustaining culturally safe and community-led healthcare. This is not simply a technical adjustment to a definition—it is a decision with real-world consequences for health equity, workforce, and the community.

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:

No comments

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:

No comments

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

Respond to the question 4b:

No comments

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:

Only response to question 3(b)