Response ID ANON-CBS3-RZBY-J

Submitted to Consultation: Proposed changes to the IVD medical device classifications and definitions
Submitted on 2025-05-08 16:38:23

Introduction

What is your name?

Name:
Associate Professor Lisa Whop

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
Yardhura Walani, National Centre for Aboriginal and Torres Strait Islander Wellbeing Research, Australian National University

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:

Can the TGA please clarify what it means by 'formal education in a relevant field of healthcare or medical discipline' and can it confirm that the proposed amendment will not exclude Aboriginal Health Workers and Aboriginal Health Practitioners from using POCT devices. If the definition will exclude these recognised workforce groups from using POCT devices, I do not agree to the amendment.

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

Respond to the question 3b:

POCT is an essential tool for reducing health inequities in rural and remote Aboriginal and Torres Strait Islander communities as it supports models of care that can be delivered close to home, by trusted local healthcare providers. It is important that the change to the definition does not exclude any healthcare workforce groups who serve Aboriginal and Torres Strait Islander peoples, especially in remote areas where medical practitioners are not available regularly. For example, Aboriginal Health Workers who have completed the Certificate 2 in Aboriginal and/or Torres Strait Islander Primary Health Care are currently using POCT devices for STI screening in the First Nations Molecular Program. Programs such as this are achieving substantial public health benefits in remote communities through reductions in infectious days and fewer onward community transmissions of STIs. For example: https://www.kirby.unsw.edu.au/news/new-research-shows-point-care-sti-testing-way-forward

Non-medical models of cervical screening led by workforces including Aboriginal Health Workers and Aboriginal Health Practitioners are essential to achieving Australia's goal of eliminating cervical cancer as a public health problem equitably. Using POCT for cervical screening in rural/remote settings is expected to expand as part of the National Strategy for the Elimination of Cervical Cancer. The Australian Department of Health is supportive of piloting and scaling up innovative and non-medical cervical screening models that are proven to be effective and safe. An excellent example of using POCT in cervical screening is the PREVENT study which enabled Aboriginal women in select WA communities to screen – supported by HPV testing on the GeneXpert – without travelling hundreds or thousands of kilometres, and receive a rapid result. This model increased participation in cervical screening for under- and never-screened women, enabling those at high risk of cervical cancer to receive timely follow up and treatment. Further information can be found at https://www.abc.net.au/news/2022-11-13/new-cervical-cancer-screening-remote-indigenous-communities/101639948

Aboriginal Health Workers and Aboriginal Health Practitioners are trusted and valued by their local communities, as they bring deep knowledge of their communities and of Aboriginal and Torres Strait Islander ways of knowing, being and doing, especially in relation to culturally safe and appropriate healthcare delivery. It is important that the proposed amendment to the definition of POCT does not put up a barrier to their delivery of essential health services.

For further information about the qualifications required for Aboriginal Health Workers and Aboriginal Health Practitioners please refer to Figure 1 - National Aboriginal and/or Torres Strait Islander Health Worker and Health Practitioner Qualification Framework, on page 8 of the 'Professional Scopes of Practice for Aboriginal and/or Torres Strait Islander Health Workers and Health Practitioners' published by the National Association of Aboriginal Health Workers and Practitioners (NAATSIHWP). This document is available at https://www.naatsihwp.org.au/storage/naatsihwp-professional-scope-of-practice-7aug24_web.pdf

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 comment

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 comment

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

Respond to the question 4b:

No comment

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, including both my name and 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