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Submitted to Consultation: Proposed changes to the IVD medical device classifications and definitions
Submitted on 2025-05-23 17:01:01

Introduction

What is your name?

Name:
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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:

Within this proposed changes section -
A) Cancer. Agree the screening and staging of Cancer was at times both Class 2 or Class 3 depending on interpretation, therefore making this clear and Class 3 is acceptable.
B) Preliminary testing and monitoring devices. Agree to remove the 'Note for paragraph (f) Rule 1.3,. Similar to the change above it's use was varied as visible on approved ARTG records, with some Class 3 cell markers and some Class 2 cell markers, this will provide clarity.
D) Newborn screening devices - no further comment

While the Classification may be acceptable (including categories list C, E, and F noted as a concern in 1(b) below), it is important to note that the associated costs and audit time resulting from an up-classification or future new products of this nature, along with higher annual fees, do not contribute to increased safety for the Australian patients. None of these changes have been proposed based on post-market evidence indicating a trend towards increased adverse events. This is primarily because Class 2 and 3 IVD devices (a) utilize the same performance dataset of validation tests and (b) are seldom the sole determining factor in patient treatment, as they constitute only a small part of a comprehensive assessment of clinical signs and symptoms.

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

Respond to the question 1b:

C) Devices to manage life-threatening conditions (and infectious agents) - If this aligns well with the European IVDR and the interpretation of what might be life threatening is the same then this would be acceptable, however it is clear already that the Australian definition of life-threatening in a clinical sense differs from that in Europe. In this case if the clinical impact is considered to outweigh the global alignment and it is acknowledged 'no' other data will be available different from that globally created - then this can be acceptable. Key to this is being aware that the 'technical data' will not differ globally, therefore only audit costs and audit time will differ for the devices Classified higher in Australia (infectious diseases such as FluA/B and SARS testing and for conditions like diabetes, thrombotic disorders and anticoagulant therapy). As such it is clear that these key therapeutic diagnostic assays will be delayed to market. If however the cost, timely audit and ongoing fees for Class 3 applications, can more closely mirror that of Class 2 then this may be acceptable.

E) Control materials - While we agree with the proposed Classification for assigned and unassigned controls, we believe the current TGA proposal to separately license controls with assigned values deviates from the original intent of the Australian IVD Regulations. This approach results in double fees and double auditing of the same data set as the linked-assigned Assay. Over the past decade, assigned or dedicated controls with specific values have been audited as part of the Assay audit and licensed together, listed on the same declaration of conformity, without requiring a separate ARTG number/audit. Therefore, the current proposal may overlook that controls with assigned values have historically been approved and fully audited under the prior IVD CMDCAS/MDSAP frameworks.

Our concern with the proposal part (E) Controls is the duplication of application audit fees, annual fees, and audits for products that share data with the Assay. It may be possible to continue with the controls having assigned values linked to their respective assay ARTG as this enables direct relationship tracking. In addition two flow on considerations support this - (a) The regulation indicating a product supplied separately shall be registered separately does not strictly imply on a separate license, just that it is located on a license under an applicable GMDN and (b) that there is not likely to be a CT term

for every assigned/dedicated control that is any different from the original assay GMDN-CT Term, thus the control and the assay fall to one GMDN CT Term.

Will TGA also consider when a laboratory creates an in-house assay by assigning values to a commercially imported IVD that did not have assigned values, that this assay will be up-classified also? Similarly if a high risk infectious disease or condition assay is a Class 3 in-house IVD assay, will the TGA work with NATA not only on the equivalent expectation for testing as imposed on commercially imported assays but also ensure the same post-market obligations exist?

F) Instruments - key notes following consultation workshops of this complex proposal.
In the first instance we feel Instruments and Software may need a further consultation in order to define the framework.
- To clarify the direct wording of the proposal; that is ensure to 'keep' the introductory line of Rule 1.6 (2) being "Despite clauses 1.1 to 1.5, the following IVD medical devices are classified as Class 1 IVD medical devices or Class 1 in-house IVD medical devices:" as this statement supports (b) specimen receptacle (CT936) and (c) microbiology media.
- We do understand the proposed amendments to re-classify instruments with an independent measuring function, that do not use reagents with critical characteristics to achieve their intended purpose, based on the risks they pose, so long as the instrument is also purely for this purpose (such as the MALDI-TOF), but not where instruments run multiple assays inclusive of those assays with known characteristics, those instruments should remain aligned with the European IVDR as Class 1 IVD.
- Specifically to Rule 1.6(2)(a) we believe instruments themselves as a base functional machine should remain Class 1, inclusive of those with software aligned with published assays that drive and influence the instrument to complete the assay per it's instructions for use. As has been raised and discussed in Consultation workshops, the latter software supporting assays has already been audited with the higher classed assay and may well have been audited with the controls linked to it, TGA appear to be proposing another 'two' audits covering the instrument at a higher risk and the software at a higher risk, certainly leading to 3 or 4 ARTG applications, confusion in both change management and for new additional assays of the same Kind. We do not feel the reality of this implementation will work due to the focus on a medical and surgical procedure pack way of thinking rather than a platform agnostic SaMD way of thinking (both these being prior frameworks to leverage).
- The proposal terminology making use of the concept of medical and surgical procedure pack definition per the Act 41BF is inappropriate. Since 2020 the concept of SaMD and SiMD has been rolled out globally and there is 'no' reason why this concept can not be used for Software and Instruments, rather than medical and surgical SOPPs. In addition, the European MDCG Guidance document 2020 and the European IVD Regulations still confirms that all instruments no matter their software are Class 1 IVDs. As such Australia would be moving ahead of other global regulators creating a deterrent to advancing technologies through the currently experienced lengthy audits that have become standard in the Australian software space and to which will provide no more clinical safety than has existed and been validated by countless local and global in house laboratories for many years.

G) Software - key notes following consultation workshops of this complex proposal
In relation to (notes on F) above - similar concerns remain
- On the topic of 'adding' interpretive software different from the original instrument User Manual, and the original Assay(s) IFU run on the instrument (a platform), it is understood that there a preference by the TGA to classify the additional software at the risk of the output it is providing. This concept would have been acceptable, if it was not inextricably linked in this proposal to up-classify the instrument as well.
- Concern. When the instrument itself has not changed, nor did any other assay software already on that instrument, a change in classification due to additional software begins a flow of all sorts of impact activities. Therefore, while we may agree with the concept, we do not agree with modifying the Class of associated devices based on the different software module/apps loaded on to that instrument. The concept we propose is that SaMD-like software loaded to a 'platform' be that a mobile phone, or an app loaded to an IVD instrument are considered platform agnostic. We would consider a further definition to SiMD, There is no reason and no prior regulator definition to leverage therefore it could be possible to that SiMD could evolve into two types of software: (1) that drives and influences the instrument in line with the instruments user manual or a known assay instruction for use and (2) SiMD that provides additional interpretive function(s), all WITHOUT impacting the base instrument. The every day example here is that of heart rate monitor apps on mobile phones, these do not make a mobile phone a Class IIb Medical Device. We do not agree with the Proposal even if the idea of separate interpretive software being added could have been acceptable, not at this stage and recommend further consultation be considered.

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:

In reviewing MDCG 2020-16 rev .4 - we note that histological stains fall under Rule 5a (pages 40-41), Class A IVDs (with highlighted examples of pap stains and gram stains). In Australia Stains are classified Class 2 IVDs Rule 1.7 (all other IVDs) how do TGA propose to align this difference especially where conformity assessment evidence will mean the CE IVDR is self-certified and not audited by a notified body.

Further in MDCG 2020-16 rev .4 Rule 5a (pages 40-41), the examples given for Rule 5a include some reagents that are more specific to NGS sequencing and nucleic acid quantitation, that by some Sponsors were considered in the Australian Rule 1.7 (all other devices are Class 2 IVD's) and not in the very general laboratory reagents Rule 1.6 (1) to which are Class 1, namely as the assay related reagents were considered more specific than a general buffer or IVD tool (dedicated pipette tips). The similar question arises, how will this be handled moving forward and will clear guidance be published if TGA feel a general reagent is Class 2 while EU IVDR guidance may consider it Class A/1. If classification is the choice of the European manufacturer, and they lean towards their understanding of IVDR, is there a problem if they choose Class A/1 and not the Australian Class 2.

In relation to pathology collection, and very specifically validated and tested collection systems intended for IVD specific assays, the term CT936 specimen receptacle explicitly includes collection for these exact pathology purposes. This also aligns with the European understanding presented in the MDCG 2020-16 rev .4 Rule 5a examples on pages 41-42). It is clear that these dedicated collection kits through both the GMDN agency and the European Regulations and MDCG considered guidance are Class A/1 IVD collection kits. They are not medical or surgical procedure packs as they are 'intended for in vitro diagnostic purposes'. This must be clarified in Australian regulations or in Australian guidance. Currently there is a clash with Regulation 3.3 where the Class of devices is put before their intended purpose, having the potential to turn true pathology IVD products into high risk medical devices. We recommend that in any workshops or guidance material created to support these classification rule changes in the future, that a reminder be made for

'all' that the intended purpose is key to all global regulations and that specimen receptacle CT936 devices are not for medical and surgical use per Regulation 3.3 / Act 41BF but are rather in vitro diagnostic/pathology test kits and 'fulfil' their GMDN definition of: IVDs that are vessels with or without additives that are intended to be used for the "collection", containment, preservation and/or transport of all clinical specimens for analysis or investigation.

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:

Generally yes, with a few comments:

We have no issue with Regulation 3.3 focusing on 'intended to be used', however we do find logical fault with (9) and (10) and believe that Class is not more important than intended purpose. The European IVDR openly leave 'out' the concept of procedure packs and systems and 'enable' the actual referenced 'quote' found in this Appendix A Annex VIII (1.2) which is that the software and instrument should be considered independently and not forced into a system together. Further IVDR guidance on specimen receptacles mentioned above as part of MDCG 2020-16 rev .4 Rule 5a examples supports the fact that it is possible to write a regulation to clarify what is an IVD and what is not a procedure pack or system. Philosophically we could argue the whole pathology laboratory process from start to end is one enormous system and therefore not a clear discrete and classical medical or surgical procedure pack or orthopedic system.

No matter the definitions of life-threatening or diseases suspected of high risk of propagation, even where acceptable, the TGA must have an understanding that the level of data provided for the audit will be no different to that of a lower risk classed device as approved by several other comparable regulators. This acknowledgement could be supported through the creation of guidance, noting that the common ISO performance requirements found globally for the same assays are 'all' that is required in Australia. Data and document differences between Class 2 and 3 IVD's are insignificant. If TGA feel they are, then further consultation during the implementation phases of these changes should be held, and with lengthier transition times. We appreciate this consideration.

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 further 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:

At this stage, it is difficult to ascertain the final outcome until a revised and more concise proposal is published, incorporating feedback from this consultation.

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:

Please refer to above. 1(c)

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 appreciate the alignment with the European IVD Regulation definitions in relation to the performance testing framework for IVDs

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

Respond to the question 3b:

Near-Patient Testing - While we agree Point of Care testing is established in Australia, it may be pertinent to include within it's definition the term Near-Patient Testing. We agree that addition of “not intended for self-testing” will provide greater clarity to the definition.

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 further 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. We suggest that 2 years may be a compromise, inclusive of all 'new' applications (so as to not delay their application entry to market) and any applications recently submitted or those being up-classified and requiring an audit to do so.

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

Respond to the question 4b:

The greatest impact we see will be to the real and valid pathology clinical diagnoses where long standing and standardised instruments with functional software are imported with approvals from around the worlds leading regulators. Currently Manufacturer's already struggle with the Australian level of software auditing; particularly in terms of the number of questions and length of time to market due to many locally nuanced questions that differ despite having comparable regulator approval, multiple COR approvals in some cases. As such, having already seen this in-depth pattern of auditing for Pathology products to which a final clinical or medical diagnosis is made based off so much more than one singular test (symptoms, a barrage of other tests) the 6 months transition time is not enough for manufacturer's to build data and reports far greater than they have completed for Europe, and significantly different to that which have been built for the FDA and other comparable regulators.

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:

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