Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Consultation: Proposed changes to IVD medical device classifications and definitions

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Introduction

In-vitro diagnostic (IVD) medical devices are regulated in Australia by the Therapeutic Goods Administration (TGA) having regard to the risks (to the individual or public health) in the context of the device's intended use. All devices carry some level of potential risk, and the TGA applies scientific and clinical expertise to ensure there is a balance between the benefits and the risks.

An Action Plan for Medical Devices is a three-part strategy to strengthen Australia's regulatory system while continuing to be patient focused and have greater transparency. It outlines actions that continue to improve the safety, performance and quality of medical devices in Australia and improve health outcomes for patients who require medical devices.

The TGA has been systematically reviewing the regulations and guidance materials relating to medical devices, with progress published on the TGA website.

The proposed regulatory refinements in this consultation paper are based on the Australian Government policy to align (wherever possible) the Australian regulatory framework with the European Union. This consultation continues with the Australian Government's reform programs, aiming to strengthen the regulation of medical devices and to increase alignment with international best practice.

This consultation seeks to confirm views on where appropriate alignment should occur with the definitions, classification rules and principles of the European Regulation 2017/746 for in vitro diagnostic medical devices (IVDR), collectively referred to as the EU Regulations.

Classification of IVD medical devices

The classification rules are based on a risk-based approach, and IVDs are classified according to the health risk (either to the public or an individual) that may arise from an incorrect result.

- The higher the potential risk an incorrect result would pose, the higher the classification.
- The higher the risk class of a device, the higher the level of assessment and monitoring required to demonstrate initial and ongoing compliance to regulations.

This consultation paper aims to obtain feedback on proposed changes to:

- Australian IVD classification principles and rules
- IVD definitions.

This consultation paper does not seek feedback about IVD self-tests:

- We are planning a separate consultation about the regulation of IVD self-tests in Australia.

Approach for the alignment

The TGA has reviewed the current Australian IVD definitions, classification rules and principles. Changes are proposed to ensure IVD medical devices supplied in Australia are appropriately classified and assessed for safety and performance based on the public and personal health risks they pose to Australians.

We have compared the intent of each Australian classification rule and principle with the intent of the corresponding EU implementation rules and principles, for IVD medical devices.

We have proposed **changes** to:

- ✓ Australian classification rules and principles, that will classify devices proportionate to the health risk posed by the intended purpose, technology and use.

- ✓ Australian classification rules that adopt certain terminology from the EU classification rules for improved clarity and to ensure the rules extend to new and emerging technologies and
- ✓ Increase clarity on specific IVD terms currently not defined in the Australian Regulations.

We have proposed **no changes** where:

- ✓ Australian classification rules and principles already align with the relevant EU classification.

This consultation does not consider the Australian classification rule 1.4 for self-tests. Self-testing IVD medical devices are intended to be used by individuals with no scientific or technical expertise, or formal training in a medical field or discipline that the test relates to. In general, rule 1.4 classifies self-tests as Class 3 IVD medical devices if the condition, ailment or defect to which the test relates is inappropriate to be diagnosed or treated without consulting a health professional and beyond the ability of the average person to evaluate accurately or treat safely without adequate supervision. Supply of self-tests in Australia is also regulated under the *Therapeutic Goods (Medical Devices – Excluded purposes) Specification 2020* (made under 41BEA of the Act) that indicates which self-testing IVD medical devices for serious diseases are allowed to be supplied and those that are prohibited from supply in Australia. We are planning a separate consultation to review the regulatory controls for IVD self-tests.

Benefits of proposed changes

The proposed changes in this consultation paper seek to increase alignment between Australian and European requirements, which will result in greater consistency in the assessment processes of the IVD medical devices supplied in Australia, shorten the time taken for products to come into the Australian market and reduce regulatory burden.

It is anticipated that adopting these proposals will improve clarity and transparency, reduce public health and safety risks, and increase consumer confidence in the regulation of IVD medical devices.

Legislative changes

We are not proposing legislative wording in this consultation but rather state the intent of the proposed changes to be adopted. Where the outcome of this consultation supports changes to the Australian definitions, classification rules and principles, subject to Government approval, the legislation or regulation changes will be drafted using Australian legal terminology. Our aim is to align the intent of the Australian classification rules and principles with that of Europe, where appropriate.

Certain terminology in Australian legislation and regulation has established meanings which may not be equivalent to that defined in Europe. In these instances, it is not proposed to replace Australian definitions with EU definitions.

Proposed changes

The IVD classification rules (Schedule 2A) and the principles for applying those rules (Regulation 3.3) are in the *Therapeutic Goods (Medical Devices) Regulations 2002*. The TGA proposes to amend those Regulations to align with the classification and implementation rules (Annex VIII) of the EU IVD Regulations (2017/746).

The proposed changes are grouped into three sections based on the anticipated impact on products already approved for supply in Australia. Approved products refer to the products included in the Australian Register of Therapeutic Goods (ARTG):

A. Classification changes with an impact on approved IVDs
B. Classification changes with no impact on approved IVDs
C. Definition changes with no impact on approved IVDs

Classification changes with an impact on approved IVDs

To ensure the classification principles and rules for IVD medical devices are clear and proportionate to the health risk posed by the current technology and use, we propose changes to the current Australian classification rules and principles as detailed below. The proposed changes will have an impact on new inclusions and existing entries included in the ARTG.

A. Cancer tests

Devices used for screening of cancer are currently classified as Class 2 IVD medical devices. The TGA proposes to re-classify these tests to Class 3 IVD medical devices and make additions to the permitted use.

European IVD Regulation 2017/746	Current Australian regulation	Proposed amendments
2.3 Rule 3 Devices are classified as Class C if they are intended:	1.3 An IVD medical device is classified as a Class 3 IVD medical device or a Class 3 in-house IVD medical device if it is intended for any of the following uses:	**The TGA proposes to include 'screening' and 'staging' in addition to 'diagnosis of cancer'**, to ensure the classification is proportionate to the risk posed to the patient and this also aligns with the EU rule.
(h) to be used in **screening**, diagnosis, or **staging** of cancer;	(f)(iii) in the diagnosis of cancer	

Rationale for proposed amendments:

Cancer is a life-threatening disease and poses a high personal risk. Hence an IVD medical device used to detect cancer is appropriate to be classified as a Class 3 IVD medical device when used either for screening, diagnosis (or aid in diagnosis) or staging.

Impact:

Devices used for cancer screening are currently classified as Class 2 IVD medical devices. The proposed change will result in re-classification of these devices to Class 3 IVD medical devices.

Sponsors of these devices seeking inclusion or currently approved for supply will be required to apply to the TGA to reclassify their device, in accordance with transitional timelines and provisions.

Note: Although there is a proposed change to tests used for cancer staging, the TGA does not expect any impact to the classification of existing tests used for cancer staging. These devices are currently under a different classification rule for disease staging (Rule 1.3(f)(ii)) as Class 3 IVD medical devices. Hence, re-classification would not be required for these IVD medical devices.

Examples (non-exhaustive):

Tests intended for cancer screening such as faecal occult blood (FOB), total prostate specific antigen (PSA), CA-125, Carcinoembryonic Antigen (CEA) would be classified as Class 3 IVD medical devices.

B. Preliminary testing and monitoring devices

Devices used for selective therapy, disease staging, and cancer diagnosis are currently classified as Class 3 IVD medical devices. Due to the note associated with the classification rule 1.3 (f) (see table below), when these devices are used for preliminary testing or for monitoring of disease, they are classified as Class 2 IVD medical devices. The TGA proposes to re-classify these tests to Class 3 IVD medical devices.

European IVD Regulation 2017/746	Current Australian regulation	Proposed amendments
No equivalent note.	Note for paragraph (f): An IVD medical device would be classified as Class 2 if: (a) a therapy decision would usually be made only after further investigation; or (b) the device is used for monitoring.	**The TGA proposes to remove 'Note for paragraph (f)'** to ensure the classification is proportionate to the risk posed to the patient.

Rationale for proposed amendments:

Note for paragraph (f) currently applies to devices used for selective therapy and management, disease staging, and cancer diagnosis (Rule 1.3(f)). These devices present similar personal health risks when used for initial investigation or for monitoring and should be regulated the same as any device used for these purposes. Users act on the results from a preliminary or monitoring test to decide on follow up action. A positive result may prompt a different course of action for further testing and treatment, as compared to a negative or normal result. Therefore, it is required that the same level of regulatory oversight should apply to these tests as they can identify life-threatening and serious diseases, even when used for preliminary testing or monitoring.

Impact:

Devices used for selective therapy and management, disease staging, and cancer diagnosis, when used for preliminary testing or monitoring, are currently classified as Class 2 IVD medical devices. The proposed change will require re-classification of these devices to Class 3 IVD medical devices.

Sponsors of these devices seeking for inclusion and currently approved for supply will be required to apply to the TGA to reclassify their devices, in accordance with transitional timelines and provisions.

Examples (non-exhaustive):

Immunohistology cell marker IVD medical devices used in cancer testing will be classified as Class 3 IVD medical devices.

C. Devices used to manage life-threatening conditions

Devices used for management of patients suffering from a 'life-threatening infectious disease' are currently classified as Class 3 IVD medical devices, while certain tests used for management of a 'life-threatening condition' are classified as Class 2 IVD medical devices. The TGA proposes to re-classify all tests used for management of patients suffering from a 'life-threatening condition' as Class 3 IVD medical devices.

European IVD Regulation 2017/746	Current Australian regulation	Proposed amendments
2.3 Rule 3 Devices are classified as Class C if they are intended:	1.3 An IVD medical device is classified as a Class 3 IVD medical device or a Class 3 in-house IVD medical device if it is intended for any of the following uses:	**The TGA proposes to replace 'life-threatening infectious disease' with 'life-threatening disease or condition'** to ensure the classification is proportionate to the

European IVD Regulation 2017/746	Current Australian regulation	Proposed amendments
(k) for management of patients suffering from a life-threatening **disease or condition**;	(i) the management of patients suffering from a life-threatening **infectious** disease;	risk posed to the patient and this also aligns with the EU rule.

Rationale for proposed amendments:

A life-threatening condition is defined as a condition where the prominent feature (i.e., affecting an important portion of the target population) is a serious illness from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of treatment based on mortality and life expectancy data. Life-threatening diseases and conditions, irrespective of whether they are infectious or non-infectious, pose a high personal health risk. Devices for management of these diseases and conditions provide an important, critical, or sole determinant for the correct patient management decision such as treatments/interventions, and hence are considered appropriate to be classified as Class 3 IVD medical devices.

Impact:

Devices used for management of life-threatening non-infectious diseases and conditions, are currently classified as Class 2 IVD medical devices. The proposed change will result in re-classification of these devices to Class 3 IVD medical devices.

Sponsors of these devices seeking for inclusion and currently approved for supply will be required to apply to the TGA to reclassify their devices, in accordance with transitional timelines and provisions.

Examples (non-exhaustive):

- HbA1c and blood glucose tests for management of patients with diabetes
- Measurement of D-Dimers in patients with thrombotic disorders
- Monitoring anticoagulant therapy with PT (Partial thromboplastin time)

D. Newborn screening devices

There is no specific rule in Australia for classification of IVD medical devices used for congenital screening in new-born babies. These screening tests are used to detect disorders that could lead to life-threatening situations or severe disabilities. Certain tests used for newborn screening are currently classified as Class 2 IVD medical devices. The TGA proposes to adopt the EU classification rule and re-classify all tests used for new-born screening to Class 3 IVD medical devices.

European IVD Regulation 2017/746	Current Australian regulation	Proposed amendments
2.3 Rule 3 Devices are classified as Class C if they are intended: (m) for screening for congenital disorders in new-born babies where failure to detect and treat such disorders could lead to life-threatening situations or severe disabilities.	No equivalent rule.	**The TGA proposes to adopt this rule** to ensure the classification is proportionate to the risk posed to the patient and this also aligns with the EU rule.

Rationale for proposed amendments:

Devices for newborn screening are those intended for screening new-born babies for a defect, such as a structural or functional abnormality, including metabolic disorders. An erroneous test result could lead to a failure to detect and treat such birth disorders, which could lead to a life-threatening situation or severe disability of the individual. These devices pose a high personal health risk and hence are considered appropriate to be classified as Class 3 IVD medical devices.

Impact:

The proposed change will result in a separate rule for classification of IVD medical devices used for newborn screening. Currently, some of these devices are regulated under the genetic testing rule and classified as Class 3 IVD medical devices and non-genetic tests are classified as Class 2 IVD medical devices. The proposed change would mean that non-genetic tests used for newborn screening of life-threatening situations or severe disabilities, will be reclassified to Class 3 IVD medical devices.

Examples (non-exhaustive):

- Haemoglobin High Performance Liquid Chromatography (HPLC) for newborn screening of haemoglobinopathies.
- Tests for phenylketonuria (PKU).
- Tests for congenital hypothyroidism and Congenital adrenal hyperplasia.

E. Control materials

Devices that are intended to be used as non-assay specific quality control materials are currently classified as Class 2 IVD medical devices. This includes non-assay specific control materials with assigned or unassigned values. The TGA proposes to re-classify the control materials with assigned values (i.e. values that are assigned by the manufacturer and not the user), to Class 3 and Class 4 IVD medical devices when used with Class 3 and Class 4 tests respectively. Control materials with unassigned values will continue to be classified as Class 2 IVD medical devices.

European IVD Regulation 2017/746	Current Australian regulation	Proposed amendments
2.7 Rule 7 Devices which are controls **without a quantitative or qualitative assigned value** are classified as class B.	1.5 Despite clauses 1.1 to 1.4, an IVD medical device that is intended to be used as non-assay-specific quality control material is classified as a Class 2 IVD medical device or a Class 2 in-house IVD medical device.	**The TGA proposes to classify controls based on assigned values** to ensure the classification is appropriate to the current use and risks posed to the patient and this also aligns with the EU rule.

Rationale for proposed amendments:

Control materials are substances, materials or articles intended by its manufacturer to be used to verify the performance characteristics of a device. Controls used for one assay (assay specific), or multiple assays (non-assay specific) have similar risks and should be regulated in the same way.

Controls where values are assigned by the manufacturer and not the user (assigned values) may be intended for one specific analyte or multiple analytes. Since they are used to monitor performance of devices of various classes, they should be classified in the same class as the device.

Controls where values are assigned by the user and not the manufacturer (unassigned controls) are appropriate to be classified as Class 2 IVD medical devices.

Impact:

Currently, all non-assay specific quality control materials (those used with multiple assays or kits) are classified as Class 2 IVD medical devices. The proposed changes will result in re-classification of some non-assay specific control materials with assigned values. These control materials will be classified as Class 3 or Class 4 based on the associated IVD medical devices.

Sponsors of these devices seeking for inclusion or currently approved for supply will be required to apply to the TGA to reclassify their devices, in accordance with transitional timelines and provisions.

Examples (non-exhaustive):

- Control materials used to verify the performance of HIV assays (and can be used with more than one HIV assay), where the manufacturer has assigned a qualitative (positive or negative) or quantitative value will be classified as Class 4 IVD medical devices.

- Control materials used to verify the performance of Syphilis assays (and can be used with more than one Syphilis assay), where the manufacturer has assigned a qualitative (positive or negative) or quantitative value will be classified as Class 3 IVD medical devices.
- Control materials used to verify the performance of TSH assays (and can be used with more than one TSH assay), where the manufacturer has assigned quantitative value will continue to be classified as Class 2 IVD medical devices.

Note: Any control material where values are expected to be assigned by the user and not provided by the manufacturer (unassigned controls) will continue to be classified as Class 2 IVD medical devices. For example, control materials used to verify performance of HIV, Syphilis, TSH assays where the manufacturer has not provided a qualitative or quantitative value.

Control materials that are assay-specific will continue to be classified as the associated assay. For example, control materials used to verify the performance of a single HIV assay are currently classified as a Class 4 IVD medical device and will continue to be classified as such.

F. Instruments

All instruments are currently classified as Class 1 IVD medical devices. The TGA proposes 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. Reagents with critical characteristics are those essential components of an IVD medical device whose unique characteristics are crucial to device performance (e.g., binding proteins, antibodies or conjugated antibodies, etc.).

European IVD Regulation 2017/746	Current Australian regulation	Proposed amendments
2.5 Rule 5 The following devices are classified as class A:	1.6 (2) **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:	**Remove 'Despite clauses 1.1 to 1.5' from statement 1.6 (2)** to ensure the classification is appropriate to the current use and risks posed to the patient and this also aligns with the EU rule**.**
(b) Instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures	(a) an instrument, intended by the manufacturer, to be specifically used for in vitro diagnostic procedures;	

Rationale for proposed amendments:

Instruments are low risk devices and classified as Class 1, since the reagents and kits used on these instruments are separately classified and assessed based on their intended purpose and the risks they pose. Due to their interdependence, the performance of the instrument is assessed as part of the assessment for reagent. However, if the instrument has an independent measuring function which does not use any additional reagents with critical characteristics, it should be classified based on its intended purpose, in line with the risk posed.

Impact:

All instruments and analysers are currently classified as Class 1 IVD medical devices. The proposed change to remove statement '*Despite clauses 1.1 to 1.5'* will result in re-classification of some Class 1 instruments / analysers with an independent measuring function that do not use any additional reagents with critical characteristics.

Sponsors of these devices seeking for inclusion or those approved for supply will be required to apply to the TGA to reclassify their device, in accordance with transitional timelines and provisions.

Note: All other instruments intended to be used with critical reagents and kits such as those for detecting infectious disease antigens and antibodies, electrolyte analysers to be used with cartridges, clinical chemistry analysers, instruments used for PCR analysis and for sequencing, etc. will continue to be classified as Class 1 IVD medical devices.

Examples (non-exhaustive):

Cell counting analysers used in haematology, ion selective electrodes, instruments measuring blood gases, electrolytes or glucose via its sensors, specific gravity measurements in urine analysis, mass

spectrophotometer for bacteria identification, breath analyser for SARS-CoV-2 detecting volatile compounds using mass spectrometry, erythrocyte sedimentation rate analyser, etc. are examples of instruments with an independent measuring function and will be re-classified based on their intended purpose.

G. Software

Currently, IVD software that drives or influences a medical device has the same classification as that medical device. The TGA proposes to amend the classification principle to clarify that software that does not exclusively drive or influence the device and is independent of the device is classified separately.

European IVD Regulation 2017/746	Current Australian regulation	Proposed amendments
Annex VIII, 1.4 Software, which drives a device or influences the use of a device, shall fall within the same class as the device. **If the software is independent of any other device, it shall be classified in its own right.**	Regulation 3.3 (5) If a medical device is driven, or influenced, by an item of software, the software has the same classification as the medical device.	**The TGA proposes to classify software that does not exclusively drive or influence the device based on its intended purpose** to ensure the classification is appropriate to the current use and risks posed to the patient and this also aligns with the EU rule.

Rationale for proposed amendments:

The definition of an IVD medical device in the *Therapeutic Goods (Medical Devices) Regulations 2002* includes software. IVD software is software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a "IVD medical device" in the Regulations. Software may be considered as IVD software regardless of its location (e.g. operating in the cloud, on a computer, on a mobile phone, or as an additional functionality on a hardware medical device) and regardless of the intended user (laboratories, healthcare professionals or laypersons). The regulations make no distinction between different forms of software; all software that meets the definition of an IVD medical device must have evidence to assure the product's safety, quality, and performance.

IVD software may be independent, or drive (operate) / influence the use of an IVD medical device.

- IVD Software is independent when it has its own intended medical purpose and meets the definition of an IVD medical device on its own. These devices are currently classified on their own, based on their intended purpose. This is proportionate to the risks they pose.
- IVD Software intended to drive or influence the use of a (hardware) medical device does not have or perform a medical purpose on its own, nor does it create information on its own. This software generally operates or controls the device either through an interface (e.g., software, hardware) or via the operator of this device and/or provides supply output related to the (hardware) functioning of that device. This software may be an integral component of the IVD medical device (i.e. the instrument with the installed/ embedded software is a single IVD) or may be supplied separately.
  - IVD Software that exclusively drives or influences an IVD medical device (instrument or analyser) has the same classification as the medical device. As the current IVD classification rules specify that all instruments that are IVDs are Class 1 IVDs, the software is therefore also a Class 1 IVD. However, this consultation paper proposes to reclassify instruments with an independent measuring function (See previous section on 'Instruments). Therefore, software driving or influencing an instrument must be classified based on the classification of the instrument.
  - IVD software which drives or influences an IVD medical device (instrument or analyser) can also have a medical purpose and do more than only driving or influencing an IVD. This software in addition could have analytical or interpretative functionality. Currently, software that drives or influences an instrument has the same classification as the instrument. However, it is appropriate that such software be classified based on their intended purpose and the risks they pose, rather than have the same classification as the instrument. If the software is an integral part or component of the instrument, the final classification of the

device will be assigned taking into consideration the classification of both the instrument and the IVD software. The device should have the highest level of classification that applies.

Impact:

All instruments are currently classified as Class 1 IVD medical devices. The proposed change in the previous section on 'Instruments' will result in re-classification of some Class 1 instruments with an independent measuring function that do not use any additional reagents with critical characteristics. IVD software used to exclusively drive / influence these instruments will be reclassified accordingly. If the IVD software is an integral component of the instrument, the software with the instrument is a single IVD medical device and reclassified as one system (hardware/software). IVD software if supplied separately, will be reclassified on its own, based on the classification of the instrument.

IVD software which does more than just driving or influencing an instrument will be reclassified based on their intended purpose and the risks they pose. If the IVD software is an integral component of the instrument, the software with the instrument is a single IVD medical device and reclassified as one system (hardware/software) based on the highest level of classification. IVD software if supplied separately, will be reclassified on its own, regardless of the instrument classification.

Sponsors of these devices seeking for inclusion or currently approved for supply will be required to apply to the TGA to reclassify their device, in accordance with transitional timelines and provisions.

Examples (non-exhaustive):

- Diagnostic system comprising of a digital slide scanner and an image analysis software using an AI algorithm for grouping of PAP-stained cervical smears as either normal or cancerous will be classified as a Class 3 IVD medical device.
- Flow cytometry data analysis software that allows automated analysis, integration, and interpretation of data from flow cytometry instruments for management of leukemias will be classified as Class 3 IVD.
- Software influencing an instrument which also includes selection of relevant fields for subsequent analysis (or for the creation and viewing of digital images), identification and pre-characterisation of cells will be classified as a Class 2 IVD.
- Software driving and influencing an ELISA microplate washer that is intended to run the instrument, will continue to be classified as Class 1 IVD medical device.

Question 1: Proposed changes to classification rules and principles that have an impact on approved products

(a) Do you agree with the proposals to change the Australian classification rules and principles as specified in Section A, noting the changes are reflective of the regulatory scrutiny based on the associated health risks?

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

(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?

Classification changes with no impact on approved IVDs

We are proposing to adopt certain terminology from the EU classification rules in the Australian classification rules for improved clarity and to ensure the rules extend to new and emerging technology such as:

- adopting certain terminologies to ensure the classification rules extend to new and emerging technologies (e.g. adoption of the term ‘cell administration’ to capture donor screening for T-cells used to generate chimeric antigen receptor (CAR) T-cells for leukemia treatments).
- proposing to include terminology for all stages of foetal development including ‘embryo’, and the population group that will be affected by the test result including ‘offspring’.

It is anticipated that the proposed changes will not have any impact on the existing IVD medical devices approved for supply.

Appendix A provides an explanation and rationale on the proposed regulatory changes.

Question 2: Proposed changes to classification rules that have no impact on approved products

a) Do you agree with the proposals to adopt certain terminology in the Australian classification rules as specified in Appendix A, noting the changes are to improve clarity?

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

c) Do you agree the proposed changes in Appendix A, would not result in any impact on existing ARTG entries of IVD medical devices?

d) Are there any other classification rules, relating to the IVD medical devices, that need to be considered as part of this proposal?

Please note:
There are some Australian IVD classification rules that differ from the European classification rules that we propose to retain. These include:

- SARS-CoV-2 IVD medical devices are classified as Class D in Europe. However, since the TGA has undertaken a full desktop evaluation of all tests supplied in Australia equivalent to a design examination, and will continue to do so via application audits, tests for detection of COVID-19 (SARS-CoV-2) will continue to be classified as Class 3 IVD medical devices in Australia. Sponsors also have post-market obligations to monitor the performance of their devices against the circulating and emerging variants of concern and notify the TGA accordingly to ensure the associated risks are mitigated. There is currently no benefit to up classifying these tests in Australia.
- Influenza (not highly virulent) IVD medical devices are classified as Class B, whereas IVD medical devices for detecting highly virulent Influenza virus are classified as Class D in Europe. However, these are classified as Class 3 IVD medical devices in Australia since Influenza is a serious illness from which death is reasonably likely to occur within a matter of months, if not treated appropriately. These IVDs will continue to be classified as Class 3 IVD medical devices in Australia.
- The European IVD Regulation requires class A sterile IVDs to be certified by a Notified Body. We propose to not require this in Australia and continue to treat Class A sterile IVDs as class 1 IVDs in Australia. Sterile IVDs must comply with the relevant Essential Principles for sterile products, and manufacturers of Class 1 sterile devices need to make a Declaration of Conformity with all the relevant Essential Principles, under Schedule 3, clause 6.6 of the Australian Medical Device Regulations.

Definition changes with no impact on approved IVDs

Some IVD-specific terms used in the Essential Principles of *Therapeutic Goods (Medical Devices) Regulations 2002*, are not defined in Australian legislation. Therefore, for the purposes of greater clarity, definitions of some key terms are proposed to be adopted from the EU framework. Additionally, to ensure emerging technologies are regulated appropriately, definitions of some key terms are proposed to be modified.

The TGA does not anticipate any impact on existing ARTG entries. Appendix B provides a detailed comparison of the Australian and EU definitions, the proposed amendments, and the rationale.

Question 3: Proposed changes to the IVD definitions

a) Do you agree with the proposal to amend the Australian definitions as specified in Appendix B?

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

c) Are there any other definitions, relating to the IVD medical devices, that need to be considered as part of this proposal?

Impacts

What would change for sponsors?

Sponsors need to verify their devices currently included in the ARTG are classified correctly, and that they have or can make available suitable evidence to demonstrate the safety, quality, and performance of their IVDs. Where applicable, if the device is subject to re-classification, they will need to apply to the TGA to re-classify their devices in accordance with the transition arrangements and the timelines.

What would change for manufacturers?

Manufacturers need to reassess the compliance of their IVD medical devices with any revised classification rules and ensure they have all the appropriate documentation required to demonstrate compliance with any relevant regulatory requirements.

Transition arrangements

We propose that the transition timelines for re-classification of impacted existing applications and ARTG entries would be six months after the current EU IVDR transition deadlines, pending approval by the Government. This would mean different deadlines for each class of IVD as follows:

- Until 30 June 2028 for Class 4 IVDs
- Until 30 June 2029 for Class 3 IVDs
- Until 30 June 2030 for Class 2 IVDs.

Question 4: Transition period

(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?

(b) Provide reasons for your position (optional).

Your feedback

Although the TGA intends to take the EU IVD medical device framework into account, we acknowledge that legislation cannot always be successfully replicated across jurisdictions. The Australian legislative instruments are structured differently, and there is variation in the legal terminology acceptable in each jurisdiction. Therefore, your views regarding the impact of changes to the Australian IVD classification framework and the IVD definitions are very important to us.

Engagement

Wherever practicable and possible, in addition to this consultation paper, TGA will also be:

- Liaising with relevant industry peak bodies to provide education, awareness, and feedback about this proposal.
- Providing relevant communication materials on the TGA website.
- Updating guidance on ‘Classification of IVD medical devices’ with explanation of classification rules, terms, and examples.

Appendices

Appendix A: Proposed classification changes with no impact on approved IVDs

European IVD Regulation 2017/746 (Annex VIII)	Current Australian regulation	Proposed amendments
1.2 If the device in question is **intended to be used** in combination with another device, the classification rules shall apply separately to each of the devices.	Regulation 3.3(3) If a medical device is **designed to be used** in combination with another medical device, each of the devices is classified separately.	**The TGA proposes to replace 'designed to be used' with 'intended to be used'.** Medical devices are classified based on their intended purpose. Hence it is appropriate to use the term 'intended to be used' to capture the intent of this rule. We expect that this change will provide greater clarity on our current regulatory approach and will not impact any devices currently included in the ARTG.
2.1 Rule 1 Devices intended to be used for the following purposes are classified as class D:	1.1 An IVD medical device intended to be used for any of the following purposes is classified as a Class 4 IVD medical device or a Class 4 in-house IVD medical device.	**The TGA proposes the following:**
- detection of the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion, transplantation or **cell administration**.	(a) To detect the presence of, or exposure to, transmissible agents in blood, blood components, **blood products**, cells, tissues or organs or any derivatives of these **products of human or animal origin**, in order to assess their suitability for transfusion or transplantation.	• **Add 'cell administration'** to the Australian classification rule to ensure recent advances in technology are captured. • **Retain 'blood products' and 'products of human or animal origin'** to align with the Australian biologicals framework. We expect that this change will provide greater clarity on our current regulatory approach and

European IVD Regulation 2017/746 (Annex VIII)	Current Australian regulation	Proposed amendments
		will not impact any devices currently included in the ARTG.
- detection of the presence of, or exposure to, a transmissible agent that causes a **life-threatening disease** with a high or **suspected** high risk of propagation.	(b) To detect the presence of, or exposure to, a transmissible agent that causes a **serious disease** with a high risk of propagation in Australia.	• **Retain 'serious disease'** to align with the Australian definition of serious disease which includes mitigation of public health impact of the disease. • **Add 'life-threatening disease'** to the Australian classification rule to be consistent with the terminology used in other classification rules. • **Add 'suspected high risk of propagation'** to ensure emerging diseases without well-established risk of propagation are captured in line with the health risk that they may pose. We expect that this change will provide greater clarity on our current regulatory approach, capture emerging diseases and also align with the EU rule. This will not impact any devices currently included in the ARTG since life-threatening diseases with a public health impact are already captured under the definition of serious disease.
2.2 Rule 2 Devices intended to be used for blood grouping, or to determine foeto-maternal blood group incompatibility, or for tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion of transplantation or **cell administration**, are classified as class C, except	1.2 (1) An IVD medical device is classified as a Class 3 IVD medical device or a Class 3 in-house IVD medical device if: (a) the device is intended to be used for detection of **biological markers** in order to assess the immunological compatibility of blood, blood components, **blood products**, cells, tissues or	**The TGA proposes to:** • **Add 'cell administration'** to the Australian classification rule to ensure recent advances in technology are captured.

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when intended to determine any of the following markers:	organs that are intended for transfusion or transplantation; and (b) the device is not a device mentioned in subclause (2).	• **Retain 'blood products' and 'biological markers'** to align with the Australian biologicals framework. We expect that this change will provide greater clarity on our current regulatory approach and will not impact any devices currently included in the ARTG.
2.3 Rule 3 Devices are classified as class C if they are intended: (b) for detecting the presence in cerebrospinal fluid or blood of an infectious agent **without a high or suspected high** risk of propagation;	1.3 An IVD medical device is classified as a Class 3 IVD medical device or a Class 3 in-house IVD medical device if it is intended for any of the following uses: (b) detecting the presence in cerebrospinal fluid or blood of an infectious agent **with a risk of limited** propagation;	**The TGA proposes the following:** • **Replace 'with a risk of limited propagation' with 'without a high or suspected high risk of propagation'** to be consistent with and align with Australian classification Rule 1.1(b). We expect that this change will provide greater clarity on our current regulatory approach and will not impact any devices currently included in the ARTG.
(c) for detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual, foetus or **embryo** being tested, or to the **individual's offspring**;	(c) detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual or foetus being tested;	• **Add 'embryo' and 'individual's offspring'** to the Australian classification rule for improved clarity to capture all stages of foetal development including embryo and the population group that will be affected by the test result including offspring.

European IVD Regulation 2017/746 (Annex VIII)	Current Australian regulation	Proposed amendments
		In practice, this rule is currently being applied to all stages of foetal development. We expect that this change will provide greater clarity on our current regulatory approach and will not impact any devices currently included in the ARTG.
(e) for determining infective disease status or immune status, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the **patient's offspring**;	(e) determining infective disease status or immune status, if there is a risk that an erroneous result will lead to a patient management decision resulting in an **imminent** life-threatening situation for the patient;	• **Add 'patient's offspring'** to the Australian classification rule to capture the population group that will be affected by the test result including offspring. • **Remove 'imminent'** from the Australian classification rule. A life-threatening situation, imminent or not imminent, poses a high personal health risk and is considered appropriate to be classified as a Class 3 device. In practice, this rule is currently being applied to life threatening situations irrespective of whether the results impact the patient themselves or their offspring. We expect that this change will provide greater clarity on our current regulatory approach and will not impact any devices currently included in the ARTG.
No equivalent rule	(f) the selection of patients:	• **Remove the statement 'the selection of patients:'.** The statement 'for the selection of patients' currently applies to devices used for selective therapy and management, disease staging, and cancer diagnosis. Selection of patients already implies that devices are used for selective therapy. Devices for disease staging and cancer diagnosis

European IVD Regulation 2017/746 (Annex VIII)	Current Australian regulation	Proposed amendments
		are not used for selection of patients. The statement is ambiguous and hence, is proposed to be removed. We expect that this change will provide greater clarity on our current regulatory approach and will not impact any devices currently included in the ARTG.
(j) for monitoring of levels of medicinal products, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision results in a life-threatening situation for the patient or the **patient's offspring**;	(h) to monitor levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an **immediate** life-threatening situation for the patient;	• **Remove 'immediate'** from the Australian classification rule. A life-threatening situation, immediate or not, poses a high personal health risk (e.g. for some drug monitoring devices) and is considered appropriate to be classified as a Class 3 device. • **Add 'patient's offspring'** to the Australian classification rule to capture the population group that will be affected by the test result including offspring. In practice, this rule is currently being applied to life threatening situations irrespective of whether the results impact the patient themselves or their offspring. We expect that this change will provide greater clarity on our current regulatory approach and will not impact any devices currently included in the ARTG.
(l) for screening in congenital disorders in the **embryo** or foetus;	(j) screening for congenital disorders in a foetus.	• **Add 'embryo'** to the Australian classification rule to capture all stages of foetal development including embryo.

European IVD Regulation 2017/746 (Annex VIII)	Current Australian regulation	Proposed amendments
		In practice, this rule is currently being applied to all stages of foetal development. We expect that this change will provide greater clarity on our current regulatory approach and will not impact any devices currently included in the ARTG.
2.5 Rule 5 The following devices are classified as class A: (a) Products for general laboratory use, accessories which possess **no critical characteristics**, buffer solutions, washing solutions, and general culture media and histological stains, intended by the manufacturer to make them suitable for in vitro diagnostic procedures relating to a specific examination	1.6 (1) A **reagent or other article** that possesses **specific characteristics**, intended by the manufacturer, to make it suitable for in vitro diagnostic procedures related to a specific examination is classified as a Class 1 IVD medical device or a Class 1 in-house IVD medical device.	**The TGA proposes the following changes:** • **Replace 'specific characteristics' with 'no critical characteristics'**. The term 'no critical characteristics' is in line with the Australian risk-based framework. • **Retain the term 'reagent or other article'** since buffer solutions, washing solutions and histological stains (mentioned in the EU rule) are captured under this term. In practice, this rule is currently being applied to those reagents whose unique characteristics are not crucial to device performance. This is better captured by 'no critical characteristics' rather than 'specific characteristics'. We expect that this change will provide greater clarity on our current regulatory approach and will not impact any devices currently included in the ARTG.

Appendix B: Proposed changes to IVD definitions

European IVD Regulation 2017/746 (Article 2)	Current Australian definition (Therapeutic Goods Regulations 2002)	Proposed amendments
'Performance Evaluation' means an assessment and analysis of data to establish or verify the scientific validity, the analytical and, where applicable, the clinical performance of a device.	No definition in the Australian Regulations.	There is currently no definition of performance evaluation in Australian legislation. The term is used in the Therapeutic Goods (Medical Devices) Regulations 2002, Essential Principle 13. Therefore, for the purposes of clarity and consistency**, TGA proposes that the EU definition be adopted into Australian legislation.**
'In Vitro Diagnostic Medical Device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following: (a) concerning a physiological or pathological process or state; (b) concerning congenital physical or mental impairments; (c) **concerning the predisposition to a medical condition or a disease**; (d) to determine the safety and compatibility with potential recipients;	**IVD medical device**, or in vitro diagnostic medical device, means a medical device that is: (a) a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with another diagnostic product for in vitro use; and (b) intended by the manufacturer to be used in vitro for the examination of a specimen derived from the human body, solely or principally for: (i) giving information about a physiological or pathological state or a congenital abnormality; or (ii) determining safety and compatibility with a potential recipient; or (iii) monitoring therapeutic measures; and **(c) not a product that is:**	**TGA proposes to amend the Australian definition:** **To include the following in paragraph (b)**, which encompasses emerging areas of IVDs: – concerning the predisposition to a medical condition or a disease – to define or monitor therapeutic measures **to remove paragraph (c)** as this has been covered in the Australian IVD classification rule 1.6 and to remove any potential ambiguity regarding the products that are not an IVD medical device.

European IVD Regulation 2017/746 (Article 2)	Current Australian definition (Therapeutic Goods Regulations 2002)	Proposed amendments
(e) to predict treatment response or reactions; (f) **to define or monitoring therapeutic measures**. Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices.	**(i) intended for general laboratory use; and** **(ii) not manufactured, sold or presented for use as an IVD medical device.**	
'Device For Near-Patient Testing' means any device that is **not intended for self-testing** but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient by a health professional;	**Point of care testing**, for an IVD medical device, means testing performed outside the laboratory environment, near to or at the side of the patient, that is not done under the supervision of a trained laboratory professional.	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.
'Analytical Performance' means the ability of a device to correctly detect or measure a particular analyte;	No definition in the Australian Regulations.	There is currently no definition of analytical performance in Australian legislation. The term is used in the Therapeutic Goods (Medical Devices) Regulations 2002, Essential Principle 13. Therefore, for the purposes of clarity and consistency, **TGA proposes that the EU definition be adopted into Australian legislation.**
'Calibrator' means a measurement reference material used in the calibration of a device;	No definition in the Australian Regulations.	There is currently no definition of calibrator in Australian legislation. The term is used in the Therapeutic Goods (Medical Devices) Regulations 2002, Essential Principle 15. Therefore, for the purposes of clarity and consistency, **TGA**

European IVD Regulation 2017/746 (Article 2)	Current Australian definition (Therapeutic Goods Regulations 2002)	Proposed amendments
		proposes that the EU definition be adopted into Australian legislation.
'Control Material' means a substance, material or article intended by its manufacturer to be used to verify the performance characteristics of a device;	No definition in the Australian Regulations.	There is currently no definition of control material in Australian legislation. The term is used in the Therapeutic Goods (Medical Devices) Regulations 2002, Essential Principle 15. Therefore, for the purposes of clarity and consistency, **TGA proposes that the EU definition be adopted into Australian legislation.**
'Companion diagnostic' means a device which is essential for the safe and effective use of a corresponding medicinal product to: (a) identify, before and/or during treatment, patients who are most likely to benefit from the **corresponding** medicinal product; or (b) identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the **corresponding** medicinal product;	**IVD companion diagnostic** means an IVD medical device: (a) that is intended by the manufacturer to be used for the examination of a specimen from the body of an individual: (i) to identify whether the individual would be likely to benefit from the use of **a particular** medicine or biological; or (ii) to identify whether the individual is likely to be at particular risk of a serious adverse reaction to the use of **a particular** medicine or biological; or (iii) to monitor the individual's response to the use of **a particular** medicine or biological; and (b) that is mentioned in product information for the medicine or biological as being essential for the safe and effective use of the medicine or biological; and (c) if the medicine or biological comprises blood, a blood component, cells, tissue or an organ, from a donor other than the individual—that is not intended by the manufacturer to be used for the examination of the specimen merely	**TGA proposes to amend the Australian definition as follow:** (i) to identify whether the individual would be likely to benefit from the use of **corresponding** medicine or biological **products**; or (ii) to identify whether the individual is likely to be at particular risk of a serious adverse reaction to the use of **corresponding** medicine or biological **products**; or (iii) to monitor the individual's response to the use of **corresponding** medicine or biological **products**; and The current definition of a companion diagnostic makes reference to "a particular" medicine or biological. This is interpreted to mean that CDx IVDs must have an intended purpose which specifically names the medicine or biological. IVDs that make broad intended purpose statements to cover classes of medicines, for example, tyrosine

European IVD Regulation 2017/746 (Article 2)	Current Australian definition (Therapeutic Goods Regulations 2002)	Proposed amendments
	to determine whether the medicine or biological is compatible with the individual.	kinase inhibitors, do not specify "a particular" medicine, rather an entire class of medicines, and under the current companion diagnostic definition would not be considered a CDx IVD. We propose to **add "corresponding medicine or biological products"** to capture CDx IVDs intended to support the safe and effective use of medicines/biologicals that may not specifically name a medicine/biological, but a **class of medicines/biologicals**.

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