



**Australian Government**

**Department of Health and Aged Care**

Therapeutic Goods Administration

# Medical Devices – Essential Principles for Safety and Performance

## Part 2: Proposed alignment with the European Regulations

Version 1.0, August 2024

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## About

The medical device regulatory framework in Australia is based on globally recognised principles, with added assurance by the Therapeutic Goods Administration (TGA).

An *Action Plan for Medical Devices*<sup>1</sup> is a three-part strategy that aims to strengthen Australia's regulatory system whilst 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.

This consultation focuses on Part 2 of reviewing the Australian (AUS) Essential Principles for Safety and Performance of medical devices to ensure they remain relevant. It also identifies where potential strengthening of the regulations could occur.

The regulatory reforms in this consultation are based on the Government policy as agreed in 2016 in response to the Review of Medicine and Medical Devices Regulation<sup>2</sup>. It was agreed that the Australian Medical Device Framework be aligned, wherever possible, with the European Union Medical Device Framework. Of note was the existing alignment already between the two frameworks.

In 2019 we consulted on Part 1, [Proposed changes to the medical device Essential Principles for safety and performance](#). Feedback indicated strong support for alignment with the General Safety and Performance Requirements (GSPR) of the EU Regulations.

This consultation seeks to confirm views on where appropriate alignment should occur with the GSPR of the European Regulation 2017/745 on medical devices (MDR) and Regulation 2017/746 for in vitro diagnostic medical devices (IVDR), collectively referred to as the EU Regulations.

## AUS Essential Principles

The AUS Essential Principles for safety and performance of medical devices are described in the [Therapeutic Goods Act 1989](#)<sup>3</sup> (the Act) and listed in the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#)<sup>4</sup>, (the Regulations). Manufacturers must be able to demonstrate that their devices meet all relevant AUS Essential Principles. Sponsors must either hold or be able to get this evidence from their manufacturer on request.

The AUS Essential Principles cover:

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<sup>1</sup> <https://www.tga.gov.au/sites/default/files/2022-08/action-plan-medical-devices.pdf>

<sup>2</sup> Australian Government response to the Review of Medicines and Medical Devices Regulation: <https://www.tga.gov.au/news/news/australian-government-response-review-medicines-and-medical-devices-regulation#devices>

<sup>3</sup> *Therapeutic Goods Act 1989*, s. 3, Part 4-1 (ss. 41BA, 41BH), and Part 4-2 (ss. 41C, 41CA)

<sup>4</sup> Part 2 (Reg. 2.1), and Schedule 1

- **General principles** (AUS Essential Principles 1-6)  
These apply to all medical devices and cover principles of health and safety, risk management, long-term safety, and that the benefits outweigh any undesirable effects.
- **Design and construction principles** (AUS Essential Principles 7-12 and 15)  
These apply on a case-by-case basis, depending on the type of device and technology used.
- **Information to be provided with a medical device** (AUS Essential Principle 13)  
This applies to all devices to ensure relevant information is provided to users.
- **Clinical evidence** (AUS Essential Principle 14)  
This applies to all devices, as appropriate for the use and classification of the device.

## Approach for the alignment

We have compared the intent of each AUS Essential Principle with the intent of the corresponding EU GSPRs, for both non-IVD and IVD medical devices and applied the approach below.

### In-scope

We have proposed **changes** where:

- ✓ EU GSPR adds new requirements to improve safety or performance
- ✓ EU GSPR adds clarity to the regulatory expectation of compliance
- ✓ EU GSPRs introduces terminology that requires a definition in the Australian legislation.

We have proposed **no changes** where:

- ✗ AUS Essential Principles align with the intent of a related EU GSPR
- ✗ AUS Essential Principle has no equivalent EU GSPR
- ✗ an EU GSPR is not relevant in the Australian context, a list of these are provided in [Appendix 1](#).

## Out-of-scope

This consultation does not consider the following:

- ✘ AUS Essential Principle 14 for clinical evidence  
The EU Regulations outline requirements for clinical evidence within the Articles and Annexes of the EU Regulations and do not have an equivalent EU GSPR. Given the difference in legislative structure, we have chosen to retain AUS Essential Principle 14 and do not consider this to be an additional Australian-specific requirement. Our clinical evidence guidance<sup>5</sup> provides clarity on compliance expectations.
- ✘ Structural differences between the Australian and European regulations  
The AUS Essential Principles structure will continue to apply to both non-IVD and IVD medical devices.
- ✘ AUS Essential Principles relate to ongoing reforms projects  
Where we are consulting separately about proposed reforms that address a specific GSPRs, related Essential Principles may be reviewed as needed, including:
  - ✘ Unique Device Identification System in Australia  
Changes will be incorporated into the AUS Essential Principles, as appropriate.
  - ✘ Software including software as a medical device  
Changes are an ongoing part of our reforms, although one minor amendment to AUS Essential Principle 13B has been included for comment, under Proposal 13.
  - ✘ Devices without a specified therapeutic function under EU GSPR 9 (MDR)
  - ✘ Electronic IFUs

We have recently consulted on proposals to supply instructions for use in more flexible formats, which closed on 28 May 2024. The outcomes of this consultation will be published on the [Consultation Hub](#), under “We asked, you said, we did” section.

## Proposal impacting Australian sponsors of IVD devices

One of the proposed amendments to Essential Principle 13 is that IVD device manufacturers be required to provide contact details for users to obtain technical assistance (Proposal 11). As such, we propose that Australian sponsors of such devices also be required to have appropriate agreements in place with their manufacturer/s to ensure technical assistance is provided to Australian customers.

For Details, refer to [Proposal 14](#): Amend Regulation 10.2.

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<sup>5</sup> Guidance on clinical evidence: <https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/quality-safety-and-performance-requirements-medical-devices/principle-14-clinical-evidence>



## Australian-specific proposals

There are some circumstances where it is necessary to introduce additional clarity to address specific safety concerns. Where such amendments have been proposed, that are not present in the EU GSPRs, we have identified these as Australian-specific (AUS-specific) proposals:

AUS-specific proposals occur under:

- Proposal 1(a), for new AUS Essential Principles
- Proposal 6(b), for AUS Essential Principle 11
- Proposal 8(b), for AUS Essential Principle 15(4)
- Proposal 9(b, c, d), for AUS Essential Principle 13.1(3, 4, 5)
- Proposal 9(e), for AUS Essential Principle 13.4 (new clause)
- Proposal 12(b), for AUS Essential Principle 13.4(3) Item 29 – for IVD devices only

## Accompanying reference document

**Attachment 1:** *Proposals to align the AUS Essential Principles with the EU GSPR*, presents each clause of the AUS Essential Principles against the equivalent EU GSPRs together with the proposed changes for alignment.

## Impacts of the alignment

It is anticipated that benefits of adopting these proposals will:

- provide clarity and consistency for manufacturers on regulatory expectations of compliance
- simplify regulatory compliance for over 90% of medical devices supplied in Australia that utilise European manufacturer evidence
- improve clarity, specificity, and transparency on managing risks associated with the design and manufacture of devices
- improve safety and performance of medical devices

It is anticipated that the disadvantage of adopting these proposals may be possible increased regulatory burden for manufacturers that do not currently utilise European manufacturer evidence to support their inclusion in the Australian Register of Therapeutic Goods (ARTG).

## 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 AUS Essential Principles, subject to Government approval, the legislation changes will be drafted using Australian legal terminology. Our aim is to align the intent of the AUS Essential Principles with the EU GSPRs.

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

## Proposals for alignment

We are seeking your feedback on proposals to align the AUS Essential Principles with the EU GSPRs, where applicable and relevant to the Australian context.

### Proposal 1: Adopt new AUS Essential Principles

This proposal considers adopting the intent of the EU GSPRs for which there is currently not a related AUS Essential Principle. The legislative text for these EU GSPRs is presented in **Attachment 1**.

#### Questions



##### Proposal 1: Adopt new AUS Essential Principles

- (a) Do you agree with our proposal to align with the intent of the EU MDR and IVDR GSPRs 2, 3 and 5 and EU MDR GSPR 22? Explain.
- (b) If you have additional comments related to the above proposals, provide your feedback.

### Proposal 2: Amend AUS Essential Principles 2 and 4

AUS Essential Principles 1-6 are presented with the corresponding EU GSPRs in **Attachment 1**.

As the intent of our AUS Essential Principles align well with the EU GSPR, we are only proposing minor amendments to AUS Essential Principles 2 and 4.

#### Questions



##### Proposal 2: Amend AUS Essential Principles 2 and 4

- (a) Do you agree with the proposal to introduce into AUS Essential Principle 2(d), the requirement to provide users with information for safety, as described in EU MDR GSPR 4(c)?
- (b) Do you agree with the proposal to amend AUS Essential Principle 4(a) to clarify that it applies to the "device lifetime", as defined in the AUS Regulations and in line with the GSPR 6/IVDR GSPR 9.2?

**device lifetime**, in relation to a medical device, means the period, indicated by the manufacturer, during which:

- (a) the device can be safely used; and
- (b) the characteristics and performance of the device are not affected by its age.

(c) If you think other changes are needed for AUS Essential Principles 1-6, please explain.

## Design and Construction: AUS Essential Principles 7 – 12 and 15

### Proposal 3: Amend AUS Essential Principle 7 – Chemical, physical and biological properties

The EU GSPRs related to this AUS Essential Principle which expand the scope or provide clarity, for which we propose to adopt a similar intent, are listed in **Attachment 1**.

#### Questions



#### Proposal 3: Amend AUS Essential Principle 7

- (a) Do you agree with the proposal to adopt the intent of the EU GSPRs, related to AUS Essential Principle 7?
- (b) If you think other changes are needed for AUS Essential Principle 7, explain.

### Proposal 4: Amend AUS Essential Principle 8 – Infection and microbial contamination

The EU GSPRs related to this AUS Essential Principle which expand the scope or provide clarity, for which we propose to adopt a similar intent, are listed in **Attachment 1**.

#### Amendment to cover IVD devices containing biological material of human origin

The EU IVDR GSPR 12 expands the scope to include biological substances of human origin.

Our IVD devices framework includes devices that contain biological material of human origin that is non-viable or rendered non-viable, although this is not captured within our AUS Essential Principles.

As such, we propose to amend AUS Essential Principle 8.2, to additionally include IVD devices that contain tissues or cells of human origin, or their derivatives, which are non-viable or rendered non-viable. Any device that includes biological material that is viable is regulated as a biological under our Biologicals Regulatory Framework.

#### Inclusions of an equivalent clause to EU MDR GSPR 13.3

The EU MDR GSPR 13.3 for non-IVD medical devices covers devices manufactured utilising biological substances other than those referred to in GSPR 13.1 and 13.2:

- 13.1 refers to derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable
- 13.2 refers to tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable

Hence, EU MDR GSPR 13.3 is a catch-all clause to include anything other than substances from human or animal origin, which are non-viable or rendered non-viable.

As such, we are proposing to introduce a similar “catch-all” clause. This may result in changes to where recombinant and microbial origin material is included but will not change the requirements for compliance.

## Questions



### Proposal 4: Amend AUS Essential Principle 8

- Do you agree with the proposal to adopt the intent of the EU GSPRs, related to AUS Essential Principle 8?
- If you think other changes are needed for AUS Essential Principle 8, explain.

## Proposal 5: Amend AUS Essential Principle 9 – Construction and environmental properties

The EU GSPRs related to this AUS Essential Principle which expand the scope or provide clarity, for which we propose to adopt a similar intent, are listed in **Attachment 1**.

## Questions



### Proposal 5: Amend AUS Essential Principle 9

- Do you agree with the proposal to adopt the intent of the EU GSPRs, related to AUS Essential Principle 9?
- If you think other changes are needed for AUS Essential Principle 9, explain.

## Proposal 6: Amend AUS Essential Principle 11 – Protection against radiation

The EU GSPRs related to this AUS Essential Principle which expand the scope or provide clarity, for which we propose to adopt a similar intent, are listed in **Attachment 1**.

In reviewing AUS Essential Principle 11 we have consulted with the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) and propose changes to AUS Essential Principle 11 to align with the EU GSPRs.

The proposals include changing the wording to refer to ionising and non-ionising radiation instead of visible and invisible radiation (for consistency with EU GSPRs and other Australian Regulations on radiation protection<sup>6</sup>).

## AUS-specific proposal

We have also included several AUS-specific proposals (under Proposal 6(b)). These aim to clarify the expectation of compliance with existing AUS Essential Principles, from:

- **AUS Essential Principle 9**, regarding disposal of any waste products
- **AUS Essential Principle 7**, regarding risks associated with leaching, such as unintended radiation when in operation and any leakage of radiation when not in operation
- **AUS Essential Principle 13**, regarding informing users and patients of any warnings, precautions, contraindications and measures to be taken in the event of a malfunction of the device or changes in its performance that may affect safety.
- **AUS Essential Principle 12.12**, regarding protection against risks associated with administration of energy or substances.

These are not new requirements, as manufacturers must comply with all relevant AUS Essential Principles. As such, we are interested in your input as to whether inclusion of reference to such clauses would be helpful in clarifying our expectation of compliance for devices that emit radiation.

## Questions



### Proposal 6: Amend AUS Essential Principle 11

- (a) Do you agree with the proposal to adopt the intent of the EU GSPRs, related to AUS Essential Principle 11?
- (b) AUS-specific: Do you agree that AUS Essential Principle 11 should re-iterate requirements from AUS Essential Principles 7, 9, 12 and 1?
- (c) If you think other changes are needed for AUS Essential Principle 11, explain.

## Proposal 7: Amend AUS Essential Principle 12 – Medical devices connected to or equipped with an energy source

<sup>6</sup> Legislation related to radiation safety include: [National Radioactive Waste Management Act 2012](#) and [Australian Radiation Protection and Nuclear Safety Act 1998](#)

The EU GSPRs related to this AUS Essential Principle expand its scope or provide clarity, for which we propose to adopt a similar intent, are listed in **Attachment 1**.

## Questions



### Proposal 7: Amend AUS Essential Principle 12

- (a) Do you agree with the proposal to adopt the intent of the EU GSPRs, related to AUS Essential Principle 12?
- (b) If you think other changes are needed for AUS Essential Principle 12, explain.

## Proposal 8: Amend AUS Essential Principle 15 – IVD medical devices only

The EU GSPRs related to AUS Essential Principle 15, Principles applying to IVD medical devices only, which expand the scope or provide clarity for which we propose to adopt a similar intent, are listed in **Attachment 1**.

### AUS-specific proposal

Proposal 8(b) includes alignment with the EU IVDR GSPR 19.3. This requires IVD medical devices intended for self-testing or near-patient testing include in the instruction for use a procedure by which the intended user:

- i. be able to verify at the time of use the device the device will perform as intended by the manufacturer and
- ii. be warned if the device has failed to provide a valid result.

AUS Essential Principle 15(4) currently requires that all IVD devices must, to the extent possible, include provision for the user to verify, at the time of use, that the device will perform as intended. We consider this to be a fundamental requirement of all IVD devices, so we do not propose to amend the existing AUS Essential Principle to only apply to devices intended for self-testing or point of care testing, as in EU IVDR GSPR 19.3.

Likewise, we consider that all IVD devices must, to the extent possible, include a procedure by which the intended user is warned if the device has failed to provide a valid result. Hence, we propose to include this requirement within AUS Essential Principle 15, to apply to all IVD devices.

## Questions



### Proposal 8: Amend AUS Essential Principle 15

- (a) Do you agree with the proposal to adopt the intent of the EU GSPRs, related to AUS Essential Principle 15?

- (b) AUS-specific: Do you agree to adopt the intention of IVDR GSPR 19.3, but to apply the requirements to all IVD devices?
- (c) If you think other changes are needed for AUS Essential Principle 15, explain.

## Information supplied by the manufacturer: AUS Essential Principle 13

### Proposal 9: Amend AUS Essential Principle 13.1 (General labelling)

The EU GSPRs related to this AUS Essential Principle which expand the scope or provide clarity, for which we propose to adopt a similar intent, are listed in **Attachment 1**.

#### AUS-specific proposals

##### *Machine-readable format*

Proposal 9(b) relates to alignment with EU GSPR 23.1(c), to allow information, under AUS Essential Principle 13.1(3), to *also* be provided in a machine-readable format:

- EU GSPR 23.1(c):
  - *Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification or bar codes.*

The AUS-specific proposal relates to reducing risks from any potential interference from such formats on the intended performance of the device:

- AUS-specific proposal:
  - Information required under AUS Essential Principle 13.1(3) may be supplemented by machine-readable information providing such information does not interfere with the performance of the device or the device's ability to meet the AUS Essential Principles.

##### *Legibility*

Proposal 9(c) relates to legibility as described in AUS Essential Principle 13.1(5), which states the legibility requirement to be 1mm. The EU GSPRs require information on the label to be legible, however it does not specify what that means.

The TGA has had complaints, particularly from users of devices intended for self-testing, that information in the instructions for use has been “too small to read”, even though it complies with the “1mm” requirement of AUS Essential Principle 13.1(5). This is because the size requirement can be interpreted as including the full size-range of letters (upper and lower case), making the main letter portion difficult for some users to read easily, without magnification.

Given the “1mm” requirement can be vague and does not always result in information being legible, we consider it more appropriate to refer to a FONT TYPE and SIZE, or equivalent, to be considered “legible”. For example, font and size to be at least equivalent to 8pt Times New Roman.

In addition to Proposal 9(c), there is also a move toward labels being designed for all abilities. As such, this proposal considers the benefit of requiring attention be given to the contrast of the text against the background for any precautions, warnings and contraindications.

### ***Single copy of IFU where multiple devices are supplied to a single user or location***

The EU IVDR GSPR 20.1(e) and the EU MDR 23.1(e) allow manufacturers to provide a single copy of the instructions for use to a single user or location, where multiple devices have been supplied, where agreed to by the customer. The EU IVDR however, explicitly excludes IVD devices intended for self-testing and near patient testing from this clause.

Proposal 15 amends the definition of lay person to apply to all devices, rather than only applying to IVD devices. As such, we propose to also exclude devices intended for use by lay persons from the provision in EU MDR GSPR 23.1(e), in the same manner as IVD devices intended for self-test and near patient testing are excluded from the equivalent provision in EU IVDR GSPR 23.1(e).

## **Questions**



### **Proposal 9: Amend AUS Essential Principle 13.1**

- (a) Do you agree with the proposal to adopt the intent of the EU GSPRs, related to AUS Essential Principle 13.1?
- (b) **AUS-specific:** Do you agree with the proposal to allow information required under AUS Essential Principle 13.1(3) to be supplemented by machine-readable information providing such information does not interfere with the performance of the device or the device’s ability to meet the AUS Essential Principles?
- (c) **AUS-specific:** For AUS Essential Principle 13.1(5), do you agree that legibility would be better defined by referring to a specific font type and size rather than “a minimum of 1mm”, such as equivalent to at least 8pt Times New Roman?
- (d) **AUS-specific:** For AUS Essential Principle 13.1(5), do you agree that legibility should incorporate consideration of text contrast against background for warnings, precautions required to be brought to the attention of the user?
- (e) **AUS-specific:** Do you agree that devices intended for use by lay persons (using the amended definition under Proposal 15) all need their own instructions for use?
- (f) If you think other changes are needed for AUS Essential Principle 13.1, explain.



## Proposal 10: Amend AUS Essential Principle 13.3 (General labelling)

The EU GSPRs related to this AUS Essential Principle which expand the scope or provide clarity, for which we propose to adopt a similar intent, are listed in **Attachment 1**.

### Questions



#### Proposal 10: Amend AUS Essential Principle 13.3

- (a) Do you agree with the proposal to adopt the intent of the EU GSPRs, related to AUS Essential Principle 13.3?
- (b) If you think other changes are needed for AUS Essential Principle 13.3, explain.

## Proposal 11: Amend AUS Essential Principle 13.4(3)1-28, 30-31 – Instructions for use

The EU GSPRs related to this AUS Essential Principle which expand the scope or provide clarity, for which we propose to adopt a similar intent, are listed in **Attachment 1**.

**Item 29** of Essential Principle 13.4(3) relates to specific requirements for IVD devices only. These requirements are presented in Proposal 12 for your input.

### Questions



#### Proposal 11: Amend AUS Essential Principle 13.4(3)1-28 (IFU)

- (a) Do you agree with the proposal to adopt the intent of the EU GSPRs, related to AUS Essential Principle 13.4(3) Item:1-31 (excluding Item 29)?
- (b) If you think other changes are needed for AUS Essential Principle 13.4(3) Item:1-31 (excluding Item 29), explain.

## Proposal 12: Amend AUS Essential Principle 13.4(3) Item 29 – IFU information for IVD devices only

The EU GSPRs related to this AUS Essential Principle which expand the scope or provide clarity, for which we propose to adopt a similar intent, are listed in **Attachment 1**.

### AUS-specific proposal

This AUS-specific proposal relates to clause (b) under EU IVDR GSPR 20.4.2. This clause allows specific particulars to be omitted for devices intended for self-testing or near patient testing. Under such circumstances, we are proposing to include an additional AUS-specific proposal:

- If any particulars of AUS EP 13.4(3)29 are omitted, under an equivalent clause to IVDR GSPR 20.4.2(b), such information must be available and presented to the Secretary upon request, according to the legislated timeframes for such requests.

### Questions "



#### Proposal 12: Amend AUS Essential Principle 13.4(3)29 (IFU – IVD devices)

- Do you agree with the proposal to adopt the intent of the EU GSPRs, related to AUS Essential Principle 13.4(3)29?
- AUS-specific:** Do you agree with the proposal that if any particulars of AUS EP 13.4(3)29 are omitted, under an equivalent clause to IVDR GSPR 20.4.2(b), such information must be available and presented to the Secretary upon request, according to the legislated timeframes for such requests?
- If you think other changes are needed for AUS Essential Principle 13.4(3)29, explain.

## Proposal 13: Amend AUS Essential Principle 13B

The intent of AUS Essential Principle 13B is for users to access sufficient information to identify the version of the software being used and ensure traceability.

We recognise that not all device manufacturers use build numbers. Inclusion of this information would depend on the version control management system used by the manufacturer.

As such, we are proposing to clarify the intent of AUS Essential Principle 13B, as for all other principles, that manufacturers are required to comply, where relevant.

**Current AUS Essential Principle 13B: Software—version numbers and build numbers<sup>7</sup>**

- (1) *For a medical device that is software, or that incorporates software, the current version number and current build number of the software must be accessible by, and identifiable to, users of the device.*
- (2) *The current version number and current build number of the software:*
- (a) *must be in English; and*
  - (b) *may also be in any other language*

**Questions****Proposal 13: Amend AUS Essential Principle 13B**

- (a) Do you think it necessary to amend AUS Essential Principle 13B to clarify that a build number be accessible by and identifiable to users of the device, only where it is used by the manufacture as a component of the manufacturer's version control management system? Explain.
- (b) If you think other changes are needed for AUS Essential Principle 13B, explain.

**Requirements of Australian sponsors****Proposal 14: Amend AUS Regulation 10.2 – Australian sponsors****Provision of technical support to Australian customers for IVD devices**

In Proposal 11, we propose to introduce requirements (under EP 13.4(3) Item 1) for manufacturers of IVD devices to include in the instructions for use, contact details to allow users to obtain technical assistance.

This is based on alignment with EU IVDR GSPR 20.4.1.

As such, it is important that Australian sponsors of IVD devices have agreements in place with their manufacturer/s to ensure an appropriate level of technical assistance is available to Australian customers.

This would be especially important for IVD devices intended for self-testing and point of care testing.

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<sup>7</sup> Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 1

## Current Regulation 10.2

Our current Regulation 10.2 Information for Sponsors, states:

- (1) The sponsor of a medical device must ensure that the sponsor's name and address are:
- (a) provided with the device in such a way that a user of the device can readily identify the sponsor; and
  - (b) located in accordance with clause 13.2 in Schedule 1.
- (2) If the sponsor of a medical device arranges for a label to be attached or affixed to the device for the purpose of complying with sub regulation (1) or for any other purpose (for example, to comply with a labelling requirement under the law of a State or Territory), the label must not in any way adulterate the device or obscure the information provided with the device by the manufacturer.

## Questions



### Proposal 14: Amend AUS Regulation 10.2

- (a) Do you agree that Australian Sponsors of IVD devices be required to have written agreements in place with their manufacturer/s to ensure an appropriate level of technical assistance be available to Australian customers?
- (b) If you think other changes are needed for AUS Regulation 10.2, explain.

## Definitions

### Proposal 15: Adopt definitions

The following definitions are being considered for adoption to provide clarity and consistency with the EU GSPRs:

Term	Definition
Interoperability	<p><b>EU definition:</b></p> <p><i>The ability of two or more devices, including software, from the same manufacturer or from different manufacturers, to:</i></p> <ul style="list-style-type: none"> <li>(a) <i>exchange information and use the information that has been exchanged for the correct execution of a specified function without changing the content of the data, and/or</i></li> <li>(b) <i>communicate with each other, and/or</i></li> <li>(c) <i>work together as intended;</i></li> </ul>

Term	Definition
Benefit-risk determination	<p><b>EU definition:</b></p> <p><i>The analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer.</i></p>
Lay person	<p><b>EU definition:</b></p> <p><i>'lay person' means an individual who does not have formal education in a relevant field of healthcare or medical discipline</i></p> <p><b>Current AUS definition:</b></p> <p><i>lay person, for the use of an IVD medical device for self-testing, means an individual who does not have formal training in a medical field or discipline to which the self-testing relates.</i></p> <p><b>Proposed change:</b></p> <p>Amend the AUS definition of <i>lay person</i> in the AUS Regulations to more broadly apply to all devices.</p>

## Questions



### Proposal 15: Adopt definitions related to the AUS Essential Principles

- (a) Do you agree with the proposal to introduce terminology and intent of the definitions for "interoperability", "benefit-risk determination" and to amend the definition for "lay person" to apply to all devices?
- (b) Provide reasons for your position (optional).

## Transitional arrangements

The TGA proposes that should the AUS Essential Principles be revised; a transition period will be put in place for compliance with any new requirements. These may include:

- for any existing or new medical device ARTG inclusion applications when the proposed amendment takes effect, sponsors will have four (4) years to comply with the revised AUS Essential Principles.
- for devices already included in the ARTG at the time the proposed amendment takes effect, sponsors will not need to re-apply for ARTG inclusion and will have six (6) years to comply with the revised AUS Essential Principles.

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## Proposal 16: Transitional arrangements

### Questions



#### Proposal 16: Transition periods

- (a) Do you agree with the proposal to apply a 4-year transition period for existing or new inclusion applications when the proposed amendment takes effect?
- (b) Do you agree with the proposal to apply a 6-year transition period for any current ARTG entries when the proposed amendment takes effect?
- (c) Provide reasons for your position (optional).

### Open comments

The online survey provides you with an opportunity to provide any other comments you have not had an opportunity to make throughout the consultation. Reference any comments to the proposals within the consultation paper.

### Fees and charges

The changes proposed under this consultation will not affect fees or annual charges.

## Appendix 1: EU GSPRs not adopted

EU GSPRs not adopted	Justification for not adopting the EU GSPRs into the AUS Essential Principles
<p><b>MDR GSPR 10.4.1. Design and manufacture of devices</b></p> <p>Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device.</p> <p>Devices, or those parts thereof or those materials used therein that:</p> <ul style="list-style-type: none"> <li>– Are invasive and come into direct contact with the human body,</li> <li>– (re)administer medicines, body liquids or other substances, including gases, to/from the body, or</li> <li>– Transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body,</li> </ul> <p>shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2:</p> <p>(a) Substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (1), or</p> <p>Substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (2) or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council (3), in accordance with the criteria that are relevant to human health amongst the criteria established therein.</p>	<p>Australia does not have the equivalent legislative framework as Europe regarding the requirements placed on carcinogenic, mutagenic or toxic to reproduction and/or endocrine-disrupting substances. As such, we propose to take a broader principles-based approach. to devices incorporating such substances as proposed under AUS EP 7.5.</p>

EU GSPRs not adopted	Justification for not adopting the EU GSPRs into the AUS Essential Principles
<p><b>GSPR 10.3</b> Devices shall be designed and manufactured in such a way as to reduce to a level as low as reasonably practicable the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device.</p> <p>Special attention shall be given to substances which are:</p> <ul style="list-style-type: none"> <li>– Carcinogenic, mutagenic or toxic to reproduction ('CMR'), in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (1), and</li> <li>– To substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and</li> </ul> <p>Which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>8</sup></p>	
<p><b>MDR GSPR 10.4.2 Justification regarding the presence of CMR and/or endocrine-disrupting substances</b></p> <p>The justification for the presence of such substances shall be based upon:</p> <ul style="list-style-type: none"> <li>(a) an analysis and estimation of potential patient or user exposure to the substance;</li> <li>(b) an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives;</li> </ul>	<p>Australia does not have the equivalent legislative framework as Europe regarding the requirements placed on carcinogenic, mutagenic or toxic to reproduction and/or endocrine-disrupting substances. As such, we propose to take a broader principles-based approach. to devices incorporating such substances. Hence the specific requirements of EU MDR GSPR 10.4.2 will not be adopted.</p> <p>However, we may include in our guidance clarification on applying the principles of AUS Essential Principle 2 in minimising risks related to such substances. For example, it would be expected that for any substances known to be carcinogenic, mutagenic or toxic to reproduction, or endocrine-disrupting, the manufacturer would:</p>

<sup>8</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 136, 29.5.2007, p. 3).



EU GSPRs not adopted	Justification for not adopting the EU GSPRs into the AUS Essential Principles
<p>(c) argumentation as to why possible substance and/ or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials; and</p> <p>(d) where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. And 10.4.4.</p>	<ul style="list-style-type: none"> <li>– undertake an analysis and estimation of potential patient or user exposure to the substance</li> <li>– undertake an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives</li> <li>– be able to justify as to why possible substance and/ or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials.</li> <li>– Include precautions and warnings for any vulnerable populations for which the device is intended to be used</li> </ul>
<p><b>MDR GSPR 10.4.3 – Guidelines on phthalates</b></p> <p>For the purposes of Section 10.4., the Commission shall, as soon as possible and by 26 May 2018, provide the relevant scientific committee with a mandate to prepare guidelines that shall be ready before 26 May 2020. The mandate for the committee shall encompass at least a benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in points (a) and (b) of Section 10.4.1. The benefit-risk assessment shall consider the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments. When deemed appropriate on the basis of the latest scientific evidence, but at least every five years, the guidelines shall be updated. 5.5.2017 L 117/96 Official Journal of the European Union EN</p>	<p>These MDR GSPRs includes a requirement on the EU Commission to publish guidelines on phthalates, cytogenic mutagenic and toxic to reproduction substances and endocrine-disrupting substances.</p> <p>Our AUS Essential Principles place requirements on manufacturers and do not place obligations on the Australian Government.</p>

EU GSPRs not adopted	Justification for not adopting the EU GSPRs into the AUS Essential Principles
<p><b>MDR GSPR 10.4.4 – Guidelines on other CMR and endocrine disrupting substances</b></p> <p>Subsequently, the Commission shall mandate the relevant scientific committee to prepare guidelines as referred to in Section 10.4.3. also, for other substances referred to in points (a) and (b) of Section 10.4.1., where appropriate.</p>	
<p><b>MDR GSPR 10.4.5 Substances - Labelling</b></p> <p>Where devices, parts thereof or materials used therein as referred to in Section 10.4.1 contain substances referred to in points (a) or (b) of Section 10.4.1 in a concentration above 0,1 % weight by weight (w/w), the presence of those substances shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances. If the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for those patient groups and, if applicable, on appropriate precautionary measures shall be given in the instructions for use</p>	<p>As Australia does not have the equivalent legislative framework as Europe regarding the requirements placed on CRM and/or endocrine-disrupting substances, we propose to take a broader principles-based approach. As such, the specific requirements of EU MDR GSPR 10.4.5 will not be adopted.</p>
<p><b>MDR GSPR 9</b></p> <p>For the devices referred to in Annex XVI, the general safety requirements set out in Sections 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons.</p>	<p>This MDR GSPR relates to the requirement for medical devices without an intended medical purpose.</p> <p>These types of devices are currently outside the scope of the Australian regulatory framework. Review of the regulation of such devices is an ongoing part of our reforms projects. As such, this EU GSPR is outside the scope of the current reforms to the AUS Essential Principles.</p>
<p><b>MDR GSPR 13. Devices incorporating materials of biological origin</b></p> <p><b>GSPR 13.1</b> For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-</p>	<p>Non-IVD devices utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable are outside the scope of the Australian medical device regulatory framework. We do not propose to adopt these EU GSPRs for non-IVD devices because these issues are addressed</p>

<b>EU GSPRs not adopted</b>	<b>Justification for not adopting the EU GSPRs into the AUS Essential Principles</b>
<p>viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply:</p> <p>(e) donation, procurement and testing of the tissues and cells shall be done in accordance with Directive 2004/23/EC;</p> <p>(f) processing, preservation and any other handling of those tissues and cells or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process;</p> <p>the traceability system for those devices shall be complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC.</p>	<p>under our biologicals regulatory framework. The exception is for IVD devices that contain substances of human origin, which are non-viable or rendered non-viable. For IVD devices, we propose to include equivalent requirements for IVD devices under AUS Essential Principle 8.2.</p>
<p><b>IVDR GSPR 20.1(d)</b></p> <p>Instructions for use shall be provided together with devices. However, in duly justified and exceptional cases instructions for use shall not be required or may be abbreviated if the device can be used safely and as intended by the manufacturer without any such instructions for use.</p>	<p>The second sentence of IVDR GSPR 20.1(d) relates to circumstances when an IFU need not be provided for an IVD device. We do not think any such circumstances would apply to IVDs of Class 2, 3 and 4. As such, we intend to retain the requirements in AUS Essential Principle 13.2(2). We do not consider this to be an additional requirement, as the EU Regulation only applies in exceptional and duly justified cases.</p>
<p><b>MDR GSPR 23.1(f)</b> Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in <a href="#">Regulation (EU) No 207/2012</a> or in any subsequent implementing rules adopted pursuant to this Regulation.</p> <p><b>IVDR GSPR 20.1(f)</b> When the device is intended for professional use only, instructions for use may be provided to the user in non-paper format (e.g., electronic), except when the device is intended for near-patient testing.</p>	<p>These MDR and IVDR GSPRs relate to electronic instructions for use. Electronic IFUs are part of our ongoing reforms. Once a policy decision has been made following the recent consultation, the AUS Essential Principles related to these EU GSPRs will be reconsidered, where appropriate.</p>

EU GSPRs not adopted	Justification for not adopting the EU GSPRs into the AUS Essential Principles
<p><b>IVDR GSPR 20.2(n)</b> The label shall bear all of the following particulars: if the instructions for use are not provided in paper form in accordance with point (f) of Section 20.1, a reference to their accessibility (or availability), and where applicable the website address where they can be consulted.</p>	
<p><b>MDR GSPR 23.2(d) IVDR GSPR 20.2 (d)</b></p> <p>The label shall bear:</p> <p>(d) if the manufacturer has its registered place of business outside the Union, the name of the authorised representative and address of the registered place of business of the authorised representative;</p>	<p>These EU GSPRs cover manufacturers whose registered place of business is outside the Union, which is not applicable in Australia.</p> <p>Our AUS Essential Principle requires the registered place of business of the manufacturer, regardless of their location.</p>
<p><b>MDR GSPR 23.2(o)</b></p> <p>The label shall bear:</p> <p>(o) if the device is a <b>single-use device that has been reprocessed</b>, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles</p>	<p>The EU MDR outlines the provisions for <b>reprocessing of single-use devices</b> in <i>Article 17</i>.</p> <p>We currently have no such provisions within our Regulations. Inclusion of such provisions, if deemed necessary, may be the focus of a separate consultation.</p>
<p><b>MDR GSPR 23.4 Information in the instructions for use</b></p> <p>The instructions for use shall contain:</p> <p>(x) for the devices covered by this Regulation pursuant to Article 1(2), information regarding the absence of a clinical benefit and the risks related to use of the device;</p>	<p>This labelling requirement applies to devices without an intended therapeutic purpose. This is the subject of ongoing reforms and will be addressed separately to this consultation.</p>
<p><b>MDR GSPR 23.4 Information in the instructions for use</b></p> <p>The instructions for use shall contain.....</p> <p>(s) [sub-point:] if the device is intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances, any limitations or incompatibility in the choice of substances to be delivered</p>	<p>Any labelling requirement related to tissues or cells, or their derivatives of human origin for non-IVD devices, have not been adopted as such products are regulated under our Biologicals Regulatory Framework.</p>

Table description: The table includes the European General Safety and Performance Requirements which are out of scope from the alignment of the AUS Essential Principles for medical devices, together with a justification.

## Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Devices Reforms Taskforce	August 2024

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Reference/Publication # D24-274038

