Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Essential Principles consultation

Our response to questions asked during the presentations on 11-12 September 2024

Version 1.0, October 2024

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Contents

Questions asked during the presentation on the Essential Principles consultation

On 11 & 12 September 2024 we provided an opportunity for stakeholders to ask questions on our public consultation. You can view the presentation slides. We were unable to answer all the questions asked. We have collated our responses into topics and summarised some questions to cover points raised.

AUS EP checklist

Will we update the EP checklist?

We will update the EP checklist to reflect any approved changes to the Essential Principles.

We will make an amended EP checklist available well before we adopt any changes.

Information will be available on our website.

We are yet to consider the format of an amended or transitional EP checklist.

Your feedback on the structure of an amended EP checklist is welcome.

Will we create a document outlining the differences with the EU GSPR checklist?

We welcome suggestions on how we can support manufacturers to simplify regulatory compliance.

EP checklist information

- Essential Principles checklist
- Demonstrating compliance with the Essential Principles.

International alignment

How will the EP changes effect MDSAP?

ISO 13485 forms the basis of the MDSAP audits which focus on a manufacturer's quality management system (QMS).

Product specific requirements, as described in the Essential Principles are not part of the MDSAP audit but covered under each country's product assessment.

Auditing Organisations include a summary of each MDSAP member's performance requirements in their training material. They also revise training material when changes occur.

MDSAP information

- Medical device single audit program (our website)
- Our frequently asked questions for the MDSAP
- Guidance on using comparable oversea regulators/assessment bodies
- Medical device single audit program (FDA website)
- MDSAP certificate requirements (FDA website)

For feedback or questions on MDSAP, please email us at MDSAP@tga.gov.au.

How will these changes effect the EU MRA?

The proposed changes to the Essential Principles will not change the mutual recognition agreement with the European Commission (EU MRA). The Essential Principles and the GSPR are not a part of the EU MRA. The EU MRA is at present under negotiation.

The European Commission did not appoint us to assess medical devices under the EU MDR and EU IVDR. Our role as a notified body under the EU MRA ended on 26th September 2024. None of the EU notified bodies issue Australian MRA certificates to manufacturers. However, we can now issue certificates to Australian manufacturers under the UK MRA.

More information is available on our MRA webpage.

How will these changes effect comparable overseas regulatory pathways?

Under our framework, we recognise the following comparable overseas regulators:

- Notified bodies appointed by the medical device regulators of European member states, under the medical device regulatory frameworks of the European Union
- the Food and Drug Administration of the United States
- Health Canada
- Medical Device Single Audit Program (MDSAP) auditing organisations
- the Ministry of Health, Labour and Welfare and Pharmaceutical and Medical Devices Agency of Japan.
- Singapore's Health Sciences Authority (HSA)

Regardless of the conformity assessment procedure used, all manufacturers would need to ensure that:

- their devices comply with all applicable Essential Principles, and
- that they have sufficient evidence to show they comply by the end of any agreed transition timeframe.

Comparable overseas regulator information

The following links inform you of how we use market authorisation evidence from comparable overseas regulators for medical devices:

- Comparable overseas regulators for medical device applications
- Overseas regulatory evidence options for a medical device application
- Q&A on using comparable overseas regulators evidence

How do these changes align with IMDRF principles?

Our Essential Principles, both existing and proposed changes, are consistent with the International Medical Device Regulators Forum (IMDRF) principles. We are a founding member of the IMDRF and continue to align our regulatory requirements through multiple IMDRF working groups.

Effect on manufacturers

What will be the cost of the changes to manufacturers?

A high portion of devices supplied in Australia already use European manufacturer evidence to support inclusion of their devices in the Register. We welcome feedback on the proposed changes from manufacturers who do not use EU manufacturer evidence to support ARTG inclusion. This input will guide our decision whether we need to conduct a full regulatory impact assessment.

We do not foresee increasing application fees and annual charges because of the proposed changes to the Essential Principles.

What support will there be for manufacturers?

Where possible, we will support manufacturers and sponsors to meet any amended requirements through:

- **Transition periods** to allow manufacturers time to comply with any new requirements applicable to their devices.
- **Guidance and education** to clarify expectations through enquiry lines, published information and webinars or workshops.
- **Compliance tools** such as EP checklist and comparison documents to reduce regulatory burden, where possible.

Please give input on the type of support that would best support you in transitioning to the proposed changes.

How will changes effect manufacturers with EC certificate that are not ISO 13485 certified?

The proposed changes will not affect manufacturers with EC certificates that are recognised under the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion)*

Determination 2018. We do not mandate ISO 13485 certification. We recognise ISO 13485 certificates issued under the MDSAP and in limited other cases, such as for:

- IVDs transitioning under the EU IVDR
- unapproved vaping devices.

The ISO 13485 is a standard that manufacturers can use to develop or ensure compliance with our conformity assessment procedures. The manufacturer can then apply for an appropriate quality management system / product assessment certification to seek inclusion in the ARTG. This can be through obtaining a TGA conformity assessment certificate, or through a comparable overseas regulator pathway.

More information

- Quality management and medical devices
- Learn about quality management systems
- Guidance on Therapeutic Goods (Conformity Assessment Standard for Quality Management Systems) Order 2019
- The guidance document Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices (including IVDs) provides an overview of suitable regulatory evidence options.
- *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018*

How will changes effect manufacturers of class I devices using the Declaration of conformity (not requiring assessment by the Secretary) procedures?

Regardless of the conformity assessment procedure used, all manufacturers would need to ensure that:

- their devices comply with all applicable Essential Principles, and
- that they have sufficient evidence to show they comply by the end of any agreed transition timeframe.

The Essential Principles do not depend on the class of a device. Manufacturers must decide which Essential Principles apply to their device based on the intended purpose they assign to the device.

Manufacturer evidence information

- Demonstrating compliance with the Essential Principles.

For extra information contact 1800 141 144 or devices@tga.gov.au.

How will these changes effect expired manufacturer evidence in eBS?

The proposed changes will not affect expired manufacturer evidence (ME). The requirements of manufacturers and sponsors remains unchanged if their ME expires. Sponsors must comply with the standard conditions of inclusion, of always having available:

- sufficient information to show the manufacturer has applied the conformity assessment procedures to the kind of medical device.

Sponsor's must **tell us within 60 days** of becoming aware that the ME has either:

- lapsed
- been revoked, suspended or cancelled.

Sponsors can tell us using the form for lapses in medical device conformity assessment certification.

Information on manufacturer evidence

- Completing a notification form for lapses in medical device conformity assessment certification
- Conformity assessment, Essential Principles and consent to supply
- Transition to new manufacturer evidence for IVD medical devices (pdf)

For more information contact 1800 141 144 or devices@tga.gov.au.

Can you give the dental industry a guide to the Essential Principles?

We will amend our guidance following any approved changes to the Essential Principles. We will consider if certain industry sectors, such as the dental industry, would benefit from targeted guidance.

Your need to include dental products and equipment in the Register when it meets the definition of a medical device. Such devices must comply with all applicable Essential Principles, unless exempt, authorised, or approved.

Dental devices

- Guidance for dental practitioners

Will there be supply interruptions because of the proposed changes?

We do not expect that the proposed changes to the Essential Principles would lead to any supply disruptions. However, we welcome your feedback if you have concerns that the proposed changes may interrupt the supply of your device.

Supply of devices in Australia

- EU MDR transition: Overview and management under the Australian regulatory framework
- Steps to supply for device manufacturers
- Steps to supply for device sponsors

How will you manage compliance when implementing regulatory changes?

We do not have plans to initiate a notification scheme for manufacturers to confirm compliance to any amended Essential Principles.

We expect you to comply with any amended Essential Principles after the end of any transition period. Sponsors must be able to give evidence of compliance when requested. For example, when we conduct post market reviews or investigations following adverse events.

Specific EP changes

How do the EP consultation proposals effect the different types of devices?

The effect of the proposed changes will depend on how the Essential Principles apply to the intended purpose of each device. The Essential Principles apply to all medical devices, regardless of classification. All manufacturers must comply with the **applicable** Essential Principles based on the intended purpose assigned to the device by the manufacturer.

In the consultation we have used the terms below to help sponsors and manufacturers find proposals that may be applicable to their devices. We describe the intent of the terms below:

- **All devices:** for proposals that **may** be applicable to **both** IVD devices and non-IVD devices.
- **All IVD devices:** for proposals that **may** be applicable to **IVD devices only**, so not applicable to non-IVD devices.
- **All non-IVD devices:** for proposals that **may** be applicable to **non-IVD devices only**, so not applicable to IVD devices.

What are the number of proposed new EP and Australian-specific EP?

New EP (not AUS-specific)

There are around 100 new EP clauses:

- Approximately 50 (excluding EP 13)
- Approximately 50 (EP 13)

The total number of individual sub-clauses in the Essential Principles (excluding EP 13) is approximately 162.

EP 13 has the highest number of **new** clauses proposed but also contains the approximately 125 individual sub-clauses.

AUS-specific proposals

There are nine AUS-specific proposals in the consultation:

- 3 are new proposals (EP 13.1 and EP 15)
- 6 clarify existing requirements (EP 11)

In EP 8, to what does “specific microbial state” refer?

The term “specific microbial state” could refer to a state:

- in which a device is designed to have a **specific limit of microbial contamination.** Specifications could be used to control and monitor the contamination to ensure safe and effective performance of a device
- other than sterility, such as devices with a **specified level of cleanliness**, as disinfected, or with no particular microorganisms.

As with all EP, the applicability would depend on the intended purpose of the device or IVD device, as assigned by the manufacturer.

In EP 9, to what does “environmental properties” refer?

The heading of EP 9 is “Construction and environmental properties”. This refers to the ability of a medical device to function safely and effectively under different environmental conditions. The manufacturer reduce the risks to do with how, where, and with what, the devise is intended to be used. See also EU MDR GSPR 14 and EU IVDR GSPR 13.

These requirements help ensure that medical devices remain safe and effective throughout their lifecycle, even when exposed to different environmental conditions.

More information

- Essential Principle 9: Construction and environmental properties
- TGA Quality, Safety, and Performance Requirements

EP 13 – Information supplied with a device (labelling & IFU)

Why change manufacturer's address requirements?

We are not changing the address requirements for manufacturers. This proposal clarifies that in EP 13, a manufacturer's address is to be a physical place of business, and not a PO Box.

Some manufacturers have multiple manufacturing sites. When you use a PO Box, we cannot confirm the site of manufacture or if we have approved the site for a particular type of device.

Why change legibility requirements?

The proposed changes to legibility requirements clarify the regulatory expectation, as there is no legislated definition of legibility. This makes it difficult for manufacturers to apply and difficult to regulate. Proposal 9(c) describes legibility in Essential Principle 13.1(5). The EU GSPRs state the label is to be "legible", without specifying what that means.

We already require a minimum of 1 mm. This does not always lead to information being legible. Therefore, we consider it more appropriate to refer to a FONT TYPE and SIZE, or equivalent.

We want to hear your views on the effect of this proposal, instead of the minimum requirement of 1 mm.

Why change contact details for technical support for IVD devices?

The proposed change for IVD manufacturers to give contact details for technical support is to align with the equivalent EU IVDR clauses:

- GSPR 20.2: that for IVD devices for self-testing, you must provide information with the device that includes "contact details for further advice and assistance".
- GSPR 20.4.1(ad): requires you to include in the instructions for use, "a telephone number and/or fax number and/or website address to obtain technical assistance".

To align with the EU IVDR, this information would be mandatory for devices intended for self-testing. It would also apply to other IVD devices, depending on the intended purpose of the device.

There is no equivalent in the EU MDR GSPR. Therefore, the proposal to include contact details for technical support, is specific to IVD devices.

What are the proposals for EP 13B & SaMD?

The proposal for EP 13 aims to clarify the requirements for software as a medical device (SaMD). This consultation does not introduce any new requirements for SaMD.

Although the European Regulations do not have an equivalent requirement, there are other international regulators that do, including the IMDRF. It is also relevant to our AI review.

Visibility of version changes to software in medical devices is needed, particularly when extra functionality can be easily deployed to connected devices. There are many existing devices being upgraded to include AI without any external indicators of the extra functionality. Some developers do

not recognise that upgrading an existing device to include AI is a functional change. Uncontrolled software changes could increase safety risks.

SaMD reforms

We will consult on continuing reforms to our regulatory framework for software as a medical device.

- Consultation: Clarifying and strengthening the regulation of Artificial Intelligence (AI) (open 12 September 2024 – 13 October 2024)
- Understanding regulation of software based medical devices (2024)

We have people dedicated to software and other challenges with regulating digital medical devices. Contact digital.devices@tga.gov.au.

Why is EP 14 out of scope, given sponsors get many s41JA requests based on EP 14?

We did not include EP 14 in the consultation as the EU Regulations do not have an equivalent EU GSPR. In Europe, the requirements for clinical evidence are instead outline in other Articles and Annexes. Given the difference in legislative structure, we have chosen to keep Essential Principle 14 and do not consider this to be an extra Australian-specific requirement.

Clinical evidence is of paramount importance as it's what demonstrates if a device works or not and what the risks of its use are. We rely on and accept evidence from several comparable overseas regulators, which have varying standards on clinical evidence.

Clinical evidence for medical devices

- Principle 14: Clinical evidence
- Clinical evidence guidelines

Why propose to make EU IVDR GSPR 19.3: “verify an IVD has performed and warn users of an invalid result”, apply to “all” devices?

All IVD devices that produce a result to end users must include a system to tell a user of an invalid result. This is a basic safety criterion under General Essential principle 2. We listed this as applying to “all” IVD devices. This was to clarify that it not only applies to IVD devices used for self-testing and near patient testing, but **also for laboratory use**.

You raised concerns that this clause would not apply to “all” devices, such as a specimen vial. For an IVD device that does not produce a test result, this Essential Principle would not apply. Please also refer back to the information provided under How do the EP consultation proposals effect the different types of devices?

Requiring IVDs to comply with the MDR GRSP 22 will mean manufacturers must adopt aspects of the MDR into their QMS to comply. Why add this extra burden to IVD manufacturers when GSPR 19 already exists?

We are not adding an extra burden for IVD manufacturers to include an EU MDR clause into their quality management system. As noted in the consultation, the MDR GSPR 22 (laypersons) and IVDR GSPR 19 (self-testing) are similar. IVDR GSPR 19 has some extra IVD-specific requirements. We would consider an IVD manufacturer compliant with the EU IVDR GSPR 19 to also be compliant with the equivalent MDR GSPR 22.

Given the overlap between IVDR GSPR 19 and MDR GSPR 22, we **may** reduce duplication by combining these clauses in our Essential Principles. We may list the extra IVD-specific requirements to apply to such devices. We are yet to develop the legislative structure and wording.

Assistive technologies, exempt devices, and other therapeutic goods (OTG)

Do assistive technologies products need to comply with the EP?

Where we regulate assistive technologies as medical devices, they are to comply with the relevant the Essential Principles. This is consistent with the EU Regulations for medical devices.

We are reviewing the regulatory framework for assistive technology.

Assistive technology regulatory reforms

- Consultation: Future regulation of assistive technologies (22 July 2024 to 13 October 2024)

Do exempt devices need to comply with EP changes?

Exempt devices must comply with the applicable Essential Principles.

You also need to meet other regulatory obligations for exempt medical devices.

More information

- For a complete list of exempt medical devices, you can refer to Schedule 4 of the Therapeutic Goods (Medical Devices) Regulations 2002.
- Should your product be on the ARTG?

What are the requirements for orthoses?

Orthoses devices need to comply with the regulatory requirements for medical devices unless they meet the criteria for exemption. Under Item 1.3B in Schedule 4 of the Therapeutic Goods (Medical Devices) Regulations 2002, externally applied orthopaedic devices are exempt from ARTG inclusion if:

- they are **manufactured in Australia** by a relevant Australian health professional, or to the instructions provided by a relevant Australian health professional, **and**
- **all** materials or other articles used to manufacture the device have been included in the ARTG.

We have listed materials and other articles used to manufacture externally applied orthopaedic devices (such as orthoses) as **specified articles.** We regulate specified articles as medical devices. You must include these devices in the ARTG and meet the EP before you can be import or supply them in Australia.

More information

- Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020.
- Do exempt devices need to comply with EP changes?

Do OTG need to comply with the EP?

We do not regulate other therapeutic goods (OTG) as medical devices and so these products do not need to comply with the EP. Only therapeutic goods defined as a medical device must comply with the Essential Principles.

Regulation of Other therapeutic goods (OTG)

- Disinfectants, sterilants and sanitary products

Transition periods and purpose of consultation

How will we apply the transition period?

We have not yet finalised the details on the transition arrangements. We will give clarity on how the transition arrangements will work well ahead of any changes.

Sponsors will not need to reapply for devices included in the ARTG before the transition period ends. We are not planning on requiring sponsors to tell us of their compliance to any amended Essential Principles. However, manufacturers must hold evidence to show such compliance. Sponsors must be able to get this the manufacturer evidence when requested, in the legislated timeframes. We may ask for evidence of compliance, for example, during a post-market review or during an adverse event investigation etc.

Where manufacturer evidence has lapsed, sponsors must tell us within 60 days. Refer also to how will these changes impact expired manufacturer evidence in eBS?

We are keen to hear from you on how the proposed transitional timeframes would affect you. We aim to work with industry to mitigate, as much as possible, disruptions to supply of devices because of the

proposed changes. At this stage we cannot give a date for the proposed changes to take effect. Once the government approves any changes, the amended legislation will outline the details of the Essential Principles, and the transition arrangements.

Why are we proposing changes to the EP?

The proposed changes to align with the EU regulatory framework for medical devices and in vitro diagnostic devices was an Australian Government decision. In 2015, the review of medicines and medical devices regulation (MMDR) report was released. This report highlighted that the Australian and European regulatory frameworks for medical devices were **historically closely aligned**, and noted minor differences between the:

- classification systems and
- Australian Essential Principles and the equivalent European requirements.

The Commonwealth accepted the MMDR recommendation that we were to align wherever possible, with the European Union regulations**,** for the:

- Essential Principles
- Classification of medical devices
- Adoption of a risk-based approach to variations to medical devices

Should we seek to apply specific requirements, we must give a clear rationale for doing so.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical device Reforms Taskforce	October 2024

Therapeutic Goods Administration

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