Australian Government

Department of Health

Therapeutic Goods Administration

Consultation: Potential reclassification of active medical devices for diagnosis and patient therapy

January 2019

TGA Health Safety Regulation

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Contents

Introduction

In 2016, the Australian Government endorsed a significant program of reform to further strengthen the regulation of therapeutic goods in Australia. The Therapeutic Goods Administration (TGA) has issued this consultation paper as part of the Government's reform program.

In 2015, the Report of the Expert Panel's *Review of Medicines and Medical Devices Regulation* (MMDR) made 58 recommendations for reform of the regulatory framework for medicines and medical devices in Australia. The Australian Government Response to the Review of Medicines and Medical Devices Regulation was released in September 2016. The Government accepted 56 MMDR recommendations including Recommendation Twenty[1] which addressed matters within the remit of the TGA. This Recommendation provided that the regulation of medical devices, wherever possible and appropriate, align with the European Union (EU) framework including the classification of medical devices.

As part of the Australian Government Department of Health, the TGA regulates therapeutic goods, and is responsible for implementing the Government's reforms.

Background

Medical devices are regulated in Australia having regard to the risks (to the individual or public health) considered 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 our assessments and decisions are made based on the balance between the benefits and the risks.

The risk classifications of medical devices take into account factors such as potential harm, level of invasiveness, reliance on power, where in the human body the device is used, terms of use, the end user (consumers or a person with appropriate knowledge and expertise), etc.

The TGA periodically reviews classification rules for medical devices to ensure they continue to be appropriate. When undertaking such assessments, the TGA has regard among other things, to the international best regulatory practice and any emerging issues.

This ensures sustainability of the Australian regulatory system for medical devices, appropriateness and robustness of assessments, and timeliness of access to medical devices.

This consultation

The focus of this paper is to obtain feedback on a proposal for the reclassification of active medical devices with an integrated or incorporated diagnostic function that significantly determines patient management.

[1] Sansom L, Delaat W, Horvath J. Review of Medicines and Medical Devices Regulation: Recommendations to the Minister for Health on the Regulatory Frameworks for Medicines, Medical Devices, Complementary Medicines and Advertising of Therapeutic Goods, July 2015, p. 10.

The EU Regulation on medical devices (2017/745)[2] (EU MD Regulation) introduced several amendments to the classification rules effectively reclassifying some categories of medical devices to higher risk classes.

The EU MD Regulation explains that the new requirements increase the robustness of the assessment process, and that the classification rules take into account the potential risks associated with the technical design and manufacture of the devices. The rules also take into account the level of invasiveness and potential toxicity of certain devices introduced into the human body as well as the place where the device performs its action in or on the human body.

The Government's program of reform aims to improve the scope, clarity and appropriateness of operation of regulations governing medical devices. This consultation paper considers the EU regulatory framework as an input into the review and reform of the Australian regulatory requirements for medical devices classification. While the new classification rule in the EU more appropriately reflects the intended use and the risk of medical devices, this paper considers the extent to which a similar approach will be appropriate in the Australian regulatory context, to further our aim of enhancing the smooth functioning of the medical devices market while also achieving high standards of quality, safety and performance.

Proposed implementation measures: summary

Aim

Having regard to the amendments implemented by the EU MD Regulation, introduce a new classification rule, which is appropriately tailored for the Australian regulatory context, for active medical devices for diagnosis and patient therapy. In the EU MD Regulations these are referred to as *"Active medical devices with an integrated or incorporated diagnostic function that significantly determines patient management (including automated external defibrillators and closed loop systems)."*

Proposals

It is proposed that a **new classification rule** be included in the Therapeutic Goods (Medical Devices) Regulations 2002, to align with Rule 22 of the EU Medical Devices Regulations (namely Regulation (EU) 2017/745).

It is proposed that the **definition of active medical device** in the Therapeutic Goods (Medical Devices) Regulations 2002 be amended to align with the definition of active device in Regulation (EU) 2017/745 (see Appendix A—Definitions: active medical devices).

Effect

Certain active medical devices would be reclassified from Class IIa (low-medium risk) or Class IIb (medium-high risk) to Class III (high risk).

Your feedback

Are you a consumer, industry stakeholder, healthcare provider, patient, industry representative body, consumer advocacy group or other interested party?

[2] The Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

We seek your views on the proposed implementation measures. Your input will assist us to address any unintended consequences so as to inform the proposal and the regulatory amendment process.

On page 12 is a list of questions to help you address the proposal in your feedback.

Please submit your feedback to the TGA by email (See How to submit on page 13).

Please note

This consultation closes on **18 February 2019**.

Before providing feedback, it is important to read the explanatory material that follows.

Where do I find the classification and definitions of active medical devices?

EU

Regulation (EU) 2017/745 (the EU MD Regulation) specifies the rules that govern the classification of a medical device.

Rule 22[3] prescribes the classification of a particular type of medical device:

> *'Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III.'*

Definitions related to active medical devices are found in Article 2 and Annex VIII of the EU MD Regulation.[4]

Australia

The classification rules for medical devices in Australia are prescribed in Schedule 2 of the Therapeutic Goods (Medical Devices) Regulations 2002[5] (the Australian MD Regulations). Active medical devices are defined in the Dictionary (r. 1.3) of the Australian MD Regulations.

Any measures we use to implement the alignment of the Australian regulation of active medical devices with that of the EU, to the extent it is appropriate to do so, will necessarily incorporate the classification requirements of Rule 22. The proposed measures will also need to take account of EU and AU differences in the definition of those active medical devices being reclassified.

[3] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, Annex VIII, Chapter III – Classification Rules, 7.9 Rule 22 (OJ L 117, 5.5.2017, p. 145). See also Chapter V, Section 1, Article 51.1 – Classification of Devices, (OJ L 117, 5.5.2017, p. 49).

[4] OJ L 117, 5.5.2017, pp. 15, 140.

[5] Classification rules for IVD medical devices are prescribed in Schedule 2A; see also *Therapeutic Goods Act 1989*, s. 41DB and Therapeutic Goods (Medical Devices) Regulations 2002, Part 3, Div. 3.1.

The current classification, under the Australian MD Regulations, of active medical devices within the scope of EU Rule 22 is outlined in 'Current classification of these devices in Australia' (page 9 of this paper).

Definitions: active medical devices

Appendix A (on page 14) has been included as a reference tool. It provides a comparison (Table A) of relevant definitions in the EU and Australian MD Regulations, and sets out:

- Australian MD Regulations definitions for an active medical device, an active medical device for diagnosis and an active medical device for therapy
- EU MD Regulation definitions for an active device, an active device intended for diagnosis and monitoring and an active therapeutic device
- an explanation of their differences
- the impact, if any, of these differences on the regulation of active medical devices in Australia
- consequential proposed amendments to definitions in Australian MD Regulations when the regulatory frameworks are aligned.

Table A may help you to address regulatory scope and definitions in your feedback.

Medical devices subject to EU MD Regulation Rule 22

In addition to describing an active medical device by function and purpose, Rule 22 names an automated external defibrillator and a closed loop system as examples of such devices.

What is an automated external defibrillator (AED)?

An AED is a portable electronic device that automatically analyses the life-threatening cardiac arrhythmias of ventricular fibrillation and pulseless ventricular tachycardia and treats them through defibrillation—the application of electricity which stops the arrhythmia—allowing the heart to re-establish an effective rhythm.

An AED system consists of an AED device, battery, pad electrode, and if applicable, an adapter. AEDs can be fully automated or semi-automated.

AEDs are found in airports, community centres, schools, government buildings and other public locations.

Why reclassify AEDs?

AEDs can be highly effective in saving the lives of people suffering cardiac arrest, when used in the first few minutes following collapse. However, some AEDs have been associated with manufacturing problems and some devices have been recalled.

Some of the known problems with particular AEDs include:

- specific electronic failure of a resistor
- capacitor charging problem that could mean the device does not deliver the electrical shock required to re-establish normal cardiac rhythm

- performance affected by water ingress.

In Australia, AEDs are currently classified as **Class IIb** (medium-high risk) devices. Reclassification to Class III (high risk) means manufacturers must apply more rigorous conformity assessment procedures to the device.[6] Sponsors will be required to obtain from manufacturers and provide to the TGA the conformity assessment documents demonstrating procedures appropriate for a Class III medical device when submitting applications for inclusion of their medical devices in the Australian Register of Therapeutic Goods (ARTG). Finally the Class III device applications are also subject to a mandatory audit assessment by the TGA, including assessment of the clinical evidence.

Strengthened assessments will drive the manufacture of better quality, reliable AEDs that are fit for purpose.

What is a closed loop system?

Closed loop systems are used to continuously monitor biological conditions in real time and then adjust a therapy in order to maintain or achieve a particular physiological state.

Some examples include: an artificial pancreas that links continuous glucose monitoring with an insulin pump to optimise the delivery of insulin for diabetics; and a closed loop deep brain stimulation (DBS) device used in the treatment of various neurological conditions.

Why reclassify closed loop systems?

Closed loop systems are devices that some people may rely on every day. They must be safe and are expected to incorporate the latest scientific and technological innovations. For example, the artificial pancreas is programmed to deliver insulin into the body through thin plastic tubing known as the 'infusion set' or 'giving set'. Errors of insulin infusion can occur in modern devices due to pump failure, infusion set blockage, infusion site problems, insulin stability issues, user error or a combination of these. In these instances, users are exposed to significant and potentially fatal hazards. Interruption of insulin infusion may result in hyperglycaemia and ketoacidosis. Conversely, delivery of excessive insulin can cause severe hypoglycaemia.

Given the patient cohort who relies on closed loop systems, tight controls over the design and production of these devices is crucial to ensure that they are safe and perform as intended.

In Australia, closed loop systems are currently **Class IIb** medical devices. Use of some types of these devices is growing, but an increased robustness of the assessment process is required, given the potential risks associated with the rate of technological and scientific progress in these devices.

Other active medical devices and the EU MD Regulation Rule 22

The EU MD Regulation Rule 22 applies to an active medical device that has an integrated or incorporated diagnostic function which significantly determines the patient's management of the device.

As outlined in the Appendix, this applies to the following definitions of medical devices in the Australian MD Regulations:

[6] Therapeutic Goods (Medical Devices) Regulations 2002, r.3.6 and Schedule 3 – Conformity assessment procedures

- an active medical device for diagnosis
- an active medical device for therapy.

Therefore, other medical devices covered by the EU MD Regulation Rule 22 (in addition to AEDs and closed loop systems) may include:

- external pacemakers
- continuous positive airway pressure (CPAP) devices
- intravascular heating/cooling system control units
- hyperthermia systems, temperature mapping units
- intraperitoneal-circulation hypothermia system control units
- mechanical bloodstream indicator injectors.

Is reclassification of any or all of these devices in Australia to Class III appropriate?

Current classification of these devices in Australia

The classification rules that currently apply to the devices described above are set out in Schedule 2, Part 4 of the Australian MD Regulations as follows:

Rule 4.2 - Active medical devices for therapy

(1) Subject to subclause (2), an active medical device for therapy that is intended by the manufacturer to be used to administer energy to a patient, or exchange energy to or from a patient, is classified as Class IIa.

(2) If the device is of a kind such that the administration or exchange of energy occurs in a potentially hazardous way, having regard to the nature, density and site of application of the energy, the device is classified as Class IIb.

Rule 4.3 - Active medical devices for diagnosis

(2) If…

(c) the device is intended by the manufacturer to be used to allow direct diagnosis or monitoring of vital physiological processes of a patient (other than a device of a kind mentioned in paragraph (3)(a));

the device is classified as Class IIa.

(3) If:

(a) the device is intended by the manufacturer specifically to be used to monitor vital physiological parameters of a patient, and the nature of the variations monitored is of the kind that could result in immediate danger to the patient (for example, variations in cardiac performance, respiration, activity of the central nervous system);…

the device is classified as Class IIb.

Proposed reclassification

The proposed reclassification will mean that some active medical devices for diagnosis and for therapy—including AEDs and closed loop systems—will be reclassified to Class III.

Class III classification requires more stringent assessment of manufacturers' quality management systems including assessment of any significant changes that may impact on safety and performance. The technical documentation related to each device is assessed, rather than that of a representative device from a group of similar devices.

Sponsors of Class III devices in Australia are required to include each device in the ARTG separately, with an individual unique product identifier (UPI) to improve their traceability.

Proposed action

It is proposed that a **new classification rule** be included in the *Therapeutic Goods (Medical Devices) Regulations 2002*, to align with the EU MD Regulation Rule 22:

Active medical devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device (such as closed loop systems or automated external defibrillators) are classified as Class III.

What will change for sponsors?

Sponsors who supply, or plan to supply, in Australia medical devices to which Rule 22 applies will be required to provide manufacturer's conformity assessment documents appropriate to devices of this classification.[7]

After the regulatory changes take effect, sponsors of active medical devices will be required to apply for inclusion of their medical devices in the ARTG as Class III.

Transitional arrangements

In Europe, the transitional arrangements for all new medical devices lawfully placed on the market that have pre-market authorisation in the form of a valid EC Certificate[8] can remain on the market until the expiry date of that EC Certificate or until 27 May 2025, whichever is the earliest.

We propose that the new classification for **new medical devices in Australia**—that is, a device included in the ARTG following successful completion of applications submitted to the TGA on or after the commencement date of the amended regulations—would start from August 2020.

If the application for ARTG inclusion for a medical device is **submitted to the TGA before the date the proposed amendment takes effect**, the device will be subject to the transitional arrangements and will have four (4) years to transition.

[7] Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018 (F2018L01410) <https://www.legislation.gov.au/Details/F2018L01410>

[8] EC certificates issued in accordance with EU Directive 93/42/EEC and which comply with the requirements in para. (2) of Article 120 of the EU MD Regulation.

Applications

At the date that the proposed amendment takes effect:

- **All new applications for marketing approval** (ARTG inclusion) for active medical devices with diagnostic function significantly determining patient management submitted to the TGA on or after the date when amended regulations take effect must be for a Class III medical device.
- **Sponsors of devices already included in the ARTG**, or those for which applications have been submitted before regulatory amendments take effect, must apply to have their device/s re-entered as Class III medical devices. All applications to reclassify devices must be submitted to the TGA by the end of the transition period. Where an application to reclassify has been submitted to the TGA but has not been determined (i.e. is still under assessment), the device can continue to be supplied under the existing ARTG entry until the Class III application is finalised (including applications not finalised at the end of the transition period).
- For those devices for which transitional provisions apply, sponsors must notify the TGA of all such devices presently supplied under the existing ARTG entry within six (6) months of the amended regulations taking effect. These devices can continue to be supplied for the duration of the transition. If the sponsor has not notified the TGA within this period, they will no longer be eligible for the transitional arrangements.
- If any **application for ARTG inclusion for a device with the current classification is in progress** on the date the regulations come into effect, it may continue. If the application is successful, the device will be included with the current classification. The sponsor must then reapply to include their device in ARTG as Class III, as per requirements set out under the transitional arrangements.

Fees and charges

Normal application and audit assessment fees will apply for applications for inclusion in the ARTG.

Normal annual charges will apply for Class III entries in the ARTG following reclassification.

Engagement

Wherever practicable, the TGA will:

- liaise with the healthcare sector, patient associations and industry peak bodies to inform and raise awareness about this proposal
- provide relevant material on the TGA website.

Feedback notes

It is important to note that while we intend to take the European medical device framework into account the Australian legislative instruments are structured differently and there is variation in the legal terminology acceptable in each jurisdiction. We acknowledge that legislation cannot always be successfully replicated across jurisdictions. Therefore, your views on the impacts of reclassifying these active medical devices to Class III are very important to us.

When considering the proposed measures, assume that the EU MD Regulation Rule 22 applies to an active medical device as defined in the Australian MD Regulations.

Please consider the possible impact of the proposed alignment with the EU MD Regulation Rule 22 by referring to descriptions of relevant devices and their functionality.

Please also keep in mind that current and future technological developments may potentially bring more categories of medical devices under this classification rule.

What we invite you to do

In your submission, we ask you to consider the questions below and provide comments related to any other matter outlined in this consultation paper.

Questions

- What impacts—including any that are unintended—do you anticipate the reclassification may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?
- Are there any further issues and questions we should consider when implementing this change (i.e. areas that need to be clarified in our guidance)?
- Other medical devices covered by the EU MD Regulation Rule 22 (in addition to AEDs and closed loop systems) may include:
  - external pacemakers
  - continuous positive airway pressure (CPAP) devices
  - intravascular heating/cooling system control units
  - hyperthermia systems, temperature mapping units
  - intraperitoneal-circulation hypothermia system control units
  - mechanical bloodstream indicator injectors.

We seek your feedback whether reclassification of any or all of these devices in Australia to Class III is appropriate.

- Are there any other groups of devices that we have not considered which might fall within the scope of this proposed change?
- Do you have any comments regarding the transitional arrangements proposed in this paper?

How to submit

Complete the online consultation submission form to upload your submission in either pdf or word format.

You can also submit your feedback directly to the TGA by email at: devicereforms@tga.gov.au.

This consultation closes on 18 February 2019.

Enquiries

If you have any questions relating to submissions please direct them to: devicereforms@tga.gov.au.

Appendix A - Definitions: active medical devices

Definitions relating to medical devices are found in the Dictionary (r. 1.3) of the Therapeutic Goods (Medical Devices) Regulations 2002. There are differences between the definitions in Regulation (EU) 2017/745 of active medical devices relevant to Rule 22 and those found in the Therapeutic Goods (Medical Devices) Regulations 2002. Table A below is a comparison of current definitions by jurisdiction.

Table A - Definitions relevant to active medical devices with diagnostic function determining patient management.

Australia[9]	EU	Difference
Active medical device: (a) means a medical device that is intended by the manufacturer: (i) to depend for its operation on a source of electrical energy or other source of energy (other than a source of energy generated directly by a human being or gravity); and (ii) to act by converting this energy; but (b) does not include a medical device that is intended by the manufacturer to transmit energy, a substance, or any other element, between an active medical device and a human being without any significant change in the energy, substance or other element being transmitted.	***'Active device'*** means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices. Software shall also be deemed to be an active device. Regulation (EU) 2017/745, Article 2(4) (OJ L 117, 5.5.2017, p. 16)	The EU definition of an active device explicitly includes software. In Australia, some software meets the definition of a medical device (by its intended purpose or because it is an accessory to another medical device). It is also considered to be an active medical device, however, it has not been expressly defined as such. Because the EU definition of ***'active device'*** expressly includes software, it is proposed to amend the Australian definition of ***active medical device*** to make the scope of this definition more clear. This is consistent with the International Medical Device Regulators Forum (IMDRF) approach on software.

[9] All Australian definitions in this column: Therapeutic Goods (Medical Devices) Regulations 2002 - Dictionary.

Australia[9]	EU	Difference
Active medical device for diagnosis means an active medical device that is intended by the manufacturer to be used on a human being, either alone or in combination with another medical device, to supply information for the purpose of detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.	***'Active device intended for diagnosis and monitoring'*** means any active device used, whether alone or in combination with other devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities. Regulation (EU) 2017/745, Annex VIII, Chapter I, s. 2.5 (OJ L 117, 5.5.2017, p. 140)	The inclusion of monitoring in the relevant EU definition has only marginal or nil impact on the actual regulation of the relevant devices. Accordingly, it is not proposed to amend the Australian definition of ***active medical device for diagnosis***. **No change is proposed**
Active medical device for therapy means an active medical device that is intended by the manufacturer to be used on a human being, either alone or in combination with another medical device, to support, modify, replace or restore biological functions or structures for the purpose of treating or alleviating an illness, injury or handicap.	***'Active therapeutic device'*** means any active device used, whether alone or in combination with other devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or disability. Regulation (EU) 2017/745, Annex VIII, Chapter 1, s. 2.4 (OJ L 117, 5.5.2017, p. 140)	The differences in terminology used in the EU and Australian definitions have only marginal or nil impact on the actual regulation of the relevant devices: • **'active therapeutic device'** and ***active medical device for therapy*** • *disability and handicap.* Accordingly, it is not proposed to amend the Australian definition of ***active medical device for therapy***. **No change is proposed**

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Therapeutic Goods Administration, Medical Devices Branch	07/01/2019

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