



Australian Government

Department of Health

Therapeutic Goods Administration

Consultation: Changes to a number of definitions and the scope of the medical device regulatory framework in Australia

January 2019

TGA Health Safety
Regulation

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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 Twenty¹ 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.

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.

Improving the clarity and broad understanding of the regulatory requirements is important to improve regulatory compliance and consequently the safety and performance of medical devices. When working on reforms, the TGA has regard among other things, to the international best regulatory practice and any emerging issues.

This consultation

The EU Regulation on medical devices (2017/745)² (EU MD Regulation) introduced several amendments, including a number of new and amended definitions and an expanded scope of products that were regulated under the EU MD Regulation (refer Annex XVI).

This consultation paper considers the EU requirements as an input to determine the extent to which a similar approach may be appropriate in Australia, and to further the smooth functioning of the medical devices market while also maintaining high standards of quality, safety and performance.

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.

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



The focus of this consultation is on identifying where the [Therapeutic Goods Act 1989](#) (the Act) and the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#) (the Australian MD Regulations) could be aligned with the EU MD Regulation, specifically:

- the definitions that underpin the medical device regulatory frameworks of both jurisdictions
- the products that fall within the scope of the regulatory framework.

Proposed implementation measures: summary

Aim

Having regard to the amendments implemented by the EU MD Regulation, to introduce a number of new and amended definitions, and a revised scope of the products regulated as medical devices.

Proposals

That the Parliament consider amending the *Therapeutic Goods Act 1989*; and that the *Therapeutic Goods (Medical Devices) Regulations 2002* be amended to incorporate some new definitions that could be aligned with the EU MD Regulation (see Appendix A—[Definitions](#)).

That a new legislative instrument under the Act be made to give effect to Annex XVI of EU MD Regulation.

Effect

Better clarity and consistency in understanding of the requirements and the products that are regulated as medical devices.

Your feedback

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

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.

At the end of this paper (starting on page 9) is a list of questions to help you address the proposal in your feedback.

Please submit your feedback to the TGA **by 18 February 2019**. See [How to submit](#) for more details.

Definitions

The EU MD Regulation aims to bring greater clarity to the EU regulatory framework. It introduces a number of new definitions and extends the scope of existing definitions in order to ensure health protections while providing more certainty for manufacturers, suppliers and users.

Specifically, the EU MD Regulation includes a clearer and more detailed definition of a medical device. One example is the express inclusion of software, implants and reagents in the definition of 'medical device' when they are intended by manufacturers to be used for 'specific medical purposes'. Products specifically intended for the cleaning, disinfection, or sterilisation of devices, are now also explicitly defined as medical devices.

The meaning of 'an accessory for a medical device' is also clarified. New inclusions to Article 2 of the EU MD Regulations include, for example, such definitions as 'unique device identification system' (UDI System) and 'nanomaterial'.

Proposed amendments

In most cases it is proposed to harmonise Australian legislation and regulation with definitions in the EU MD Regulation. The aim is to improve clarity and consistency to enhance the smooth functioning of the medical devices market while also achieving timely access and high standards of quality, safety and performance.

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

Appendix A – Definitions

A comprehensive list of relevant definitions for Australia and the EU can be found in the tables of [Appendix A](#). Regulatory definitions are compared and linked directly to a relevant proposed amendment. As well as providing you with useful detail, the Appendix will give you an understanding of the scope of the Australian Government's regulatory reform program for medical devices.

Scope of the EU MD Regulation: groups of products without an intended medical purpose

The EU MD Regulation captures products that meet the definition of a 'medical device' and/or 'accessory'.

There are also groups of products that are not intended for a 'specific medical purpose' as prescribed in the definition of 'medical device' which are listed in Annex XVI. Under the EU MD Regulations, devices 'without an intended medical purpose', as described in Annex XVI, must meet the same requirements as the analogous devices with a medical purpose. These requirements will include conformity assessment and clinical evaluation.

The product groups listed in Annex XVI are:

1. **Contact lenses** or other items intended to be introduced into or onto the eye.
2. **Products intended to be totally or partially introduced into the human body through surgically invasive means** for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.
3. Substances, combinations of substances, or **items intended to be used for facial or other dermal or mucous membrane filling** by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.
4. Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.
5. **High intensity electromagnetic radiation** (e.g. infra-red, visible light and ultraviolet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.
6. **Equipment intended for brain stimulation** that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

There are acknowledged historical inconsistencies in the regulatory oversight of these products in both Europe and Australia. The EU regulatory approach acknowledges the fact that there are comparable risks of possible harm associated with the use of such devices whether they are intended for medical use or not.

For example, surgically invasive implants and injectable fillers used for cosmetic purposes have many similar risks—such as compatibility, contamination and infection—to those used for medical purposes. Laser and intense pulsed light equipment have a known risk of burns, blistering, scarring, skin pigmentation changes and eye damage. This is regardless of whether the equipment is being used for medical or cosmetic purposes such as hair removal or skin rejuvenation.

The EU MD Regulation also provides the European Commission with the power to amend the list of product groups in *Annex XVI* and add new groups of products if there is a public health imperative.

This method of capturing groups of products by means of a prescriptive list is similar to powers prescribed in Australia under subsection 41BD(2B) of the Act, allowing the Secretary of the Department of Health (or their delegate) to specify a particular group (class) of products to be ‘medical devices’.

In the global environment, a lack of consistency in the regulatory approach creates confusion for industry and increases health risks for users of these devices. The proposed alignment with the EU MD Regulation will ensure clear regulatory control over these products, bringing consistency to quality, safety and performance standards.

**Note**

The Australian and EU classification rules for medical devices were drafted with **medical intended use as central to the assignment of a risk class to the device**.

Because Annex XVI products do not have an intended medical purpose, the Regulation requires that the application of the classification rules to such products should apply as for medical devices with the same functionality and risk profile. Therefore, **Australian classification rules may need to be amended accordingly**.

Appendix B – Products without medical intended purpose

[Appendix B](#) provides further information on the groups of products without an intended medical purpose listed in Annex XVI.

Proposed amendment

It is proposed that the products listed in Annex XVI be regulated as medical devices in Australia.

Transitional arrangements

It is proposed, subject to the approval of regulatory amendments, which the proposed regulatory changes to definitions and requirements for products without medical purpose will come into effect from August 2020.

We would not plan for any amendments to take effect ahead of the European transition timetable unless there is an urgent public health need to do so.

Applications for products without intended medical purpose

On or after the date when amended requirements take effect sponsors of any product from any group listed in Annex XVI will be required to submit an application for inclusion of their product as a medical device in the [Australian Register of Therapeutic Goods](#) (ARTG). Sponsors will be required to obtain from the manufacturer a conformity assessment document appropriate for the product (in accordance with the relevant classification, description, [Global Medical Device Nomenclature](#) (GMDN) code/term, and intended use) and provide it to the TGA with their application³.

Fees and charges

Normal application and audit assessment fees will apply for applications for inclusion of products without intended medical purpose in the ARTG.

³ <https://www.tga.gov.au/publication/use-market-authorisation-evidence-comparable-overseas-regulators-assessment-bodies-medical-devices-including-ivds>

Normal annual charges will also apply.

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 it is intended to take the European medical device framework into account, Australian legislative instruments are structured differently and there is variation in the legal terminology acceptable and commonly used in each jurisdiction.

Specifically while the European framework is set down in the regulation, the Australian legislative structure means that certain changes must be made to the Act, other changes would be made in the Regulations, and some amendments may require a delegate of the Minister to make new legislative instruments or Orders.

EU	Australia
<p><i>Medical Devices Regulation (2017/745/EU)</i></p> <p>Covers products previously regulated under EU Medical Devices Directive (93/42/EEC) and Active Implantable Medical Devices Directive (90/385/EEC).</p> <p><i>Article 120 - Transitional provisions</i></p> <p>The transitional period will end 26 May 2020 for any new device. For devices already on the market, the transition period ends when their current EC Certificate expires.</p>	<p><i>Therapeutic Goods Act 1989</i></p> <p><i>Therapeutic Goods (Medical Devices) Regulations 2002</i></p> <p>Legislative instruments and Orders</p> <p>All the above cover medical devices, active implantable medical devices, IVD devices.</p>

Please consider the possible impact of the proposed amendments, especially for products without intended medical purpose, by referring to classification rules and regulatory requirements for medical devices similar in terms of description, characteristics, functionality, and risks profile.

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: DEFINITIONS

- Do you have comments about the proposed changes to the definitions (refer Appendix A)?
- Are you a consumer, patient, consumer advocacy group, healthcare provider, industry stakeholder, industry representative body or other?
- Will you be affected by the proposed definition changes? If yes, how?
- What benefits or disadvantages might be there for patient, consumer or public health and safety in these proposed definition changes?
- If you are an Australian business, please provide information on potential impacts relating to these changes including:
 - the number of products affected
 - benefits or disadvantages related to the safety and performance of your products
 - changes to administrative or regulatory obligations of sponsors
 - any operational impacts on your business
 - costs that these changes may impose on your operations.



QUESTIONS: PRODUCTS WITHOUT INTENDED MEDICAL PURPOSE

- Are you a consumer, patient, consumer advocacy group, healthcare provider, industry stakeholder, industry representative body or other?
- Are you affected by the proposal to regulate as ‘medical devices’ a prescribed list of specified groups of products that don’t have an intended medical purpose? If yes, how?
- What benefits or disadvantages are there for patients, consumers or public health and safety in regulating specified products without an intended medical purpose as medical devices?
- Would a prescriptive list of specified products that do not have an intended medical purpose regulated as medical devices simplify the regulatory expectations around such products?
- If you are an Australian business, please provide information on potential impacts relating to these changes including:
 - the number of products affected
 - benefits or disadvantages related to the safety and performance of your products
 - changes to administrative or regulatory obligations on sponsors
 - any operational impacts on your business
 - costs that these changes may impose on your operations.

How to submit

Complete the [online consultation submission form](#) to upload your submission in either pdf or word format.

Enquiries

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

Appendix A – Definitions

Abbreviations used

Act	<i>Therapeutic Goods Act 1989</i>
ARTG	Australian Register of Therapeutic Goods
GSPR	General Safety and Performance Requirements
IVD	in vitro diagnostic (EU MD Regulation) in vitro diagnostic (AU MD Regulations)
URPTG	Uniform Recall Procedure of Therapeutic Goods

Table A1 - The main definitions

EU MD Regulation (2017/745)	Australian definition	Proposal for amendments
<p>(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:</p> <ul style="list-style-type: none"> – diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, – diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, – investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, – providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, <p>and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.</p> <p>The following products shall also be deemed to be medical devices:</p> <ul style="list-style-type: none"> – devices for the control or support of conception; – products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point. 	<p>Act, section 41BD:</p> <p>A medical device is:</p> <ul style="list-style-type: none"> (a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following: <ul style="list-style-type: none"> (i) diagnosis, prevention, monitoring, treatment or alleviation of disease; (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability; (iii) investigation, replacement or modification of the anatomy or of a physiological process; (iv) control of conception; <p>and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or</p> (aa) any instrument, apparatus, appliance, material or other article specified under subsection (2A); or (ab) any instrument, apparatus, appliance, material or other article that is included in a class of instruments, apparatus, appliances, materials or other articles specified under subsection (2B); or (b) an accessory to an instrument, apparatus, appliance, material or other article covered by paragraph (a), (aa) or (ab). <p>Note: Declarations under subsection (3) exclude articles from the scope of this definition. Declarations under section 7 can also have this effect: see subsection 7(4).</p>	<p>For clarity and consistency purposes we propose that the EU definition replaces the definition of 'medical device' in the Australian legislation.</p> <p>Because, in principle, the intent of this definition in the EU MD Regulation is consistent with our interpretation of the products that are regulated as medical devices we do not anticipate any impact (rather than greater clarity and consistency) on the regulation of medical devices in Australia.</p>
<p>(2) 'accessory for a medical device' means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s).</p>	<p>Act section 3:</p> <p>accessory, in relation to a medical device covered by paragraph 41BD(1)(a), (aa) or (ab), means a thing that the manufacturer of the thing specifically intended to be used together with the device to enable the device to be used as the manufacturer of the device intended.</p>	<p>For clarity and consistency, we propose that the EU definition replaces the present definition of 'accessory' in the Australian legislation (section 3 of the TG Act).</p> <p>Section 41BD(1)(b) of the Act is not proposed to be amended at this time.</p>

EU MD Regulation (2017/745)	Australian definition	Proposal for amendments
<p>(49) 'sponsor' means any individual, company, institution or organisation which takes responsibility for the initiation, for the management and setting up of the financing of the clinical investigation.</p>	<p>Act, section 3:</p> <p>sponsor, in relation to therapeutic goods, means:</p> <p>(a) a person who exports, or arranges the exportation of, the goods from Australia; or</p> <p>(b) a person who imports, or arranges the importation of, the goods into Australia; or</p> <p>(c) a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere);</p> <p>but does not include a person who:</p> <p>(d) exports, imports or manufactures the goods; or</p> <p>(e) arranges the exportation, importation or manufacture of the goods; on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia.</p>	<p>In Australian legislation, the term sponsor refers to an importer, exporter or manufacturer of therapeutic goods.</p> <p>Specifically, for medical devices the sponsor is a person in relation to whom a medical device is included in ARTG (i.e. it covers a broad range of responsibilities, while the definition of sponsor in the EU MD Regulation is very narrow and is only used in the context of clinical investigations of devices).</p> <p>Therefore, because the EU definition of 'sponsor' is substantially different to the established Australian meaning, we do not propose to align it with the European definition.</p> <p>Rather, we propose to clarify this term in the Australian legislation to mean the sponsor is the person in relation to whom a medical device is included in the ARTG, respectively covering all related sponsor's responsibilities.</p>
<p>(12) 'intended purpose' means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation.</p>	<p>For the purposes of paragraph (1)(a), the purpose for which an instrument, apparatus, appliance, material or other article (the main equipment) is to be used is to be ascertained from the information supplied, by the person under whose name the main equipment is or is to be supplied, on or in any one or more of the following:</p> <p>(a) the labelling on the main equipment;</p> <p>(b) the instructions for using the main equipment;</p> <p>(c) any advertising material relating to the main equipment;</p> <p>(d) technical documentation describing the mechanism of action of the main equipment.</p> <p>Dictionary (regulation 1.3) Australian MD Regulations:</p> <p>intended purpose, of a medical device, means the purpose for which the manufacturer of the device intends it to be used, as stated in:</p> <p>(a) the information provided with the device; or</p> <p>(b) the instructions for use of the device; or</p> <p>(c) any advertising material applying to the device; or</p> <p>(d) any technical documentation describing the mechanism of action of the device.</p>	<p>The term 'intended purpose' is crucial in the context of medical devices.</p> <p>The intended purpose of a medical device defined in the Act is broader than the EU definition.</p> <p>The EU definition in addition to label and instructions for use, only refers to promotional or sales materials or material provided with a clinical evaluation as the source to determine the intended purpose of the device. However certain engineering and other technical documentation may provide better clarity regarding the intended purpose of the goods.</p> <p>For this reason, the TGA does not propose to align with this EU MD Regulation definition.</p>

Table A2 - Other definitions - proposed to be reflected in the Australian legislation

EU MD Regulation (2017/745)	Australian definition	Proposal for amendments
<p>(24) 'benefit-risk determination' means 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.</p>	<p>There is no equivalent definition in the Australian legislation.</p> <p>Although classification rules and essential principles in the Australian MD Regulations, Schedule 1, 2 and 2A, refer to the benefits and risks.</p> <p>For example, essential principle 1(b)(i) requires a medical device to be designed and produced in a way that ensures that any risks associated with the use of the device are acceptable risks when weighed against the intended benefit. Similarly, essential principle 6 refers to:</p> <p style="padding-left: 40px;">The benefits to be gained from the use of a medical device for the performance intended by the manufacturer must outweigh any undesirable effects arising from its use.</p>	<p>Medical device regulatory requirements largely have regard to the balance between anticipated or real benefits weighed against the risks associated with the use of a medical device.</p> <p>Therefore in order to improve clarity and consistency and respectively compliance, the TGA proposes to define this in the Australian legislation.</p>
<p>(44) 'clinical evaluation' means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer.</p>	<p>Dictionary (regulation 1.3), Australian MD Regulations:</p> <p>clinical evaluation procedures means the conformity assessment procedures set out in Part 8 of Schedule 3.</p>	<p>The EU definition is consistent with the interpretation of this term in Australia, and with its use in the guidance document: Clinical Evidence Guidelines: Medical Devices.</p> <p>Therefore for clarity and consistency the TGA proposes to incorporate this definition in our legislation.</p>
<p>(5) 'implantable device' means any device, including those that are partially or wholly absorbed, which is intended:</p> <ul style="list-style-type: none"> – to be totally introduced into the human body, or – to replace an epithelial surface or the surface of the eye, <p>by clinical intervention and which is intended to remain in place after the procedure.</p> <p>Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device.</p>	<p>Dictionary (regulation 1.3), Australian MD Regulations:</p> <p>implantable medical device means a medical device (other than an active implantable medical device) that is intended by the manufacturer:</p> <ul style="list-style-type: none"> (a) to be, by surgical intervention, wholly introduced into the body of a human being, and to remain in place after the procedure; or (b) to replace, by surgical intervention, an epithelial surface, or the surface of an eye, of a human being, and to remain in place after the procedure; or (c) to be, by surgical intervention, partially introduced into the body of a human being, and to remain in place for at least 30 days after the procedure. 	<p>Because the definition of implantable device in the EU MD Regulation and implantable medical device in the Australian MD Regulations are more or less consistent, we do not, on replacement of the latter with the former definition, anticipate any impact on the regulation of an implantable medical device in Australia.</p> <p>For clarity and consistency with the EU MD Regulation of an implantable device, we propose that the EU definition replaces the present definition of implantable medical device in the Australian legislation.</p>
<p>(14) 'instructions for use' means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken.</p>	<p>No equivalent definition, although the Australian legislation includes multiple references to 'instructions for use'.</p>	<p>There are numerous references in the Australian legislation to instructions for use, which are critical to the safe operation of a medical device, but at present the term is not defined.</p> <p>Therefore, for clarity and consistency, we propose to incorporate the definition of instructions for use in the Australian legislation.</p>

EU MD Regulation (2017/745)	Australian definition	Proposal for amendments
<p>(26) 'interoperability' is the ability of two or more devices, including software, from the same manufacturer or from different manufacturers, to:</p> <p>(a) 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</p> <p>(b) communicate with each other, and/or</p> <p>(c) work together as intended.</p>	<p>No equivalent definition.</p>	<p>Interoperability is used in the EU MD Regulation in the revised equivalent of the Essential Principles (see Cl 14.5 of Annex 1, Chapter II, Requirements regarding design and manufacture). Specifically, Cl 14.5 requires 'Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.'</p> <p>Essential Principle 9.1 in the Australian medical regulations presently sets out requirements for medical devices intended to be used in combination with other devices or equipment. It does not include specific requirements equivalent to Cl 14.5. However, Essential Principle 9.1 is consistent with Cl 14.5 and therefore, for clarity and to achieve consistency, it is appropriate to incorporate the EU MD Regulation definition of interoperability in the Australian legislation.</p>
<p>(6) 'invasive device' means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.</p>	<p>Dictionary (regulation 1.3) Australian MD Regulations:</p> <p>'invasive medical device' means a medical device that is intended by the manufacturer to be used, in whole or in part, to penetrate the body of a human being through a body orifice or through the surface of the body.</p>	<p>Because the definitions of invasive device in the EU MD Regulation and invasive medical device in the Australian MD Regulations are more or less consistent, we do not, on replacement of the latter with the former definition, anticipate any impact (additional to clarity and consistency) on the regulation of an invasive medical device in the Australian legislation.</p> <p>Therefore for clarity and consistency we propose to incorporate the EU MD Regulation definition of invasive medical device in the Australian legislation.</p>
<p>(13) 'label' means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices.</p>	<p>Act section 3:</p> <p>label, in relation to therapeutic goods, means a display of printed information:</p> <p>(a) on or attached to the goods; or</p> <p>(b) on or attached to a container or primary pack in which the goods are supplied; or</p> <p>(c) supplied with such a container or pack.</p>	<p>The current definition of label in the Australian TG Act is drafted mostly having regard to the goods other than medical devices. The definition in EU MD Regulation is more or less consistent with the interpretation applied to the term label for medical devices. Therefore, we do not, on replacement of the definition, anticipate any impact (additional to clarity and consistency) on the regulation of labelling requirements for a medical device in the Australian legislation.</p> <p>For this reason, we propose that the EU definition of label (specific for medical devices) is incorporated in the Australian legislation.</p>

EU MD Regulation (2017/745)	Australian definition	Proposal for amendments
<p>(38) 'lay person' means an individual who does not have formal education in a relevant field of healthcare or medical discipline</p>	<p>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.</p>	<p>Currently, in Australia, the concept of lay person is used only in reference to self-testing in vitro diagnostic medical devices (IVDs).</p> <p>However, with rapid innovation in the medical technology sector, consumers are being offered ever more sophisticated products and services without the oversight of a healthcare or medical professional.</p> <p>Lay person is specifically referenced in the EU MD Regulation in the revised equivalent of the Essential Principles (see Cl 22.1 of Annex 1, Chapter II, Requirements regarding design and manufacture). Clause 22 deals with the protection against risks posed by medical devices which are intended by the manufacturer for use by lay persons.</p> <p>For example, Cl 22.1 requires 'Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply.' Additional obligations are included in Cl 22.2 and 22.3.</p> <p>Therefore it is proposed to incorporate this definition in the Australian legislation to ensure that the term lay person is well understood.</p>
<p>(39) 'reprocessing' means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device.</p>	<p>No equivalent definition, although there are definitions of related concepts: The Dictionary in the Australian MD Regulations defines reusable surgical instrument, and regulation 1.5 describes refurbishment. Section 41BG of the Act also refers to assembling, processing, adapting the device.</p>	<p>The EU MD Regulation states in Article 17 that reprocessing and further use of single-use devices may only take place where permitted by national law and in accordance with that Article. In the Australian context, it somewhat relates to the State and Territory regulations which are generally guided by Australian Standard 4187 and AS/NZS 4815. There is no intention to change this situation, and this consideration is not within the scope of our proposals.</p> <p>The introduction of this definition in our legislation, may however add clarity to the reprocessing process. For this reason, the TGA proposes to incorporate this definition.</p>
<p>(23) 'risk' means the combination of the probability of occurrence of harm and the severity of that harm.</p>	<p>No equivalent definition, although the Australian MD Regulations contain multiple references to risk.</p>	<p>At present in the Australian MD Regulations, risk is used, but not defined, and takes its ordinary meaning. Risk is referred to extensively in the Australian MD Regulations, including in the Essential Principles in Schedule 1, and in the classification rules (Schedules 2 and 2A).</p> <p>Therefore for clarity and consistency the TGA proposes to incorporate the EU definition of risk in the Australian legislation.</p>

EU MD Regulation (2017/745)	Australian definition	Proposal for amendments
(8) 'single-use device' means a device that is intended to be used on one individual during a single procedure.	No comparable definitions in Australian legislation, although the term single-use is used in the Australian MD Regulations.	<p>Devices for a single use are currently referred to in the Essential Principles in Schedule 1 of the Australian MD Regulations, which require that information about whether a device is intended for a single use only is provided with the medical device, and with the instructions for the use of a medical device. The EU MD Regulation refers to single-use devices principally in relation to the reprocessing of such devices, in Article 17.</p> <p>The TGA proposes to incorporate this definition for consistency and to provide greater clarity on the kinds of devices which will qualify as single-use devices.</p>
(37) 'user' means any healthcare professional or lay person who uses a device.	No equivalent definition, although this term is used in the Australian MD Regulations.	<p>The term user is currently used, particularly in the Essential Principles in Schedule 1 of the Australian MD Regulations.</p> <p>For consistency and clarity the TGA proposes to incorporate the EU definition in the Australian legislation.</p>

Table A3 - Definitions not proposed to be aligned with

EU MD Regulation (2017/745)	Australian definition	Proposal for amendments
<p>(57) 'adverse event' means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational device.</p>	<p>There is no definition of adverse event in the Act, although section 41MP(2) provides an indirect definition:</p> <p>(2) The information with which subsection (1) is concerned is information of the following kinds:</p> <p>(a) information relating to:</p> <p>(i) any malfunction or deterioration in the characteristics or performance of the kind of device; or</p> <p>(ii) any inadequacy in the design, production, labelling, instructions for use or advertising materials of the kind of device; or</p> <p>(iii) any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;</p> <p>that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health;</p> <p>(b) information relating to any technical or medical reason for a malfunction or deterioration of a kind referred to in subparagraph (a)(i) that has led the manufacturer to take steps to recall devices of that kind that have been distributed;</p> <p>(c) information that indicates that a device of that kind does not comply with the essential principles;</p> <p>(d) information that indicates that a certificate or other document (other than a certificate or other document issued by the Secretary under this Act) used for the purpose of an application under subsection 41FC(1) to signify:</p> <p>(i) compliance with the essential principles; or</p> <p>(ii) the application of relevant conformity assessment procedures to a device of that kind or the application of requirements, comparable to those procedures, to a device of that kind;</p> <p>has been restricted, suspended, revoked or is no longer in effect.</p>	<p>There is no specific definition of adverse event in Australian legislation, although section 41MP of the Act and Regulation 5.7 of the Australian MD Regulations detail information about device malfunctions and other events which must be provided to the TGA, and the timeframes within which the information must be provided.</p> <p>The EU MD Regulation definition of adverse event is limited to the clinical investigation of a device. However in Australia, the term adverse event has already an established meaning, encompassing the entire life cycle of a device from clinical investigation to use and withdrawal from the market.</p> <p>For these reasons, the TGA proposes not to adopt the EU definition of adverse event.</p>

EU MD Regulation (2017/745)	Australian definition	Proposal for amendments
<p>(43) 'CE marking of conformity' or 'CE marking' means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing.</p>	<p>No equivalent definition.</p>	<p>The EU MD Regulation uses this term in the context of requiring manufacturers to affix CE marking of conformity to medical devices as a public demonstration that relevant third party assessment (or, in the case of Class I medical devices, self-assessment) has been undertaken, however there is no such requirement in Australia.</p> <p>The Australian legislation does not require devices to carry CE marks, rather any medical device (unless exempt) must be included in the ARTG in order to be able to be legally imported, exported and/or supplied in Australia.</p> <p>Therefore this definition is not required in the Australian legislation.</p>
<p>(71) 'common specifications' (CS) means a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system.</p>	<p>Comparable powers are provided in the Act under section 41CB:</p> <p>(1) Without limiting the scope of section 41CB, an order establishing a medical device standard for kinds of medical devices may be specified by reference to:</p> <p>(a) the safety or performance characteristics of the devices; or</p> <p>(b) a monograph in the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopeia National Formulary; or</p> <p>(c) a monograph in a publication approved by the Minister for the purposes of this subsection; or</p> <p>(d) such a monograph as modified in a manner specified in the order; or</p> <p>(e) a standard published by a standards organisation; or</p> <p>(f) such other matters as the Minister thinks fit.</p>	<p>Article 9 of the EU MD Regulation gives the European Commission authority to prepare a CS where no harmonised standards exist, where the relevant harmonised standards are considered insufficient, or where there is a need to address public health concerns.</p> <p>In Australia, the legislation does not refer to common specifications. However, section 41CB of the Act gives the Minister powers to establish medical device standards. It is taken that this power is similar in intent to common specifications and therefore it is unnecessary to define this term in the Australian legislation.</p> <p>Further, common specifications are most likely to be dependent on the public health concerns in a particular regulatory jurisdiction, and these concerns may somewhat vary between Australia and the EU. Future EU common specifications will be considered for relevance in the Australian context prior to being adopted into our domestic requirements.</p> <p>The TGA proposes not to adopt this definition.</p>

EU MD Regulation (2017/745)	Australian definition	Proposal for amendments
<p>(40) 'conformity assessment' means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled.</p>	<p>Act, section 41DA:</p> <ol style="list-style-type: none"> (1) The regulations may set out requirements relating to the obligations of manufacturers of medical devices. (2) These requirements are to be known as the conformity assessment procedures. (3) The conformity assessment procedures, or any part of the conformity assessment procedures, may: <ol style="list-style-type: none"> (a) be limited in their application to one or more medical device classifications; or (b) apply differently to different medical device classifications, different kinds of medical devices or different manufacturers. (4) Without limiting subsection (1), the regulations may relate to all or any of the following: <ol style="list-style-type: none"> (a) application of quality management systems for the manufacture of medical devices; (b) certification of compliance with the essential principles, or the quality management systems for the manufacture of medical devices; (c) notification of, and assessment of, changes to a manufacturer's product range, product design or quality management systems; (d) declarations to be made by manufacturers of medical devices that conformity assessment procedures have been applied to the devices; (e) marks to be affixed to medical devices indicating the application of the conformity assessment procedures to the devices; (f) monitoring and inspecting the design of medical devices or the manufacturing processes for medical devices; (g) monitoring the performance of medical devices; (h) corrective action required in relation to the design, manufacture, packaging, labelling and supply of medical devices; (i) keeping records of the manufacture of medical devices, the design of medical devices or the manufacturing processes for medical devices. 	<p>The Australian definition of conformity assessment is more appropriate in the Australian context, which differs from the EU context in several legal and constitutional respects.</p> <p>For this reason, the TGA proposes not to adopt this EU definition.</p>

EU MD Regulation (2017/745)	Australian definition	Proposal for amendments
<p>(41) 'conformity assessment body' means a body that performs third-party conformity assessment activities including calibration, testing, certification and inspection.</p>	<p>Act, section 3: Australian conformity assessment body means an Australian corporation that is the subject of a conformity assessment body determination made under the regulations.</p>	<p>A conformity assessment body is defined in the Australian legislation in the context of requirements for Australian conformity assessment bodies. This term is also used in context of the use of overseas regulator conformity assessment documents for the purposes of inclusion medical devices in ARTG.</p> <p>Therefore this term has somewhat different legal meaning in Australia, and for this reason, TGA proposes not to adopt this definition.</p>
<p>(34) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service.</p>	<p>There is no equivalent definition, but there are multiple references to distribute and distributed in the Act and the Australian MD Regulations.</p>	<p>In accordance with the Australian legislation this function is to be performed by either a sponsor themselves or by another person (physical or legal) on behalf of the sponsor.</p> <p>For the definition of <i>'sponsor'</i> refer the Act, section 3. Specifically this definition (among other things) refers to a person who exports, imports or manufactures the goods on behalf of another person, and this definition provides that such person is not a sponsor. Which effectively implies that any person (physical or legal) who distributes the devices on behalf of the sponsor, is not within the scope of the TG Act, and all responsibilities regarding a medical device remain with the sponsor.</p> <p>However, any person who wants to legitimately distribute (i.e. supply) medical devices on their own initiative (i.e. not on behalf of another person who is the sponsor) must include the device in the ARTG themselves, and become the sponsor. This is further explained in Act, Division 3, Part 4-11 - Medical devices not included in the Register and related matters.</p> <p>The concept of sponsor has a well-established meaning in Australia with the well-defined responsibilities for a medical device. TGA does not propose to change the regulatory role of the sponsor, and for this reason (in general terms) considers that incorporating the definition of distributor in the Australian legislation may not be necessary.</p>

EU MD Regulation (2017/745)	Australian definition	Proposal for amendments
<p>(9) 'falsified device' means any device with a false presentation of its identity and/or of its source and/or its CE marking certificates or documents relating to CE marking procedures. This definition does not include unintentional non-compliance and is without prejudice to infringements of intellectual property rights.</p>	<p>Act, section 42E:</p> <p>(2) Goods are counterfeit if any of the following contain a false representation of a matter listed in subsection (3):</p> <ul style="list-style-type: none"> (a) the label or presentation of the goods; (b) any document or record relating to the goods or their manufacture; (c) any advertisement for the goods. <p>(3) The matters are as follows:</p> <ul style="list-style-type: none"> (a) the identity or name of the goods; (b) the formulation, composition or design specification of the goods or of any ingredient or component of them; (c) the presence or absence of any ingredient or component of the goods; (d) the strength or size of the goods (other than the size of any pack in which the goods are contained); (e) the strength or size of any ingredient or component of the goods; (f) the sponsor, source, manufacturer or place of manufacture of the goods. 	<p>Many penalty provisions in the Act are drafted with reference to counterfeit therapeutic goods, particularly section 42E, which sets out a criminal offence of manufacturing, supplying, importing or exporting counterfeit therapeutic goods in or from Australia.</p> <p>Section 42EA provides for a civil penalty for the same offence. Section 61(4A)(fa) empowers the Secretary to release, to certain bodies, therapeutic goods information relating to cases or possible cases of counterfeit therapeutic goods.</p> <p>Counterfeit is a concept with a well-established history in the Australian therapeutic goods context and internationally, and for this reason the TGA proposes not to adopt this EU definition, and to retain the Australian terminology of counterfeit.</p>

EU MD Regulation (2017/745)	Australian definition	Proposal for amendments
<p>(31) 'fully refurbishing', for the purposes of the definition of manufacturer, means the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it into conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device.</p>	<p>Australian MD Regulations, regulation 1.5:</p> <p>(1) A refurbishment of a medical device is taken to have occurred if the medical device, or a part of the device, is substantially rebuilt from one or more used medical devices of that kind so as to create a medical device that is able to be used for the purpose originally intended by the manufacturer of the original device.</p> <p>(2) Without limiting subregulation (1), a refurbishment of a medical device may involve the following actions:</p> <p>(a) stripping the device into component parts or sub-assemblies;</p> <p>(b) checking parts of the device for suitability for reuse;</p> <p>(c) replacing component parts or sub-assemblies of the device that are not suitable for reuse;</p> <p>(d) assembling reclaimed or replacement component parts or sub-assemblies of the device or another used device;</p> <p>(e) testing a reassembled device against the specifications of the original device or, if the manufacturer has revised those specifications, the revised specifications;</p> <p>(f) identifying an assembled device as a refurbished device.</p>	<p>Fully refurbishing is defined, but not used, in the EU MD Regulation, although two references to refurbishing are made in Annex VI, relating to the UDI system (regarding which we will be consulting separately).</p> <p>Regulation 1.5 of the Australian MD Regulations provides a comprehensive definition of refurbishment and gives specific examples of activities which may constitute refurbishment.</p> <p>This more detailed definition is intended to give manufacturers, hospital staff and consumers, better understanding of their obligations. Accordingly, the TGA proposes not to adopt this EU definition.</p>
<p>(70) 'harmonised standard' means a European standard as defined in point (1)(c) of Article 2 of Regulation (EU) No 1025/2012.</p>	<p>No equivalent definition.</p>	<p>The Australian legislation has a provision that allows determination of certain standards for the purposes of demonstrating compliance with the Essential Principle and conformity assessment procedures.</p> <p>This definition therefore may not be consistent with the established meaning in our legislation; therefore the TGA proposes not to adopt this terminology.</p>
<p>(36) 'health institution' means an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health.</p>	<p>No equivalent definition.</p>	<p>The term 'health institution' in its general meaning is well-understood in the Australian context, and therefore it does not appear to be necessary to explicitly define it. Therefore the TGA proposes not to incorporate this definition in our legislation.</p>
<p>(33) 'importer' means any natural or legal person established within the Union that places a device from a third country on the Union market.</p>	<p>Act section 3:</p> <p>sponsor, in relation to therapeutic goods, means:</p> <p>...</p> <p>(b) a person who imports, or arranges the importation of, the goods into Australia;...</p>	<p>TGA does not propose incorporating the definition of an 'importer' for the same reasons as outlined for item (34) 'distributor'.</p>

EU MD Regulation (2017/745)	Australian definition	Proposal for amendments
(27) 'making available on the market' means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.	Act, section 3: supply includes: (a) supply by way of sale, exchange, gift, lease, loan, hire or hire purchase; and (b) supply, whether free of charge or otherwise, by way of sample or advertisement; and (c) supply, whether free of charge or otherwise, in the course of testing the safety or efficacy of therapeutic goods in persons; and (d) supply by way of administration to, or application in the treatment of, a person.	This definition currently falls within supply as defined in section 3 of the Act, which applies to all types of therapeutic goods, and has a well-established meaning in the Australian therapeutic goods context. The Act contains numerous references to supply , particularly in relation to criminal offences and civil penalties for the supply of medical devices. For this reason TGA proposes not to adopt this EU definition.
(42) 'notified body' means a conformity assessment body designated in accordance with this Regulation.	No equivalent definition.	This definition is only required in the context of the use of comparable overseas regulatory approvals and defined in this context. TGA does not propose to adopt this definition.
(22) 'performance' means the ability of a device to achieve its intended purpose as stated by the manufacturer.	Act section 4(1A) provides: <i>The reference ... to the efficacy of therapeutic goods is a reference, if the goods are medical devices, to the performance of the devices as the manufacturer intended.</i>	In accordance with the Australian legislation, the meaning of performance of the device is as intended by the manufacturer. Therefore it does not appear to be necessary to include a separate definition for the <i>performance</i> . For this reason, the TGA does not propose to adopt this definition.
(28) 'placing on the market' means the first making available of a device, other than an investigational device, on the Union market.	Act, section 3, definition of supply as above.	The TGA proposes not to adopt this EU definition for the same reason as for item (27) 'making available on the market'.
(29) 'putting into service' means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose.	Act, section 3, definition of supply as above.	The TGA proposes not to adopt this EU definition for the same reason as for item (27) 'making available on the market'.
(62) 'recall' means any measure aimed at achieving the return of a device that has already been made available to the end user.	No equivalent definition.	Recalls of medical devices are already provided for by section 41KA of the Act. This section, read together with the (URPTG), sets out a comprehensive procedure for the recall of all types of therapeutic goods by Commonwealth, State and Territory governments. At present the word recall is not defined in the Act however has a well-established meaning. For this reason the TGA proposes not to adopt this definition.

EU MD Regulation (2017/745)	Australian definition	Proposal for amendments
<p>(58) 'serious adverse event' means any adverse event that led to any of the following:</p> <p>(a) death,</p> <p>(b) serious deterioration in the health of the subject, that resulted in any of the following:</p> <p>(i) life-threatening illness or injury,</p> <p>(ii) permanent impairment of a body structure or a body function,</p> <p>(iii) hospitalisation or prolongation of patient hospitalisation,</p> <p>(iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function, (v) chronic disease,</p> <p>(c) foetal distress, foetal death or a congenital physical or mental impairment or birth defect.</p>	No equivalent definition.	<p>This EU definition of serious adverse event is limited to the clinical investigation of a device. The term serious adverse event already has an established meaning in the Australian setting and denotes a broader concept that is not limited to the device trial/investigation phase.</p> <p>There is currently no definition of serious adverse event in Australian legislation. However, expectations around reporting of adverse events are prescribed in the Australian MD Regulations, and Regulation 5.7 details adverse events that will require reporting, i.e. this term has a well-established meaning.</p> <p>For this reason, the TGA proposes not to adopt the EU definition.</p>
<p>(63) 'withdrawal' means any measure aimed at preventing a device in the supply chain from being further made available on the market.</p>	No equivalent definition.	<p>At present, the word withdrawal is not defined in the Act, but rather has a broadly accepted ordinary meaning when the device is no longer available on the market.</p> <p>As the term withdrawal has an established meaning, the TGA does not propose it is necessary to define this term.</p>

Table A4 - Definitions which will be consulted on separately

Title of consultation	Medical Devices Regulation EU 2017/745 (MDR) Article 2 Medical Devices Regulation EU 2017/745 (MDR)
Clinical Trials	'clinical investigation' 'investigational device' 'clinical investigation plan' 'clinical data' 'subject' 'clinical evidence' 'clinical performance' 'clinical benefit' 'investigator' 'informed consent' 'ethics committee' 'device deficiency'
Conformity Assessment Procedures	'generic device group' 'non-viable' 'derivative'
Custom-made medical devices	'custom-made device' 'manufacturer'

Post Market Requirements	<p>'post-market surveillance'</p> <p>'market surveillance'</p> <p>'corrective action'</p> <p>'field safety corrective action'</p> <p>'field safety notice'</p> <p>'incident'</p> <p>'serious incident'</p> <p>'serious public health threat'</p>
Procedure Packs	<p>'procedure pack'</p> <p>'system'</p> <p>'compatibility'</p>
Reclassification	<p>'nanomaterial'</p> <p>'particle'</p> <p>'agglomerate'</p> <p>'aggregate'</p> <p>'active device'</p>
Unique Device Identifier	<p>'Unique Device Identifier' ('UDI')</p> <p>'authorised representative', <i>economic operator</i> etc.</p>

Appendix B - Products without medical intended purpose

Article 1(2) of the EU MD Regulation (2017/745/EU) provides that some groups of products that do not have an intended medical purpose, falls within the scope of the EU MD Regulation.

These are products for which a manufacturer claims only an aesthetic or another non-medical purpose, but which are similar to other products that meet the definition of medical devices in terms of functioning and risk profile. Annex XVI provides a list of groups of products that come within this category.

Previously, these products have not been consistently regulated, and the 2017 EU MD Regulation has introduced requirements around the manufacturing and surveillance to ensure protection of the health and safety of recipients and users of these products.

While the products captured under Annex XVI do not have an intended medical purpose, the risks posed by these devices are similar to when such devices are used for a medical purpose.

The products listed in Annex XVI are:

1. Contact lenses or other items intended to be introduced into or onto the eye.
2. Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.
3. Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.
4. Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.
5. High intensity electromagnetic radiation (for example, infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.
6. Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

The EU MD Regulation also provides the European Commission with the power to amend the list of products of Annex XVI and add new groups of products if required in order to protect the health and safety of users or other aspects of public health.

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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