Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Update to medical device definitions and requirements for system or procedure packs

Information for sponsors and manufacturers

Last updated:
1 October 2020

On **25 August 2020**, two changes will commence:

- **new medical device definition and a number of other related definitions** in the *Therapeutic Goods Act 1989* (the Act) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations); and
- minor amendments to the **requirements for system or procedure packs** in the Regulations.

If you are a sponsor or a manufacturer of a medical device, **you must comply with the new definitions**.

If you are the sponsor of a system or procedure pack, **the action you will need to take to comply with the new requirements will depend on the status of your product**.

Note that the changes coming into effect on 25 August 2020 do **not** include the proposed expansion of the medical devices regulatory scope to include some products that do not have an explicit medical intended purpose (e.g. products for beauty therapy). More information will be provided on the proposed expansion of the medical devices regulatory scope at a later date.

Sponsors and manufacturers should be aware that further changes to regulatory requirements for system or procedure packs will be occurring at a later date.

This document is a guide to assist sponsors and manufacturers with the changes. It is the responsibility of each sponsor and/or manufacturer to understand and comply with these requirements, and to seek professional advice if necessary.

Background

In October 2019, the Therapeutic Goods Administration (TGA) conducted a public consultation seeking feedback (https://www.tga.gov.au/node/283529) on a proposal to change a number of definitions and the scope of the medical devices regulatory framework in Australia. The proposed regulatory changes supported the commitment made in the Australian Government Response to the Review of Medicines and Medical Devices Regulation (https://www.tga.gov.au/node/287037) to align Australian medical device regulations, where possible and appropriate, with the European Union framework.

Stakeholders who responded to the public consultation on Proposed clarification of the regulatory requirements for medical device systems or procedure packs (https://www.tga.gov.au/node/288005) and Changes to a number of definitions and the scope of the medical device regulatory framework in Australia (https://www.tga.gov.au/node/288005) were broadly supportive of the proposed amendments in the consultation paper. These included the proposal to introduce definitions for *system* and *procedure pack* and amend the definitions of *medical device* and *accessory* in the Act; and introduce definitions for *instructions for use*, *user* and *re-useable surgical instrument* in the Regulations.

Changes to definitions in the Act

Definitions for *medical device* in section 41BD of the Act, *accessory* in subsection 3(1) of the Act and *system or procedure packs* in section 41BF of the Act have been amended to reflect the new definitions in the *Therapeutic Goods Amendment (2020 Measures No. 1) Act 2020* (https://www.legislation.gov.au/Details/C2020A00075).

Definition before amendment	**Amended definition from 25 August 2020**
Section 41BD What is a *medical device*	**Section 41BD What is a *medical device***
(1) A *medical device* is:	(1) A ***medical device*** is:
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).	
(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	(a) any instrument, apparatus, appliance, **software, implant, reagent,** 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:

Definition before amendment	Amended definition from 25 August 2020
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: (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; 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 (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). (2) 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: (a) the labelling on the main equipment;	(i) diagnosis, prevention, monitoring, **prediction, prognosis,** 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 or **pathological** process or **state**; (iv) control **or support** of conception; **(v) in vitro examination of a specimen derived from the human body for a specific medical purpose** 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 (aa) any instrument, apparatus, appliance, **software, implant, reagent,** material or other article specified under subsection (2A); or (ab) any instrument, apparatus, appliance, **software, implant, reagents,** 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, **software, implant, reagent,** material or other article covered by paragraph (a), (aa) or (ab). **(c) a system or procedure pack** Note: Declarations under subsection (3) exclude articles from the scope of this definition. Declarations under section 7 can

Definition before amendment	Amended definition from 25 August 2020
(b) the instructions for using the main equipment; (c) any advertising material relating to the main equipment; (d) technical documentation describing the mechanism of action of the main equipment. (2A) The Secretary may, by notice published in the Gazette or on the Department's website, specify a particular instrument, apparatus, appliance, material or other article for the purposes of paragraph (1)(aa). The notice is not a legislative instrument. (2B) The Secretary may, by legislative instrument, specify a particular class of instruments, apparatus, appliances, materials or other articles for the purposes of paragraph (1)(ab). (3) The Secretary may, by order published in the Gazette or on the Department's website, declare that a particular instrument, apparatus, appliance, material or other article, or that a particular class of instruments, apparatus, appliances, materials or other articles, are not, for the purposes of this Act, medical devices. Note: A declaration under this section does not stop articles from being therapeutic goods. (4) A declaration under this section takes effect on the day on which the declaration is published in the Gazette or on the Department's website or on such later day as is specified in the order.	also have this effect: see subsection 7(4). (2) For the purposes of paragraph (1)(a), the purpose for which an instrument, apparatus, appliance, **software, implant, reagents,** 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: (a) the labelling on the main equipment; (b) the instructions for using the main equipment; (c) any advertising material relating to the main equipment; (d) technical documentation describing the mechanism of action of the main equipment. (2A) The Secretary may, by notice published in the *Gazette* or on the Department's website, specify a particular instrument, apparatus, appliance, **software, implant, reagent,** material or other article for the purposes of paragraph (1)(aa). The notice is not a legislative instrument. (2B) The Secretary may, by legislative instrument, specify a particular class of instruments, apparatus, appliances, **software, implant, reagents,** materials or other articles for the purposes of paragraph (1)(ab). (3) The Secretary may, by order published in the *Gazette* or on the Department's website, declare that a particular instrument, apparatus, appliance, **software, implant, reagents,** material or other article, or that a particular class of instruments, apparatus, appliances,

Definition before amendment	Amended definition from 25 August 2020
	software, implants, reagents, materials or other articles, are not, for the purposes of this Act, medical devices. Note: A declaration under this section does not stop articles from being therapeutic goods. (4) A declaration under this section takes effect on the day on which the declaration is published in the *Gazette* or on the Department's website or on such later day as is specified in the order.
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.	***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 **or assist** the device to be used as the manufacturer of the device intended.

The amended definitions for *medical device* and *accessory* provide additional clarification around certain aspects of "what is a medical device" or "an accessory to a medical device" that were already considered within the scope of the existing definition, but not explicitly stated in legislation. These clarifications include software, implants and reagents, and goods used for the in vitro examination of a specimen collected from the human body for medical purposes. These amendments also support harmonisation activities by aligning more closely with the equivalent definitions in the European Union.

Definition before amendment	Amended Definition from 25 August 2020
Section 41BF System or procedure packs (1) A package and therapeutic goods in the package are a ***system or procedure pack*** if: (a) the package and the therapeutic goods are for use as a unit, either in combination as a system or in a medical or surgical procedure; and	**Section 41BF System or procedure packs** Two or more goods (including at least one medical device) are a ***system or procedure pack*** if: (a) all of the goods are to be interconnected or combined for use in a medical or surgical procedure; or

Definition before amendment	Amended Definition from 25 August 2020
(b) the package contains at least one medical device; and (c) the package and the therapeutic goods do not constitute a composite pack. (2) To avoid doubt, a system or procedure pack is a medical device.	(b) all of the goods are packaged together for use in a medical or surgical procedure.

The new definition of *system or procedure packs* clarifies a number of aspects of the current definition and is designed to more closely align this terms with the *system* and *procedure pack* definitions in Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices (the EU Regulations) - combining the scope of both these definitions in the updated definition of *system or procedure packs*.

Under the new definition two or more goods will be a system or procedure pack if:

- at least one of the goods is a medical device; and
- either:
    - all of the goods are to be interconnected or combined for use in a medical or surgical procedure (i.e. regardless of whether the goods or some of the goods are packaged together or not); or
    - all of the goods are packaged together for use in a medical or surgical procedure (i.e. regardless of whether the goods or some of the goods are to be interconnected or combined for use in the medical or surgical procedure).

Goods that are interconnected or combined for use, or packaged together, but not for the purpose of being used in a medical or surgical procedure would not constitute a system or procedure pack.

Although orthopaedic loan kits are used in a medical or surgical procedures, not all of the components in the kit are to be interconnected or combined for use, or packaged together. For this reason, orthopaedic loan kits are not considered to meet the new definition of *system or procedure packs*. However, the kit itself is still a medical device and is to be regulated in a similar manner to other medical devices.

Procedure packs such as a first aid kit or systems such as an implantable ventricular circulatory assist system or blood glucose monitoring system meet the new definition of *system or procedure packs* and will therefore continue to be regulated as system or procedure packs if they meet the requirements for medical devices that are used for a special purpose.

Changes to definitions in the Regulations

The addition of a definition for instructions for use and user, along with the amendment of the definition of reusable surgical instrument have been amended in the Therapeutic Goods Legislation Amendment (2020 Measures No. 1) Regulations 2020 (https://www.legislation.gov.au/Details/F2020L00946).

Definition before amendment	Amended Definition from 25 August 2020
No current definition	i***nstructions for use,*** in relation to a medical device, includes information provided by the manufacturer of the device to inform a user of the device of the intended purpose of the device, of the proper use of the device and of any precautions to be taken in relation to the use of the device. Note: These Regulations contain requirements relating to instructions for use of a medical device. For example, clauses 13.1 to 13.4 of Schedule 1 (about essential principles) deal with information that must be included in instructions for the use of a medical device.
No current definition	***user*** of a medical device means any person (including a health professional) who uses the device.
reusable surgical instrument means a medical device that is intended by the manufacturer: (a) to be used surgically, without being connected to an active medical device, for cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or any other similar procedure; and (b) to be reused after the appropriate procedures specified by the manufacturer in the instructions for use have been carried out.	***reusable surgical instrument*** means a medical device that is intended by the manufacturer: (a) to be used surgically, without being connected to an active medical device, for cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or any other similar procedure; and (b) to be reused after the appropriate procedures **(such as cleaning, disinfection and sterilisation)** specified by the manufacturer in the instructions for use have been carried out.

Requirements for system or procedure packs

There are minor consequential amendments to the requirements for system or procedure packs in the Regulations to reflect the new definition of these products in the *Therapeutic Goods Amendment (2020 Measures No. 1) Act 2020* (https://www.legislation.gov.au/Details/F2020L00946). These minor amendments mainly relate to the special conformity assessment procedures set out in Clause 7.5, Schedule 3, of the Regulations. These changes will not involve any changes to obligations for sponsors or manufacturers of such medical devices.

If you are a sponsor of a system or procedure pack, the action you will need to take to comply with the amendments to the Act and the Regulations will depend on the status of your product.

Sponsors with a medical device included in the Australian Register of Therapeutic Goods (ARTG) prior to 25 August 2020

If you have a system or procedure pack medical device included in the ARTG (that is supported by declaration of conformity under Clause 7.5, Schedule 3, of the Regulations) with a start date before 25 August 2020, there is no impact to you because of the introduced change.

Sponsors with an application to include a medical device in the ARTG lodged before 25 August 2020

If you have submitted to the TGA an application for inclusion in the ARTG for a system or procedure pack medical device (that is supported by declaration of conformity under Clause 7.5, Schedule 3, of the Regulations) before 25 August 2020, your application will be assessed and the device will be included in the ARTG. There is no impact to you because of the introduced change.

Sponsors intending to submit an application to include a new medical device in the ARTG on or after 25 August 2020

If you are intending to submit an application for inclusion in the ARTG for a system or procedure pack medical device (that is supported by declaration of conformity under Clause 7.5, Schedule 3, of the Regulations), you will need to apply using the new template for manufacturer's Declaration of Conformity (https://www.tga.gov.au/node/288300) for system or procedure packs.

Although this requirement is effective from 25 August 2020, the TGA will continue to accept an application for inclusion in the ARTG that are supported by declarations of conformity using the previous template, **up until 31 October 2020**. From 1 November 2020, sponsors will be required to use the new template when submitting an application for inclusion in the ARTG.

For the new template for manufacturer's declaration of conformity for system or procedure packs under Clause 7.5, Schedule 3, of the Regulations see Declaration of conformity templates (medical devices) (https://www.tga.gov.au/node/288300).

For further information see Medical device inclusion process (https://www.tga.gov.au/node/285202).

Upcoming changes

System or Procedure Packs

Other changes to the requirements for systems or procedure packs set out in Regulation 3.10 and Clause 7.5, Schedule 3, of the Regulations were proposed in the consultation paper (https://www.tga.gov.au/node/283543). Following consideration of input from respondents of the public submissions (https://www.tga.gov.au/node/288005), targeted workshops will commence on 25 November 2021. These proposed amendments will clarify that:

- the manufacturer of the system or procedure pack (SOPP) will be required to hold a current conformity assessment document for each medical device placed in the SOPP that demonstrates that the relevant conformity assessment procedures have been applied to those devices in the SOPP.
- if the SOPP is intended to be supplied sterile, the manufacturer of SOPP will be required to declare that the minimum conformity assessment procedures appropriate for ensuring the sterility have been applied to the SOPP and that the sterilisation of the system or procedure pack has been carried out in accordance with the instructions from all original manufacturers of all goods put into the SOPP.
- if the manufacturer of the SOPP intends to open or modify the packaging of any goods, or otherwise process or modify any of the goods that are placed in the SOPP, the SOPP manufacturer assume the responsibility for the safety and performance of these goods, including applying the relevant conformity assessment procedures outlined in Division 3.2 of the Regulations to the SOPP.

Further, overall there was broad support amongst respondents (https://www.tga.gov.au/node/288005) for the proposal in the consultation paper to reconsider the existing record retention requirements that apply to system or procedure packs using the special conformity assessment procedure pathway.

The record retention requirements set out in Clause 7.6, Schedule 3, of the Regulations that apply to medical devices used for a special purpose (including system or procedure packs) have been amended. The amendment in the Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019 (https://www.legislation.gov.au/Details/F2020C00726) reflect the new requirement that the manufacturer must retain documentation about the device for at least for 5 years (for a device that is not an implantable medical device) or 15 years (for a device that is an implantable medical device).

This requirement will commence on 25 February 2021 and will apply to system or procedure packs that are medical devices used for a special purpose that are manufactured on or after that date.

Detailed guidance will be made available to stakeholders to clarify obligations for sponsors and manufacturers resulting from the changes to the Regulations.

Beauty therapy products such as lasers and IPL devices

Further discussions are occurring with targeted stakeholders about the proposed regulation of products for beauty therapy, such as lasers and IPL devices, prior to considering further regulatory amendments. For more information, see Submissions received: Changes to a number of definitions and the scope of the medical device regulatory framework in Australia (https://www.tga.gov.au/node/285485)

Contact us

Please contact the TGA at devices@tga.gov.au should you have further queries or comments.

Topics:

Medical devices (https://www.tga.gov.au/products/medical-devices)