Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019

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23 July 2020

Update - 23 July 2020

The Governor-General in Council has made regulations which delay the commencement of a number of medical device reforms in Australia. This delay reflects the challenges identified by the medical devices industry and healthcare professionals to redirect their efforts to regulatory changes as they have focussed on the COVID-19 crisis.

The delay will allow additional time for the Therapeutic Goods Administration (the TGA) to further consult with the medical device industry and health care professionals on guidance material and implementation details relating to the reforms.

You can find out more information below and here: Delays to the commencement of certain medical device regulatory changes (https://www.tga.gov.au/node/287070)

Overview

The *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations) were amended on 12 December 2019.

This is the first package of regulatory changes for the broader medical device reforms and follows a number of public consultations which occurred late 2018 through early 2019.

Changes to the commencement of the Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019

The Governor-General in Council has made regulations which delay the commencement of a number of medical device reforms from the *Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019*. This is to reflect the challenges identified by the medical devices industry and healthcare professionals as they have focussed on the COVID-19 crisis.

The delay will allow additional time for the Therapeutic Goods Administration (the TGA) to further consult with the medical device industry and health care professionals on guidance material and implementation details relating to the reforms.

An overview of the changes agreed in December 2019 and July 2020 is provided below and detailed guidance will be made available.

It is important to note that the delay to the commencement of the reforms does **not** change the end of the transition period. This remains at 31 October 2024. This means there is now less time to transition to the new arrangement for these devices.

Software

Regulation of software will continue to be risk and principles based.

What's changing

The Regulations have been amended in relation to software-based medical devices including programmed and programmable hardware (referred to collectively as 'programmed or programmable medical device, or software that is a medical device'):

- New classification rules have been introduced to classify devices of this kind according to their potential to cause harm through the provision of incorrect information.
    - The rules are largely aligned with the software rules in the EU MDR 2017
    - In some cases, a device will be a lower classification (where a relevant healthcare professional is involved);
    - Devices that provide direct diagnosis or monitoring will be the same class in most cases.
    - Devices intended to provide therapy via the provision of information (e.g., a medical device intended to provide cognitive behavioural therapy) will potentially be a higher

class in some cases.
    - The new classification rules **will not** apply to in vitro diagnostic (IVD) medical devices.
- Essential principle 12.1 has been amended to clarify the expectations around these types of devices, including with regards to cyber security; the management of data and information; and requirements relating to development, production, and maintenance.
- Essential Principle 13.2(3) has been amended to allow information, where applicable, to be provided electronically rather than on a leaflet for medical devices that are software.
- A new requirement has been introduced, as Essential Principle 13B, for identification of current version and build number to be made accessible by, and identifiable to, users of medical devices that are, or that incorporate, software.

Further guidance will be provided in late 2020.

Important dates

The new software regulations will commence on **25 February 2021** for new applications for inclusion.

Transitional arrangements for medical devices that are included in the ARTG on this date will apply.

Personalised medical devices

What's changing

Regulatory changes have been introduced to:

- Reduce the scope of the existing definition of custom-made medical device.
- Introduce new definitions in relation to personalised medical devices.
- Change the exemption requirements for custom-made medical devices to:
    - require annual reporting of custom-made devices supplied in the previous financial year;
    - allow the TGA to inspect production facilities;
    - require documentation about the device to be retained for 5 years (for non-implantables) or 15 years (for implantables); and
    - require manufacturers to provide information about each custom-made medical device to the intended recipient

- Introduce a new concept of *Medical Device Production System* (MDPS) and a framework for regulating medical device production systems which will allow healthcare providers to produce personalised devices for treating their patients, without the need for manufacturing certification. An MDPS will have the same classification as the medical device the system is intended to create.
- Update the classification rule 5.4 for medical devices that record diagnostic images to include non-visible spectrum imaging mechanisms for this purpose and not just X-rays, and also includes models of patient anatomy. As a result some devices will be Class IIa rather than Class I.

Important dates

The new personalised medical device regulations will commence on **25 February 2021**.

For those custom-made devices that will be patient-matched medical devices under the new definition, transitional arrangements will apply.

Similarly, transitional arrangements will apply in relation to medical devices that record diagnostic images and that are anatomical models.

IVD companion diagnostics

What's changing

The regulations have been amended to further align with the USFDA and EU with respect to the devices known as "IVD companion diagnostics". Under the changes a definition of "IVD companion diagnostic" will be included in the Regulations identifying these devices based on their use in the selection of patients for selective therapy and management. Products that meet the definition will be regulated as Class 3 IVDs and will be required to undergo compulsory audit.

Important dates

For IVD companion Diagnostics seeking inclusion and a new application is received on or after **1 February 2020** the new rules apply.

Transitional arrangements apply to IVD companion diagnostics that, on **31 January 2020**:

- are included in the ARTG; or
- are the subject of an effective application for inclusion in the ARTG that has not been finally determined; or

- are not included in the ARTG but are covered by a current conformity assessment certificate issued by the TGA; or
- are not included in the ARTG but are covered by an effective application for a conformity assessment certificate that has not been finally determined; or
- are in-house IVDs that are Class 1, Class 2 or Class 3 (noting that IVD companion diagnostics will be Class 3 under the new Regulations but Class 1-3 in-house IVDs are exempt from inclusion in the ARTG).

A new application for inclusion that complies with the amended Regulations must be made before **30 June 2022** (for commercially supplied IVD companion diagnostics).

Draft guidance on IVD companion diagnostics is now available at: IVD Companion Diagnostics: Guidance on proposed regulatory requirements (https://www.tga.gov.au/node/285209)

Reclassification of devices

Device area	Overview	Current state	Future state
Spinal implantable medical devices	Implantable devices that are intended to be a motion-preserving device for the spine or that come into contact with the spinal column will be reclassified from Class IIb to Class III. Spinal fusion implantable devices, such as screws, cages, plates, hooks or rods that are intended to be used during spinal fusion surgical procedures, will remain classified as Class IIb.	All spinal implantable medical devices are currently classified as Class IIb.	Implantable devices that are intended to be a motion-preserving device for the spine or that come into contact with the spinal column will be classified as Class III. Spinal fusion implantable devices that are intended to be used during spinal fusion surgical procedures will remain classified as Class IIb. All spinal implantable medical devices must be selected for an application audit.

Device area	Overview	Current state	Future state
Active medical devices for therapy with diagnostic function	Active medical devices for therapy that includes a diagnostic function which significantly determines patient management by the device (such as automated external defibrillators or closed loop systems) will be reclassified from Class IIa or Class IIb to Class III.	Currently Class IIa or Class IIb.	Class III Note: It is intended that continuous positive airway pressure (CPAP) machines will remain Class IIa.
Active implantable medical devices	Active implantable medical devices (AIMD) will be reclassified from Class AIMD to Class III.	Class AIMD	Class III
Medical devices that administer medicines or biologicals by inhalation	Invasive medical devices intended to administer medicines or biologicals by inhalation will be classified as Class IIa, unless their mode of action has an essential impact on the efficacy and safety of the medicines or biologicals, or they are intended to treat life-threatening conditions, in which case they will be classified as Class IIb.	Class I or Class IIa	Class IIa or ClassIIb
Medical devices composed of substances that are introduced into the body through a body orifice or applied to the skin	Devices composed of substances, or combinations of substances, that are introduced into the human body through a body orifice or applied to the skin, and are absorbed or locally dispersed in the human body after introduction or application, will be classified as either Class IIa, Class IIb or Class III.	Class I (non-sterile, sterile or with measuring function) or Class IIa	Class IIa, Class IIb or ClassIII
Medical devices used in direct contact with the heart, central circulatory or central nervous systems	Surgically invasive medical devices intended to be used in direct contact with the heart, CCS or the CNS will be classified as Class III.	Class IIa	Class III

Important dates

New classification rules will apply to all new applications for ARTG inclusion from **25 November 2021**.

Transitional arrangements apply to devices that are:

- already included in the ARTG as at **25 November 2021**; or
- are the subject of an application for inclusion in the ARTG submitted to the TGA prior to **25 November 2021** and the application fee has been paid.

Further information and guidance about the new classification rules and transitional arrangements will be available in 2020.

Topics:

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