Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Medical device labelling obligations

During the COVID-19 pandemic, many businesses are encountering therapeutic goods regulations for the first time. This information explains the labelling requirements for medical devices to help manufacturers and sponsors meet their obligations.

Last updated:
16 April 2020

This information explains the labelling requirements for medical devices to help manufacturers and sponsors meet their obligations. Labelling refers to labels and other information that must be provided with a medical device.

All medical devices supplied in Australia must meet the relevant Essential Principles for safety and performance to ensure the device is safe and performs as intended. Essential Principle 13 of Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (https://www.legislation.gov.au/Series/F2002B00237) (the Regulations) outlines the requirements for information that must be provided (#provided) with a medical device, including labelling and instructions for use.

Manufacturer obligations

The manufacturer of a medical device is the person who is responsible for the design, production, packaging and labelling of the device. Manufacturers must have evidence demonstrating compliance with the relevant Essential Principles for their medical device, including those that relate to labelling and instructions for use.

The manufacturer's name and address must appear on the device's label, instructions for use and other information that are provided with the medical device. For further information, see Manufacturer's ongoing responsibilities (https://www.tga.gov.au/node/287916).

Note

Parties who carry out relabelling of a device under the manufacturer's instruction, including sponsors and sub-contractors, do not meet the legislative definition of a manufacturer.

Information that must be provided with a medical device

Clause 13.3 in the Regulations lists all information that must be provided with a medical device. The manufacturer should ensure that all information is provided in English, having regard to the training and knowledge of potential users of the device:

Note

Information about the device can be supplied in multiple languages but, if the device is supplied in Australia, one of those languages **must** be English.

The following table is an extract from the Regulations and lists information that must be provided with a medical device.

Item	Information to be provided
1	The manufacturer's name, or trading name, and address
2	The intended purpose of the device, the intended user of the device, and the kind of patient on whom the device is intended to be used (if this information is not obvious)
3	Sufficient information to enable a user to identify the device, or if relevant, the contents of packaging
4	Any particular handling or storage requirements applying to the device
5	Any warnings, restrictions, or precautions that should be taken, in relation to use of the device
6	Any special operating instructions for the use of the device
7	If applicable, an indication that the device is intended for a single use only
8	If applicable, an indication that the device has been custom-made for a particular individual or health professional and is intended for use only by that individual or health professional
9	If applicable, an indication that: a. if the device is a medical device other than an IVD medical device-the device is intended for pre-market clinical investigation; or

Item	Information to be provided
	b. if the device is an IVD medical device-the device is intended for performance evaluation only
10	For a sterile device, the word 'STERILE' and information about the method that was used to sterilise the device
11	The batch code, lot number or serial number of the device
12	If applicable, a statement of the date (expressed in a way that clearly identifies the month and year) up to when the device can be safely used
13	If the information provided with the device does not include the information mentioned in item 12-a statement of the date of manufacture of the device (this may be included in the batch code, lot number or serial number of the device, provided the date is clearly identifiable)
14	If applicable, the words 'for export only'

Sponsor obligations

The person legally responsible for including a medical device on the Australian Register of Therapeutic Goods (ARTG), is referred to in the legislation as a 'Sponsor'. Regulation 10.2 requires sponsors to ensure their name and address are provided with all devices supplied by them within Australia. This information should be located;

- in a manner that allows the sponsor to be readily identified by a user of the device; and
- in a way that is appropriate for the device in accordance with Essential Principle 13.2.

Sponsors should ensure that their name and address is provided on the device itself.

If it is not practicable to do so, this information should be included on the packaging used for the device.

If it is not practicable for these details to be provided on the device itself or the packaging used for the device, the sponsor's name and address must be included in a leaflet supplied with the device.

Sponsors may choose to affix a label containing sponsor's name and address to the device's packaging in order to meet their regulatory obligations under Regulation 10.2.

Note

Affixing a label to the device's packaging in order to comply with Regulation 10.2 does not mean the sponsor meets the definition of a manufacturer.

If you are a sponsor and you affix a label to the device in order to comply with Regulation 10.2, the label must not in any way adulterate the device or obscure the information provided with the device by the manufacturer.

There are penalties associated with failing to meet Regulation 10.2.

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