Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Labelling medical devices to meet regulatory requirements

Guidance on how medical device labelling requirements help manufacturers and sponsors fulfil their responsibilities.

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Purpose

Labelling means the labels and information that come with a medical device.

All medical devices in Australia must meet safety and performance standards. The Regulations state that medical devices must include information like labels and instructions.

See Essential Principle 13 of Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations) This outlines the requirements for labelling and instructions for use.

Legislation

Therapeutic Goods (Medical Devices) Regulations 2002

Manufacturer obligations

The manufacturer of a medical device is the person responsible for the:

- design
- production
- packaging and
- labelling of the device.

Medical device manufacturers need evidence that they follow the Essential Principles. This including those that relate to labelling and instructions for use.

On the device's label it must include:

- the manufacturer's name and address,
- instructions for use and other information provided with the medical device.

> **Note**
>
> Relabelling devices under the manufacturer's instructions (sponsors and subcontractors) doesn't make you are 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 in English.

> **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.

This table is from the Regulations and has information that must be given with a medical device.

Item	Information we need
1	The manufacturer's name, or trading name, and address
2	The device's intended use, the intended user, and the kind of patient it's intended for. If this information is not obvious.
3	Provide enough information so the user can identify the device, or packaging contents.
4	Any particular handling or storage requirements applying to the device
5	Any device warnings, restrictions, or precautions
6	Any special operating instructions for the use of the device
7	If applicable, a single use only indication
8	If the device is specifically made for one person or health professional, it should only be used by them. An indication that the device has been custom-made needs to be included.
9	If applicable, an indication that: a. The device is intended for premarket clinical investigation if it's not an IVD; or b. if the device is an IVD medical device, it is only intended for performance evaluation.
10	For sterile devices, the word 'STERILE' and how it was sterilised
11	The batch code, lot number or serial number of the device
12	Provide the date (month and year) until which the device can be used safely, if applicable.
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.

Item	Information we need
14	If applicable, the words 'for export only'

Sponsor obligations

A 'Sponsor' is the person who adds a medical device to the Australian Register of Therapeutic Goods.

Under Regulation 10.2, sponsors name and address must be all devices they supply within Australia. See Sponsor's ongoing responsibilities.

This information should be:

- 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 under Essential Principle 13.2.

On the device itself, sponsors should put their names and addresses.

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

These details must be in a leaflet if they can't be on the device or packaging.

Sponsors can put their name and address on the device's packaging. This helps them meet their regulatory obligations under Regulation 10.2.

Note

Affixing a label to the device's packaging 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 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.

Topics: Labelling and packaging Medical devices safety

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Changes made across page to make content simpler and clearer.

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