Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Best practice for Patient Information Leaflets and Patient Implant Cards

Guidance

In addition to the legislated requirements, there are other features of leaflet and card design that can be very helpful for patients.

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In addition to the legislated requirements, there are other features of leaflet and card design that can be very helpful for patients. This information is not mandatory, but is included to further improve the way this information is provided. Please ensure you read this information in junction with the medical device patient leaflets and patient implant cards.

General design principles

When designing your leaflet or card, think about the recipient of the device by considering:

- age of users
- target patient group

- literacy of users

- visual acuity.

This part of the guidance will assist you with some of these considerations.

Use simple language

Wherever possible, plain language should be used so that information is easy to understand. Vague and unnecessarily complex language should be avoided. Manufacturers or sponsors may wish to use readability assessment programs available in many word processing programs.

Manufacturers are responsible for the content of the leaflets. Sponsors are responsible for ensuring that the Essential Principles are met for inclusion of the device into the Australian Register of Therapeutic Goods.

User-friendly design

You should consider the recipient of the device and any specific requirements they might have.

For example, if your device is likely to be implanted in the elderly, you may consider using larger text than the minimum requirement.

Use of images in the leaflet

It can be useful to use pictures or images (diagrams or drawings) to describe the device. For example, images showing where on the body the device would be implanted, or a list of where the device may be implanted could be helpful to patients.

If images are used, they must not be used in such a way as to promote a particular device or make or model of the device, over other alternative therapies or devices (see Compliance with advertising legislation).

Colour contrast

Colour contrast is an important tool in ensuring legibility of text for consumers and it may facilitate better understanding of the device and its functionality.

The Vision Australia colour contrast analyser can be used to assist you in deciding on how to present your text. This is available on the Vision Australia website.

Using other aspects in addition to colour

Individuals can perceive colours differently, some people are colour-blind and colours can look different in different lighting conditions. For these reasons, if colour was the only element used to distinguish information on a patient implant card for example, it may be difficult or confusing to identify the required information and we may consider this to be unacceptable under Clause 13A.3(4), Schedule 1, part 2 of the Therapeutic Goods (Medical Devices) Regulations 2002.