Patient information leaflets

Consumer preferences

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1 March 2018
Patient information leaflets

Scope of requirement is the same for patient information leaflets as for patient implant cards:

• an implantable medical device or an active implantable medical device
• not a suture, staple, dental filling, dental brace, tooth crown, screw, wedge, plate, wire, pin, clip or connector.

Format requirements largely unspecified, but must:

• be in English (may also be in other languages)
• text must be legible and at least 1 millimetre high (more relevant to card)
Patient information leaflets

Broadly required to include:

- information identifying the device, or the kind of device;
- the intended purpose of the device;
- information explaining how to use the device safely;
- other information about the device that the manufacture considers would be useful for patients.

Intended to be a living document:

- Update for emerging evidence eg safety issues, new clinical evidence and research
- Operate in conjunction with the patient implant card, which will be static at the time of issue
Regulatory requirements

Information to be included in the patient information leaflet:

1. (a) the name of the device; and
   (b) the model of the device

2. (a) the intended purpose of the device; and
   (b) the kind of patient on whom the device is intended to be used

3. Any special operating instructions for the use of the device

4. (a) the intended performance of the device; and
   (b) any undesirable side effects that could be caused by use of the device
Regulatory requirements

5. Any residual risks that could arise due to any shortcomings of the protection measures adopted as mentioned in subclause 2(2)

Essential Principle 2
Design and construction of medical devices to conform with safety principles

(1) The solutions adopted by the manufacturer for the design and construction of a medical device must conform with safety principles, having regard to the generally acknowledged state of the art.

(2) Without limiting subclause (1), in selecting appropriate solutions for the design and construction of a medical device so as to minimise any risks associated with the use of the device, the manufacturer must:
   (a) first, identify hazards and associated risks arising from the use of the device for its intended purpose, and foreseeable misuse of the device; and
   (b) second, eliminate, or reduce, these risks as far as possible by adopting a policy of inherently safe design and construction; and
   (c) third, if appropriate, ensure that adequate protection measures are taken, including alarms if necessary, in relation to any risks that cannot be eliminated; and
   (d) fourth, inform users of any residual risks that may arise due to any shortcomings of the protection measures adopted.

(3) In paragraph (2)(d):
   *residual risk*, for a medical device, means the risk remaining after the measures described in paragraphs (2)(a), (b) and (c) have been applied.
Regulatory requirements

6. (a) warnings about risks that could arise from the interaction of the device with other equipment; and

(b) precautions and other measures that, because of those risks, should be taken by the patient or a health professional

Example 1: The risk of electrical interference from electro-surgical devices.

Example 2: The risk of magnetic field interference from magnetic resonance imaging devices.
Regulatory requirements

8. (a) the materials and substances included in the device; and
     (b) any manufacturing residuals that could pose a risk to the patient

9. (a) a notice that any serious incident that occurs in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration; and
     (b) the address of the Therapeutic Goods Administration’s website
Regulatory requirements

7. (a) the nature and frequency of regular or preventative examination, monitoring or maintenance of the device that should be undertaken; and
(b) symptoms that could indicate that the device is malfunctioning; and
(c) precautions and other measures that should be taken by the patient if the performance of the device changes or the patient experiences any of the symptoms mentioned in paragraph (b); and
(d) the expected device lifetime; and
(e) anything that could shorten or lengthen the device lifetime; and
(f) precautions and other measures that should be taken at, or near, the end of the expected device lifetime; and
(g) other circumstances in which the patient should contact a health professional in relation to the operation of the device
Patient information leaflet and Consumer Medicine Information (CMI)

Similarities:
• Intended for consumers
• Focused on safe and appropriate use
• Warnings for consumers
• Encourage reporting of issues

Differences:
• Delivery of products varies:
  – prescription medicines versus surgical procedure
  – ongoing use versus single episode of care
  – implantables are permanent, use of medicines can be discontinued
• Regulatory assessment - Australia for medicines, often overseas for devices
Questions

Scope:

• Is anything missing?
• Is anything not useful?
• Does anything need to be changed?

Format:

• How is this information best presented to and for patients?
• How is this information best delivered to patients, both initially and over time?

Any other feedback?