Medical Devices Consumer Webinar

An Introduction to Patient Implant Card and Patient Information Leaflet for Implantable Medical Devices

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Consumers Shaping Health

What is the TGA?

Therapeutic Goods Administration (TGA)

- A government agency - part of the Australian Government Department of Health
- Responsible for ensuring therapeutic goods (medicines and medical devices) in Australia are safe for consumers and fit for intended purpose
- The role includes ensuring that on balance the risks of the product are acceptable when weighed against intended benefit
- The TGA monitors post market performance of therapeutic goods and also regulates the advertising of the goods ranging from vitamins and sunscreens, through to vaccines, prescription medicines and **medical devices**.

What is a medical device?

Medical devices:

- Are used on humans
- Have therapeutic benefits
- Generally have a physical or mechanical effect on the body or are used to measure or monitor functions of the body.

"Medical devices range from a bandage that you would put on a scratch to high risk products such as pacemakers that are implanted in your body" (TGA, 2018).

Therapeutic Goods Administration (TGA) 2018, https://www.tga.gov.au/what-medical-device

Regulating medical devices

The TGA follow a risk-based approach for the regulation of medical devices:

- **Classification** of the medical device
- **Assessing compliance** – quality, safety and performance
- **Implementing** appropriate **regulatory controls** for manufacturing process
- Include in the **Australian Register of Therapeutic Goods**
- Subject to **monitoring by the TGA** once available for supply.

Medicine and Medical Devices Regulation Review

Recommendation number 20:

Align the regulation of medical devices by the Australian **National Regulatory Authority** with the European Union framework, wherever possible. This includes:

A) Classification of medical devices

B) Essential principles/requirements

C) Adoption of a risk-based approach to variations to medical devices.

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Medical Devices Regulations Reform

	Patient Information Leaflet	Patient Implant Card
Urogynaecological mesh		
New devices	1 Dec 2018	1 Dec 2018
Existing devices	1 Dec 2019	1 Dec 2019
Surgical mesh		
New devices	1 Dec 2018	1 Dec 2020
Existing devices	1 Dec 2021	1 Dec 2021
Implantable devices (other than those exempted)		
New devices	1 Dec 2018	1 Dec 2020
Existing devices	1 Dec 2021	1 Dec 2021

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Scope of Requirements

An implantable medical device or an active implantable medical device

Devices exempt from the requirement of a patient information leaflet and patient implant cards:

- Clips, connectors, pins, plates, screws, staples, sutures, wedges, wires
- Dental braces, fillings & tooth crowns.

What information will be included?

Patient information leaflets:

- Information identifying the device (such as name, type, model)
- Intended purpose and kind of patient on whom the device is intended to be used
- Issues to consider before deciding to use the device
- Any special operating instructions
- Intended performance and potentially undesirable side effects from using the device.

What information will be included?

Patient information leaflets:

- Other useful information about the device
- Where to go for further information
- Sponsor
- Date of information

What information will be included?

Patient implant card:

1. Information identifying the device

- Including: device name, device model, serial no., manufacturers name, address and website details.

What's next?

Consumer Focus group

- Seek consumer feedback on the patient information leaflet and patient implant cards to ensure they are consumer friendly
- Focus group will be provided with the documents with on-line feedback forms to review
- Group discussions via teleconference
- CHF will consolidate the on-line and discussion feedback and report back to the TGA.

What's next?

Consumer Workshop

- Two face-to-face consultation to get consumer input into the dissemination process
- One in Sydney and one in Melbourne, 16-17 July 2018
- CHF will consolidate feedback from the workshops and report back to the TGA.

Questions?

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