



Therapeutic Goods (Medical Devices) Amendment (Registry Systems for Enhancing Safety) Regulation 2014

Select Legislative Instrument No. 196, 2014

I, General the Honourable Sir Peter Cosgrove AK MC (Ret'd),
Governor-General of the Commonwealth of Australia, acting with the
advice of the Federal Executive Council, make the following regulation.

Dated 11 December 2014

Peter Cosgrove
Governor-General

By His Excellency's Command

Fiona Nash
Assistant Minister for Health

OPC60902 - B

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<i>No. 196, 2014</i>	<i>Therapeutic Goods (Medical Devices) Amendment (Registry Systems for Enhancing Safety) Regulation 2014</i>	<i>i</i>
<i>OPC60902 - B</i>		

1 Name

This is the *Therapeutic Goods (Medical Devices) Amendment (Registry Systems for Enhancing Safety) Regulation 2014*.

2 Commencement

This instrument commences on the day after it is registered.

3 Authority

This instrument is made under the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Therapeutic Goods (Medical Devices) Regulations 2002

1 After regulation 10.4

Insert:

10.4A Secretary may maintain a system to enhance safe and effective use of particular medical devices

- (1) The Secretary may, for the purpose of performing his or her functions, or exercising his or her powers, in relation to therapeutic goods (including under the Act or under another law), maintain either or both of the following:
 - (a) a system that is designed to enhance the safe and effective use of implantable breast medical devices (an *implantable breast medical devices registry*);
 - (b) a system that is designed to enhance the safe and effective use of implantable cardiac medical devices (an *implantable cardiac medical devices registry*).
- (2) An implantable breast medical devices registry, or an implantable cardiac medical devices registry, may involve any of the following:
 - (a) collecting and analysing data and information in relation to the relevant medical devices;
 - (b) monitoring the safety and performance of the relevant medical devices;
 - (c) identifying particular medical devices (if any) in relation to which there are safety or performance risks or concerns;
 - (d) providing information about the safety and performance of the relevant medical devices to:
 - (i) authorities or bodies of the Commonwealth, a State or a Territory that have functions relating to therapeutic goods or health; or
 - (ii) health professionals; or
 - (iii) persons or bodies involved in the manufacture, importation or supply of the relevant medical devices in Australia; or
 - (iv) patients; or

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- (v) the general public.
- (3) For paragraph (2)(a), the following are examples of data and information that may be collected and analysed in relation to the relevant medical devices:
- (a) data and information relating to the safety and performance of the relevant medical devices;
 - (b) data and information about any revision procedures relating to the relevant medical devices and the reasons for those procedures;
 - (c) in relation to each particular medical device that has been implanted in a patient:
 - (i) information identifying the medical device, including the brand and batch or serial number; and
 - (ii) the date on which the medical device was implanted; and
 - (iii) the name of the hospital or surgery where the medical device was implanted; and
 - (iv) data or information that tracks the performance of the medical device and the patient outcomes following implant of the medical device.
 - (4) The Secretary may enter into a written agreement with a person or body for the purpose of maintaining an implantable breast medical devices registry or an implantable cardiac medical devices registry.
 - (5) An implantable breast medical devices registry or an implantable cardiac medical devices registry:
 - (a) may be maintained at a place and in a form that is acceptable to the Secretary; and
 - (b) may involve keeping records, or carrying out other actions, by electronic means.

2 Dictionary

Insert:

implantable breast medical device means any of the following implantable medical devices:

- (a) breast implants or mammary implants;
- (b) breast tissue expanders;

- (c) any other medical device that is of a similar kind, or has a similar function, to a medical device mentioned in paragraph (a) or (b).

implantable cardiac medical device means any of the following implantable medical devices or active implantable medical devices:

- (a) cardiac stents;
- (b) cardiac valves (whether mechanical or of biological origin);
- (c) electronic devices for regulating heart rate or managing dysrhythmia;
- (d) any other medical device that is of a similar kind, or has a similar function, to a medical device mentioned in paragraph (a), (b) or (c).