EXPLANATORY STATEMENT

Select Legislative Instrument No. 196, 2014

Therapeutic Goods Act 1989

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

The object of the *Therapeutic Goods Act 1989* (the Act) is to establish and maintain a national system of controls for the quality, safety, efficacy/performance and timely availability of therapeutic goods that are used in Australia or exported from Australia. The Therapeutic Goods Administration (the TGA), which is part of the Department of Health, is responsible for administering the Act.

Subsection 63(1) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing matters required or permitted to be prescribed by the Act or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The Therapeutic Goods (Medical Devices) Amendment (Registry Systems for Enhancing Safety) Regulation 2014 (the Regulation) amends the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Principal Regulations) to empower the Secretary of the Department of Health to maintain systems (medical device registries) for enhancing the safe and effective use of implantable breast medical devices and implantable cardiac medical devices. The purpose of maintaining medical device registries is to assist the Secretary in performing his or her functions, or exercising his or her powers, in relation to therapeutic goods, including performing functions or exercising powers under the Act or another law.

Clinical registries are systems or mechanisms for monitoring the appropriateness and effectiveness of health care by collecting, analysing and reporting health-related information. Clinical registries can be used to collect information about the treatment of a particular type of disease, the use of a type or types of procedure or the use of a type of medical device in order to gain a detailed picture of the treatment of the disease, clinical use and efficacy of that type of procedure or the use of that type of medical device. For example, there are registries that monitor and release information in relation to matters such as joint replacement surgery, the incidence and treatment of different forms of cancer, renal failure management and cardiothoracic surgery.

Clinical registries collect relevant health-related information from both public and private healthcare providers including, for instance, collecting information about the medical procedure or types of medical devices, the details of the date that the procedure or episode of care was carried out and information about the performance or effectiveness of the medical procedure or medical device and patient outcomes.

The Australian Government, through the Department of Health, is currently supporting the development of two clinical registries – one for implantable breast medical devices and one for implantable cardiac medical devices. The Department, on behalf of the Australian Government, has entered into a contract with Monash University for the establishment of a registry for implantable breast medical devices to be known as the Australian Breast Device Register. A separate contract has also been made between the Department and the

Australasian Cardiac Outcomes Registry Ltd for the establishment of a registry for implantable cardiac medical devices to be known as the Cardiac Devices Register.

The Regulation enables the future maintenance of these registries, or other alternative registries of the same kind, to be undertaken by the Secretary under the Act and Principal Regulations, in so far as they monitor the safe and effective use of implantable breast medical devices and implantable cardiac medical devices. In particular, the Regulation, by empowering the Secretary to maintain such systems, enables the Secretary to spend money in the maintenance of such systems.

The Regulation enables the Secretary to maintain systems (registries) to monitor the safe and effective use of implantable breast medical devices and implantable cardiac medical devices through the collecting and analysing of, and reporting on, information and data relating to the safety and performance of these types of medical devices. Through the monitoring of the safety and performance of implantable breast medical devices and implantable cardiac medical devices, the Secretary, health care providers (such as hospitals and medical practitioners), medical device manufacturers and sponsors and others involved in the supply of these types of medical devices will be able to receive timely warning of device failure and to obtain information and data relating to the safety and performance of these types of medical devices more generally. The information collected and made available will also enable patients and the general public to be better informed about the safety and performance of these types of medical devices.

The Regulation describes the principal features of a "registry" of the relevant type to monitor the safe and effective use of implantable breast medical devices and implantable cardiac medical devices and identifies, by way of example, the main types of information that may be collected and analysed for that purpose. The types of devices that may be monitored under such registries would include implantable breast medical devices and implantable cardiac medical devices that are or have been supplied in Australia whether those medical devices have been available for general commercial supply (and on the Australia Register of Therapeutic Goods at any time), or supplied under an exemption or approval provided by the Act.

Details of the Regulation are set out in the Attachment.

The Act does not specify conditions that would need to be met before the power to make the Regulation may be exercised.

The Regulation is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The Regulation commences on the day after it is registered on the Federal Register of Legislative Instruments.

Consultation

In the 2013-14 Budget the Australian Government announced its decision to establish two clinical registries for implantable breast medical implants and implantable cardiac medical devices.

The Government had previously prepared a Regulation Impact Statement (RIS) to support an in-principle decision to develop clinical registries for implantable breast medical devices and

implantable cardiac medical devices, and committed to examine options to track the use and performance of such devices and funding models. In 2013 a further Regulation Impact Statement was prepared to assist the Australian Government in deciding how to best implement the decision to support the registries. A broad range of stakeholder organisations were consulted in developing the 2013 RIS, including health profession organisations, industry and consumer groups and Commonwealth, State and Territory Government health and human service agencies. There was general support for clinical registries for implantable breast medical devices and implantable cardiac medical devices, with the main differences of opinion relating to the best way to fund such registries.

Authority: Subsection 63(1) of the *Therapeutic Goods Act 1989*

ATTACHMENT

Details of the *Therapeutic Goods (Medical Devices) Amendment (Registry Systems for Enhancing Safety) Regulation 2014*

Section 1 – Name of regulation
This section provides for the Regulation to be referred to as the *Therapeutic Goods (Medical Devices) Amendment (Registry Systems for Enhancing Safety) Regulation 2014.*

Section 2 – Commencement
This section provides for the Regulation to commence on the day after it is registered.

Section 3 – Authority
This section provides that the Regulation is made under the *Therapeutic Goods Act 1989* (the Act).

Section 4 – Schedule(s)
This section provides that each instrument that is specified in a Schedule to the Regulation is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Regulation has effect according to its terms.

Schedule 1 – Amendments of the *Therapeutic Goods (Medical Devices) Regulations 2002*

Therapeutic Goods (Medical Devices) Regulations 2002

Item 1 – After regulation 10.4
This item inserts new regulation 10.4A after regulation 10.4.

Subregulation 10.4A(1) enables the Secretary to maintain a system to monitor the safe and effective use of implantable breast medical devices (described as an "implantable breast implant medical devices registry") and a system to monitor the safe and effective use of implantable cardiac medical devices (described as an "implantable cardiac medical devices registry"). The maintenance of such registries by the Secretary is discretionary – the Secretary is under no obligation to do so.

The purpose for maintaining such registries is to assist the Secretary in the performance of his or her functions, or the exercise of his or her powers, in relation to therapeutic goods. The Secretary's powers and functions in relation to therapeutic goods can be found in the Act, the regulations or another law (including a law of a State or Territory).

Subregulation 10.4A(2) describes the key features of an implantable breast medical device registry and an implantable cardiac medical device registry. The key features include the collection and analysis of data and information in relation to relevant medical devices, the monitoring of the safety and performance of the relevant medical devices and the reporting on the safety and performance of the medical devices being monitored.

Subregulation 10.4A(3) identifies examples of the kinds of data and information that may be collected and analysed through an implantable breast medical device registry and an implantable cardiac medical device registry. Examples include data and information about revision procedures relating to the relevant medical devices. Subregulation 10.4A(3) is intended to be broad in its scope. The data and information that may be collected and

analysed includes data and information about an implantable breast medical device or an implantable cardiac medical device that has not been supplied in Australia where the collection of such data and information is relevant for monitoring implantable breast medical devices or implantable cardiac medical devices that are or have been supplied in Australia.

Other kinds of data and information that is not included in this list may also be collected and analysed such as demographic data.

Subregulation 10.4A(4) allows the Secretary to enter into a written agreement with a person or body for the person or body to maintain an implantable breast medical device registry or an implantable cardiac medical device registry.

Subregulation 10.4A(5) provides that the registries may be maintained at a place and in a form that is acceptable to the Secretary, and may involve the keeping of records, or the carrying out of other actions, by electronic means.

Item 2 – Dictionary

This item inserts definitions for the terms "implantable breast medical device" and "implantable cardiac medical device" in the dictionary to the Principal Regulations.

The definition of implantable breast medical device covers breast or mammary implants, breast tissue expanders and any other medical device that is of a similar kind, or has a similar function. The definition is intended to cover new types of breast implants or breast tissue expanders that may be developed in the future.

The definition of implantable cardiac medical device covers particular types or categories of implantable cardiac medical devices and those that are of a similar kind or have a similar function to those identified in the definition. The definition is intended to cover new types of implantable cardiac medical devices that may be developed in the future.

Statement of Compatibility with Human Rights for a legislative instrument that raises human rights issues

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

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

This legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The *Therapeutic Goods (Medical Devices) Amendment (Registry Systems for Enhancing Safety) Regulation 2014* (the Regulation) is made under subsection 63(1) of the *Therapeutic Goods Act 1989*. The Regulation amends the *Therapeutic Goods (Medical Devices) Regulations 2002* to empower the Secretary of the Department of Health to maintain systems (medical device registries) to monitor the safe and effective use of implantable breast medical devices and implantable cardiac medical devices.

The Australian Government, through the Department of Health, is currently supporting the development of two clinical registries – one for implantable breast medical devices and one for implantable cardiac medical devices. The Department, on behalf of the Australian Government, has entered into a contract with Monash University for the establishment of a registry for implantable breast medical devices to be known as the Australian Breast Device Register. A separate contract has also been made between the Department and the Australasian Cardiac Outcomes Registry Ltd for the establishment of a registry for implantable cardiac medical devices to be known as the Cardiac Devices Register.

The Regulation enables the future maintenance of these registries, or other alternative registries of the same kind, to be undertaken by the Secretary under the Act and Principal Regulations, in so far as they monitor the safe and effective use of implantable breast medical devices and implantable cardiac medical devices. In particular, the Regulation, by empowering the Secretary to maintain such systems, enables the Secretary to spend money in the maintenance of such systems.

The Regulation enables the Secretary to maintain systems (registries) to monitor the safe and effective use of the relevant devices through the collecting and analysing of, and reporting on, information and data relating to the safety and performance of these types of medical devices. Through such monitoring, the Secretary, health care providers (such as hospitals and medical practitioners), medical device manufacturers and sponsors and others involved in the supply of these types of medical devices will be able to receive timely warning of device failure and to obtain information and data relating to the safety and performance of these types of medical devices more generally. The information collected and made available will also enable patients and the general public to be better informed about the safety and performance of these types of medical devices.

Human rights implications

This legislative instrument engages the right to protection against arbitrary interference with privacy, protected in Article 17 of the International Covenant on Civil and Political Rights (ICCPR). The right to privacy in Article 17 of the ICCPR prohibits unlawful or arbitrary interferences with a person's privacy, family, home and correspondence.

The maintenance of the registries is expected to involve the collection of some personal information, such as relevant clinical data about patients. The collection of clinical data is necessary in order to monitor the performance of particular medical devices over time. The maintenance of the registries may also involve the collection of patient contact information, with consent, in order to be able to assist health service providers, if necessary, to contact patients in the event of a recall. The *Privacy Act 1988* regulates the handling of person information about individuals. The Privacy Act establishes Australian Privacy Principles dealing with the collection, use, storage and disclosure of information. To the extent that personal information is collected for the purpose of the registries, such information would be managed in accordance with the Australian Privacy Principles. The regulation allows the Secretary to enter into a written agreement with a person or body for the person or body to maintain the registries. Any person or body contracted to maintain the registries will be subject to additional contractual requirements to protect the privacy of the persons from whom any personal information is collected and provide for the security of the information.

Conclusion

This legislative instrument is compatible with human rights because, to the extent that it may limit human rights, those limitations are reasonable, necessary and proportionate.

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