

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Information (Medical Devices) Specification 2017

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

Section 61 of the Act contains a number of provisions that permit the Secretary of the Department of Health (Secretary) to release certain kinds of therapeutic goods information to various persons and bodies in particular circumstances.

Subsection 61(5AA) of the Act permits the Secretary to release therapeutic goods information where particular matters that have been specified by the Minister under subsection 61(5AB) are satisfied.

The *Therapeutic Goods Information (Medical Devices) Specification 2017* (the Specification) is made by the Minister under subsection 61(5AB) of the Act. It specifies three matters relating to the release of therapeutic goods information by the Secretary under subsection 61(5AA) of the Act: a particular kind of therapeutic goods information that may be released, the kinds of person to whom that information may be released, and the purposes for which that information may be released.

Therapeutic goods information is defined in subsection 61(1) of the Act as information in relation to therapeutic goods that is held by the Department and which relates to the performance of the Department's functions (including functions relating to the EC Mutual Recognition Agreement or the EFTA Mutual Recognition Agreement).

The Specification has the effect of permitting the Secretary to release information about the materials used in the production of specified medical devices to persons that have been or may have been implanted with a specified medical device, or to a treating medical practitioner of such a person, for the purposes of informing the person or their treating medical practitioner about the specified medical device.

The Specification commenced on the day after it was registered on the Federal Register of Legislation.

BACKGROUND

The Specification applies to particular information about a 'specified medical device', which is defined to mean an implantable medical device or an active implantable medical device as defined in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

The kind of therapeutic goods information mentioned in the Specification is information regarding the materials, including their chemical and physical properties, used in the production of a specified medical device (or generally used in the type of specified medical device), including possible residues of the materials.

The Specification does not include formulation details, for example the chemical composition of a specified medical device and the relative quantities of ingredients, in the specified information. There is no intention that such information be released under subsection 61(5AA) of the Act under the auspices of the Specification.

The Specification would facilitate the release by the Secretary of information about whether the material was used in the manufacture of the device and/or present as a residue and potentially (where relevant) the quantity of the material that may be present in the device. For example, whether or not a heavy metal, e.g., platinum, was used as a catalyst in the manufacture of silicone shell and gel components of silicone breast implants and/or the presence of any platinum residue in those components and the concentration (e.g., ppm).

The kind of information that may be released under subsection 61(5AA) pursuant to the Specification will be limited to information already held by the TGA.¹ This will generally be information that has been provided to the TGA by the sponsor of a specified medical device in connection with seeking inclusion in the Australian Register of Therapeutic Goods and/or as a result of information collected by the TGA in performing its regulatory activities, e.g., as a result of an audit of a specified medical device. Neither sponsors nor manufacturers will be asked to provide additional information for the purposes of a proposed release by the TGA under subsection 61(5AA) of the Act in accordance with the terms of the Specification.

The kinds of person mentioned in the Specification are persons who have been or may have been implanted with a specified medical device, or any medical practitioner who has treated or is treating any person who has been or may have been implanted with a specified medical device. It is intended that information released under subsection 61(5AA) will be released upon a request for the information by a kind of person mentioned in the Specification. There is no intention to publish more broadly the information mentioned in the Specification.

The purposes specified in the Specification are for informing a person or their medical practitioner about a specified medical device that has been or may have been implanted in the person.

Information concerning the materials contained in an implantable device provides transparency for patients and medical practitioners about the materials in implants and may also have relevance in relation to potential allergens for persons who may have been implanted with the device.

Therapeutic goods information about therapeutically active substances (including the quantity) and the presence or absence of excipients in medicines and in medical devices that contain or incorporate medicines is already identified in regulation 46 of the *Therapeutic Goods Regulations 1990* as information that the Secretary is permitted to release under subsection 61(6) of the Act. The Specification will have the effect of permitting the release of a similar type of information about specified medical devices as that identified under

¹ The definition of ‘therapeutic goods information’ in subsection 61(1) of the Act is limited to information in relation to therapeutic goods ‘that is held by the Department’. The definition does not extend to information held by a sponsor and/or manufacturer that is not already held by the Department.

regulation 46 in respect of medicines and medical devices that contain or incorporate medicines.

CONSULTATION

A draft of the Specification was discussed in May 2017 at a meeting of the Regulatory and Technical Consultative Forum and attendees were provided with a draft copy of the Specification.

The stakeholders that attended the meeting included a number of bodies that represent specific industries relating to medical devices, including AusBiotech, Australian Dental Industry Association, IVD Australia, Medical Technology Association of Australia, and the Australian Medical Manufacturers and Distributors Association.

A key issue raised by stakeholders at the meeting was whether a proposal to release information under subsection 61(5AA) under the auspices of the Specification would allow the TGA to require sponsors or manufacturers to give the TGA additional information. The Specification does not work to give the TGA such a power. As set out above, the information that may be released under section 61 is limited to information already held by the TGA.

At the meeting, it was also clarified that the provision was not intended to be used to release formulation information.

Following the meeting, attendees were given an opportunity to submit further comments on the Specification in writing to the Medical Devices Secretariat. No further comments or submissions were received by attendees.

The Specification is a legislative instrument for the purposes of the *Legislation Act 2003*.

Statement of Compatibility with Human Rights for a legislative instrument that does not raise any human rights issues

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

Therapeutic Goods Information (Medical Devices) Specification 2017

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 Legislative Instrument

The *Therapeutic Goods Information (Medical Devices) Specification 2017* is made under subsection 61(5AB) of the *Therapeutic Goods Act 1989* (the Act) by a delegate of the Minister for Health.

It will permit the Secretary of the Department of Health to release information regarding the materials, including their chemical and physical properties, used in the production of a specified medical device (or generally used in the type of specified medical device), including possible residues of the materials, to any person who has been or may have been implanted with a specified medical device or their treating medical practitioner for specified purposes.

A ‘specified medical device’ is defined to mean an implantable medical device or an active implantable medical device as defined in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Human rights implications

As this instrument does not include any measures other than permitting the release to persons outlined above of information of the kind outlined above, it does not engage any of the applicable rights or freedoms.

Conclusion

This legislative instrument is compatible with human rights as it does not raise any human rights issues.

John Skerritt, delegate of the Minister for Health