

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices) Amendment (Implantable Medical Devices) Regulations 2017

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 Expert Panel Review of Medicines and Medical Device Regulation (the Review), conducted in 2014-2015, identified opportunities for reform to improve the regulation of therapeutic goods in Australia, while maintaining the safety and quality of therapeutic goods available in Australia. The Australian Government accepted 56 of the 58 Recommendations made by the Expert Panel. One of these Recommendations was that the regulation of medical devices in Australia should, wherever possible, be aligned with the European Union (EU) framework, including in respect of the classification of medical devices and in terms of the essential principles requirements (Recommendation 20). The essential principles establish mandatory requirements or standards for medical devices, and provide minimum benchmarks relating to device safety and performance.

The purpose of the *Therapeutic Goods (Medical Devices) Amendment (Implantable Medical Devices) Regulations 2017* (the Regulations) is to amend the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to more closely align two aspects of the regulatory framework for medical devices in Australia with that in the EU: the classification of medical devices that are surgical meshes (including, in particular, urogynaecological meshes), and requirements relating to the provision of information to assist patients (in the form of leaflets and patient cards) with certain implantable medical devices.

The Regulations do so by up-classifying surgical meshes from Class IIb medical devices to Class III and requiring manufacturers of implantable, and active implantable, medical devices (other than a number of specified kinds of devices like screws and most dental implants such as fillings, tooth crowns and braces) to include patient information leaflets and cards with their products. This commences from 1 December 2018 and will be fully implemented by 1 December 2021. The timing of implementation is dependent on whether such devices are new (i.e. where they are the subject of an application for marketing approval made before 1 December 2018) and on whether such implantable devices are urogynaecological meshes or not.

These changes better address safety concerns relating to these products, particularly concerns raised by some patients that they were not aware of the details of medical devices that they were implanted with, and had not given informed consent for their surgery. They also bring the regulatory framework for these products closer to that of the approach of the EU, which

introduced a revised regulatory framework for medical devices on 25 May 2017 including the up-classification of surgical meshes and the introduction of mandatory requirements to provide patient cards and information to patients fitted with any implantable device.

Some differences between the Australian and European frameworks will be present for a time in respect of these devices, principally in terms of the period for manufacturers and sponsors of existing meshes and other implants to transition to the new requirements. In Europe, the transition period will commence in May 2020 and conclude in 2024, while in Australia the Regulations commence on 1 December 2018 and the transition will conclude on 30 November 2021.

Details of the Regulations are set out in the Attachment.

The Act specifies no conditions that need to be satisfied before the power to make the Regulations may be exercised.

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations commence on 1 December 2018.

Consultation

In response to Recommendation 20 of the Review, public opinion was sought between July 2017 and September 2017 on options to harmonise Australia's approach with the EU across a three year transition period. Key stakeholders were alerted to the consultation via the TGA's website and by email. Twenty-two submissions were received, with broad acceptance for alignment with the EU. The main aspect where there was not agreement related to the speed of the implementation of these measures, with industry support for the longer, EU, transition timeframe (2020-2024), and consumer groups' concerned that a three year transition period may be too long.

The Regulations attempt to balance both concerns, by requiring urogynaecological meshes to transition more quickly to the new requirements as these products have been associated with particular safety concerns (expressed during the recent Inquiry of the Senate Community Affairs Reference Committee into the 'Number of women in Australia who have had transvaginal mesh implants and related matters'), while providing additional time for industry to prepare by commencing the Regulations in December 2018 and providing transitional arrangements.

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

Details of the *Therapeutic Goods (Medical Devices) Amendment (Implantable Medical Devices) Regulations 2017*

Section 1 – Name

This section provides for the Regulations to be referred to as the *Therapeutic Goods (Medical Devices) Amendment (Implantable Medical Devices) Regulations 2017*.

Section 2 – Commencement

This section provides for the Regulations to commence on 1 December 2018.

Section 3 – Authority

This section provides that the Regulations are made under the *Therapeutic Goods Act 1989* (the Act).

Section 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 the Regulations has effect according to its terms.

Schedule 1 – Amendments

Part 1- Surgical mesh

Therapeutic Goods (Medical Devices) Regulations 2002

Item 1– Subclause 3.4(4A) of Schedule 2

Section 41DB of the Act enables regulations to be made specifying classifications for medical devices, and related matters. Under subregulation 3.2(1) of the MD Regulations, a medical device other than an in vitro diagnostic medical device (IVD) has the classification applying under the classification rules set out in Schedule 2 to the MD Regulations.

Subclause 3.4 of Schedule 2 to the MD Regulations applies to surgically invasive medical devices intended for long-term use and to implantable medical devices. Subject to subclauses 3.4(3), (4) and (4A), such devices are currently classified as Class IIb.

Item 1 repeals current subclause 3.4(4A) of Schedule 2 and substitute a new subclause 3.4(4A), with the effect of reclassifying surgical meshes from Class IIb to Class III devices from 1 December 2018 (noting that item 5 below sets out transitional arrangements for kinds of devices that are included in the Australian Register of Therapeutic Goods (the Register) because of an application for marketing approval made before that date).

Surgical mesh was first developed for the repair of abdominal hernias (a weakening in the abdominal wall). Gynaecologists later used surgical mesh devices to treat other conditions in an effort to reduce failure rates associated with traditional surgical approaches. As these procedures became more common, the TGA received increased reports of complications from mesh surgery. TGA has closely monitored the available clinical information relating to these products, and has identified a need to up-classify surgical mesh medical devices from the current Class IIb (medium risk) classification, to the Class III (high risk) classification. In addition, on 15 February 2017, the Senate Community Affairs Reference Committee

commenced an Inquiry into the number of women in Australia who have had transvaginal mesh implants, and related matters, which is expected to report on 30 November 2017.

The reclassification of surgical mesh is intended to better align the regulation of such products with Europe, where these products have also been up-classified, and to increase pre-market scrutiny for all surgical meshes to ensure that surgical meshes used for urogynaecological purposes, and those used for other purposes such as hernia repairs, are fit for purpose and meet requirements that are consistent with European union regulations. The up-classification of mesh is not restricted to urogynaecological meshes, but covers all surgical meshes (including permanent absorbable or non-absorbable synthetic mesh, biological and composite mesh- examples include abdominal hernia surgical mesh, and stress urinary incontinence surgical mesh).

Part 2- Patient information

Therapeutic Goods (Medical Devices) Regulations 2002

Item 2 - After clause 13.4 of Schedule 1

Item 2 introduces a new clause 13A - Patient implant cards and patient information leaflets – to the essential principles in Schedule 1 to the MD Regulations. Within new clause 13A, there are new clauses 13A.1 to 13A.4.

Scope of patient implant card and patient information leaflet requirements – 13A.1

New clause 13A.1 provides for the scope of the application of new clauses 13A.2 to 13A.4, namely that they apply to a medical device that is:

- (a) an implantable medical device or an active implantable medical device; and
- (b) not a suture, staple, dental filling, dental brace, tooth crown, screw, wedge, plate, wire, pin, clip or connector.

Patient implant cards – 13A.2 and 13A.4

New subclause 13A.2(1) requires that, for a medical device covered by new clause 13A.1, a patient implant card that complies with new subclause 13A.2(2), and new clause 13A.4, must be provided with the device.

Under new subclause 13A.2(2), the patient card must include the name and model of the device, either the batch code, lot number or serial number of the device, the device's unique device identifier (if any) (item 3 below introduce a definition for this term) and the manufacturer's name, address and website. Under new clause 13A.4, this information must be in English (and may also be in any other language) and any number, letter or symbol must be legible and at least one millimetre high.

The introduction of patient implant cards is principally designed to ensure that patients are aware of the details of the device that they have been implanted with and that health practitioners can also identify particular devices, and to better enable the traceability of the device and patient in order to more quickly and effectively alert patients and health practitioners to safety issues such as precautions or recalls.

Patient information leaflets – 13A.3

New subclause 13A.3(1) requires that, for a medical device covered by new clause 13A.1, a patient information leaflet that complies with new subclauses 13A.3(2) – (4), and with new clause 13A.4, must be provided with the device.

Under new subclause 13A.3(2), the leaflet must include information identifying the device or kind of device and its intended purpose and include any other information the manufacturer considers would be useful for patients, and must explain how to use the device safely. In addition, under new subclause 13A.3(3), the leaflet must include the information in the table under that provision such as, for example, the kinds of patients for whom the device is intended to be used, warnings about risks that could arise from the interaction of the device with other equipment (e.g. a magnetic resonance imaging machine) and the nature and frequency of recommended regular or preventative examination, monitoring or maintenance.

The leaflet must be written so as to be readily understood by patients (subclause 13A.3(4)) and, as with patient cards, new clause 13A.4 requires that the information in the leaflet be in English (as well as in any other language) and that any number, letter or symbol be legible and at least one millimetre high.

The introduction of patient information leaflets is principally designed to complement the new requirement for patient implant cards by providing a source of additional and more detailed information about an implantable device. These leaflets will be patient-targeted documents with information relating to the device's approved use, intended patient population, potential adverse effects and relevant precautions for users. Such leaflets are modelled on consumer medicines information documents which have served as an up to date source of information about medicines for many decades.

Item 3 – Dictionary

Item 3 amends the Dictionary in the MD Regulations to provide for the following new definitions relevant to the proposed patient information amendments:

- **device lifetime** – this is one of the fields of information required to be set out in a patient information leaflet under new subclause 13A.3(3), and relates to the period indicated by the manufacturer during which the device can be safely used and in which the characteristics and performance of the device will not be affected by its age;
- **patient implant card** and **patient information leaflet**, which have the meanings given by clauses 13A.2 and 13A.3, respectively;
- **residual risk**, which relates to another of the fields of information required to be set out in a patient information leaflet, and will mean the risk remaining in relation to a medical device after a manufacturer has taken the steps set out in current subclause 2(2) of Schedule 1 to the MD Regulations (these include identifying hazards and associated risks arising from the use of the device for its intended purpose and any foreseeable misuse of the device, and eliminating or reducing these risks as far as possible through a policy of safe design and construction); and
- **unique device identifier** – this is required to be included in a patient card, and means the unique device identifier (if any) assigned to the device by the manufacturer in accordance with the EU Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017, as in force on 1 December 2018 (a copy of this regulation is available, for free and in English, on the website for access to EU law, www.eur-lex.europa.eu).

Part 3- Application and transitional provisions

Therapeutic Goods (Medical Devices) Regulations 2002

Item 4 – In the appropriate position in Part 11

Item 4 adds a new Division 11.5 to the MD Regulations to provide for transitional arrangements relating to the proposed amendments.

New regulation 11.28- Definitions

New regulation 11.28 sets out definitions for four terms: ‘amending regulations’, ‘finally determined’, ‘inclusion day’ and ‘pre-commencement entry’, which are relevant to the proposed transitional arrangements in new Division 11.5.

In particular, **inclusion day**, for an entry of a kind of medical device in the Register, is defined as the day on which the inclusion of that kind of device in the Register commences, and an entry of a kind of device in the Register is defined as a **pre-commencement entry** if that kind of device is included in the Register because of an application made before 1 December 2018, whether the inclusion day for the entry occurred before, on or after 1 December 2018. This regulation also defines **unique product identifier** as the unique means of identification given to a device by its manufacturer to identify the device and any variants.

New regulation 11.29- Surgical mesh-application of amendments

Under new regulation 11.29, the amendments in Part 1 of this Schedule in relation to the up-classification of surgical meshes apply:

- on and after 1 December 2018, for a kind of device for which an application for inclusion in the Register is made on or after that date;
- on and after 1 December 2020, for a pre-commencement entry that is a uro-gynaecological mesh; and
- on and after 1 December 2021, for a pre-commencement entry that is a surgical mesh other than a uro-gynaecological mesh.

For sponsors of pre-commencement entries of surgical mesh in the Register, the up-classification of their product from the date mentioned above means that, from that date, their existing Class IIb entry in the Register will be incorrectly classified and, as such, may be cancelled under paragraph 41GN(1)(f) of the Act (this provides a power for the Secretary of the Department of Health to cancel a kind of device from the Register if satisfied that any certification made by the device sponsor when applying to include their device in the Register (e.g. that their device is correctly classified) is, *or is no longer*, correct).

However, new subregulations 11.29(3) and (4) will have the effect that if a sponsor of a pre-commencement entry applies before 1 December 2020 or 1 December 2021 (depending on whether their device is a uro-gynaecological mesh or not) for their product to be included in the Register as a Class III device, and has given the Secretary the notice required under new regulation 11.30 (see below), their Class IIb entry will not be cancelled until their Class III application is finally determined or they withdraw that application or it lapses under section 41FK of the Act.

Under new subregulation 11.29(5), such an application will be finally determined at the first point at which a decision has been made on whether or not to grant the application and there is no longer any possibility of a change in the outcome of that decision.

New regulation 11.30- Surgical mesh- Secretary must be notified of unique product identifiers of devices supplied under pre-commencement entries

New regulation 11.30 introduces, for the purposes of subsection 41FN(5A) of the Act, a statutory condition that will apply to the inclusion in the Register of a pre-commencement surgical mesh.

This condition requires sponsors of such kinds of device to give the Secretary a notice, before the later of 1 May 2019 (i.e. 6 months after the proposed Regulations commence) and the day 2 months after the product's inclusion day, listing:

- the unique device number assigned to that kind of device by the Secretary under section 41FL of the Act; and
- the unique product identifier for each device of that kind that the sponsor supplies in Australia – this identifier (referred to in regulation 1.6 of the MD Regulations) is given to a device by its manufacturer to identify certain devices and any variants.

New regulation 11.31- Patient information- application of amendments

Under new regulation 11.31, the amendments in Part 2 of this Schedule in relation to the provision of both patient implant cards and patient information leaflets apply to a kind of device that is a uro-gynaecological mesh:

- on and after 1 December 2018, for a kind of device for which an application for inclusion in the Register is made on or after that date; and
- on and after 1 December 2019, for a pre-commencement entry.

For a kind of device other than a uro-gynaecological mesh, the amendments in Part 2 of this Schedule apply:

- in relation to patient information leaflets – on and after 1 December 2018, for a kind of device for which an application for inclusion in the Register is made on or after that date, and on and from 1 December 2021 for a pre-commencement entry; and
- in relation to patient implant cards – on and after 1 December 2020, for a kind of device for which an application for inclusion in the Register is made on or after that date, and on and from 1 December 2021 for a pre-commencement entry.

The above arrangements are intended, in particular, to transition implantable medical devices that are uro-gynaecological meshes to the new requirements first, given the safety concerns relating to such products.

Statement of Compatibility with Human Rights

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

The *Therapeutic Goods (Medical Devices) Amendment (Implantable Medical Devices) Regulations 2017* (the Regulations) are made under subsection 63(1) of the *Therapeutic Goods Act 1989* (the Act) and amend the *Therapeutic Goods (Medical Devices) Regulations 2002*. The Regulations take effect on 1 December 2018.

The purpose of the Regulations is to amend the *Therapeutic Goods (Medical Devices) Regulations 2002* to more closely align two aspects of the regulatory framework for medical devices in Australia with that in the EU: the classification of medical devices that are surgical meshes (including, in particular, urogynaecological meshes), and requirements relating to the provision of information to assist patients (in the form of leaflets and patient cards) with certain implantable medical devices.

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Human rights implications

As the Amendment Regulations do not introduce any changes to the MD Regulations other than to implement the changes outlined above, they do not appear to 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.

Greg Hunt, Minister for Health