

## **EXPLANATORY STATEMENT**

### **Select Legislative Instrument No. 46, 2015**

#### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods (Medical Devices) Amendment (Joint Replacements) Regulation 2015*

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 (Joint Replacements) Regulation 2015 (the Regulation) amends the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Principal Regulations) to introduce a number of definitions to clarify what is meant by the concept of “a medical device that, either alone or with other such devices, comprises a total or partial shoulder, hip or knee joint replacement” that was included in the Principal Regulations in 2012.

On 1 July 2012, implantable medical devices intended by their manufacturer to be total or partial shoulder, hip or knee joint replacements were reclassified in the Principal Regulations from Class IIb medical devices to the higher risk classification of Class III, so that they would have an increased degree of pre-market assessment.

A two year transition process was provided for in the *Therapeutic Goods (Medical Devices) Amendment Regulation 2012 (No. 1)* (the 2012 Amendment Regulations) to give sponsors of such devices already in the Register as Class II devices until 30 June 2014 to apply to the TGA to include their products in the Register as Class III devices.

This deadline has now been extended to 30 June 2015 by the *Therapeutic Goods (Medical Devices) Amendment (Joint Replacements) Regulation 2014*, which commenced on 1 May 2014. If such a sponsor does not submit a Class III application by that date, its Class IIb devices will be taken to be cancelled from the Register on 1 July 2015. If the sponsor does submit a Class III application by 30 June 2015, the relevant Class IIb entry will remain in the Register while the Class III application is being considered.

In recent times, industry has expressed concerns over a need for greater clarity about:

- which implanted medical devices form part of a total or partial replacement of a shoulder, hip or knee joint (and which should therefore be classified as Class III); and
- which implanted medical devices can be used to assist a replacement joint rather than forming part of the replacement joint itself (and which should therefore be classified as Class IIb) in particular patients if required.

The Regulation addresses such concerns by making it clear that the first category is limited to implantable devices (defined as “joint replacement medical devices”) that are intended, working alone or together with other such devices, to:

- replace the articulating surface of a shoulder, hip or knee joint; or
- provide primary fixation to the bone for the replacement articulating surface; or
- connect with such a device and operate as an intrinsic element of the joint replacement.

The Regulation also makes it clear that implanted medical devices that can be used in particular patients to provide stability, bone substitution, additional fixation or other assistance for the joint replacement such as screws, plates or wedges (all defined as “ancillary devices”) are not Class III medical devices.

These definitions reflect that, in practice, joint replacements are normally systems comprised of a number of components. Some of these components are essential parts of the reconstructed joint, whereas others are intended to be available to the surgeon to supplement or assist a replacement joint where the circumstances of a particular patient warrant their use.

The Regulation has the effect that any implantable medical devices that do not meet the new definition of a “joint replacement medical device” (which are these “essential parts”) will not need to be approved for marketing as Class III devices.

The sponsors of a number of implantable medical devices that, under the Regulation, are regarded as “ancillary devices” have already sought inclusion in the Register of those devices on the basis of the 2012 Amendment Regulations. The Regulation accordingly provides for the refund of any relevant fees and annual charges paid by sponsors of those devices on the basis that they were Class III devices. In order to continue to be marketed in Australia, such devices need to be included in the Register as Class IIb devices (once this occurs, affected sponsors will have the option of requesting the Secretary to cancel their Class III entries, or the Secretary could cancel those on the Secretary’s own initiative given that the classification of the products as Class III devices will be incorrect).

Details of the Regulation are set out in the Attachment.

The Act does not specify conditions that need to be met before the power to make the proposed 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.

## **Consultation**

There has been extensive consultation on the proposal to clarify the definition of medical devices affected by the re-classification. Those consulted included the Medical Technology Association of Australia’s Orthopaedic Working Group, the Australian Orthopaedic Association, the National Joint Replacement Register, the Consumer Health Forum, relevant Clinical Advisory Groups of the Prostheses List Advisory Committee, the Advisory Committee on Medical Devices and the Orthopaedic Subcommittee of the Advisory Committee on the Safety of Medical Devices. Overall, there was support for the proposed

definitions. While the definitions have been refined during the drafting process, they remain consistent with the draft definitions supported by industry and clinical groups.

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

**ATTACHMENT****Details of the *Therapeutic Goods (Medical Devices) Amendment (Joint Replacements) Regulation 2015*****Section 1 – Name of Regulation**

This section provides that the title of the Regulation is the *Therapeutic Goods (Medical Devices) Amendment (Joint Replacements) Regulation 2015*.

**Section 2 – Commencement**

This section provides for the Regulation to commence the day after it is registered.

**Section 3 – Authority**

This section would provide that the *Therapeutic Goods (Medical Devices) Amendment (Joint Replacements) Regulation 2015* is made under the *Therapeutic Goods Act 1989* (the Act).

**Section 4 – Schedule**

This section provides that 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****Item 1 – Division 11.2 (heading)**

This item replaces the current heading of Division 11.2 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Principal Regulations) with a new heading to indicate that the Division contains provisions about transitionals relating to joint replacements.

This item also introduces a new regulation 11.22A, which contains a short description of the purpose of the Division.

**Item 2 – Subregulation 11.22(1)**

Subregulation 11.22(1) currently states that regulation 11.22 of the Principal Regulations applies to an implantable medical device that is intended by the manufacturer to be a total or partial shoulder, hip or knee joint replacement.

As item 8 introduces a new definition of a “joint replacement medical device” that explains what devices, in effect, constitute such replacements, item 3 replaces the current subregulation 11.22(1) with a reference to that new definition.

**Item 3 – At the end of Division 11.2**

On 1 July 2012, implantable total or partial shoulder, hip or knee joint replacements were reclassified, by amendments made by the *Therapeutic Goods (Medical Devices) Amendment Regulation 2012 (No. 1)*, from Class IIb medical devices to Class III medical devices to ensure they would be subject to an increased degree of pre-market assessment. However, no definition of these products was included.

In response to concerns for greater clarity about which medical devices constitute a total or partial replacement of a shoulder, hip or knee joint, item 8 introduces a number of new definitions, including in particular a definition of a “joint replacement medical device” and also definitions of “hip joint”, “knee joint” and “shoulder joint”.

As a result of the changes in item 8, a number of joint-related medical devices that have already been included in the Australian Register of Therapeutic Goods (the Register) as Class III devices since 1 July 2012 no longer fall within that classification because they do not come within the definition of a joint replacement medical device.

Accordingly, item 3 introduces a new regulation 11.23, which provides for the Secretary to refund sponsors of these products any fees and charges paid by them for the purposes of seeking inclusion in the Register as a Class III medical device.

Where the relevant device was previously included in the Register as a Class II medical device, this will be limited to the refund of application fees.

However, if the device was included in the Register for the first time since 1 July 2012 as a Class III device, application audit fees relating to the verification and assessment of their application and supporting evidence, as well as applications fees, would have been paid. These sponsors may also have been paid an annual charge for a Class III medical device in respect of the inclusion of each of their products in the Register – this is a higher charge than the annual charge payable for a Class IIb device.

Item 3 therefore also provides, in new subregulation 11.23, for the refund to those affected sponsors of amounts of annual charges that were paid since the products were included in the Register on the basis that they were Class III medical devices rather than Class IIb medical devices.

#### **Items 4 and 5 – Amendments to clause 3.4 of Schedule 2**

These items make minor consequential amendments to subclauses 3.4(2) and (4) of Schedule 2 to the Principal Regulations, to accommodate the amendments in items 6 and 7.

#### **Items 6 and 7 – After subclause 3.4(4) of Schedule 2**

Subparagraph 3.4(4)(f) of Schedule 2 to the Principal Regulations sets out the current classification rule for implantable medical devices. Under this rule, a device intended by the manufacturer to be a total or partial shoulder, hip or knee joint replacement is classified as a Class III medical device.

As item 8 introduces a new definition (“joint replacement medical device”), items 6 and 7 would replace the current classification rule in subparagraph 3.4(4)(f) with a new rule that any implantable medical device that comes within the definition of joint replacement medical device will be a Class III device.

#### **Item 8 Dictionary**

Item 8 introduces a number of new definitions to the Dictionary in the Principal Regulations.

Item 8 defines a joint replacement medical device, as being an implantable device (which is itself a defined term):

- that is intended by the manufacturer to operate (either alone or with other implantable medical devices) to replace (in whole or in part) a shoulder, hip or knee joint; and
- that (either alone or with other implantable medical devices) has a specified function; but
- does not include an ancillary device (as defined by item 8).

The specified functions are to either:

- replace or substitute for the articulating surface of a shoulder, hip or knee joint; or
- provide primary fixation to the bone for the replacement articulating surface; or
- connect directly or indirectly with an implantable medical device that has one of the above two functions, and operate as an intrinsic element of the joint replacement (i.e. as an element without which the new joint as a whole could not function).

Under the Act, Class III medical devices are included in the Register as separate entries. This is the reason that the constituent parts of what, when implanted in a patient, together form the hip, shoulder or knee replacement are, under this definition, separate joint replacement medical devices. Thus a patient may have 3 or possibly more “joint replacement medical devices” implanted by the surgeon to replace the hip, shoulder or knee.

Item 8 also defines an ancillary medical device - i.e. those implantable medical devices excluded from the definition of a joint replacement medical device – as an implantable medical device that:

- consists of screws, plates or wedges; or
- was intended by the manufacturer to be used to provide stability, additional fixation or other assistance for, or bone substitution to facilitate the use of, a joint replacement medical device where the individual requirements of a patient make it appropriate to do so..

A surgeon operating on a particular patient may, for example, decide that apart from implanting 3 Class III joint replacement medical devices to replace the patient’s hip (and using Class IIb screws to keep them in place), to also use a Class IIb ancillary device to provide additional stability for the replacement hip in the patient.

For clarity, item 8 also defines precisely what is meant by each of a shoulder joint, hip joint and knee joint.

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

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

### ***Therapeutic Goods (Medical Devices) Amendment (Joint Replacements) Regulation 2015***

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 (Joints Replacements) Regulation 2015* (the Amendment Regulation) is made under subsection 63(1) of the *Therapeutic Goods Act 1989* (the Act).

Implantable medical devices intended by their manufacturer to be total or partial shoulder, hip or knee replacements were reclassified from Class IIb to Class III medical devices on 1 July 2012, subjecting them to an increased degree of pre-market assessment by the Therapeutic Goods Administration (TGA) proportionate to their risk.

Such products that had marketing approval from the TGA before 1 July 2012 or were the subject of an application for marketing approval that had not been finally determined at that date, have until 30 June 2015 to apply for marketing approval for their products as Class III medical devices. After that date, the inclusion of the Class IIb device will be automatically cancelled.

The principal purpose of the Amendment Regulation is to amend the Therapeutic Goods (Medical Devices) Regulations 2002 (the Principal Regulations) to clarify what is meant by a “medical device that is a total or partial shoulder, hip or knee joint replacement” by the inclusion of a definition of “joint replacement medical devices”. Only medical devices coming within this definition will need to be approved for marketing as Class III medical devices.

Other joint-related implantable medical devices (defined as “ancillary medical devices”), such as screws, plates or wedges, or other items that are intended to be available to be used by the surgeon to provide stability, additional fixation etc. for the joint replacement will remain as Class IIb medical devices.

The instrument will allow for the refund of fees and charges where ancillary medical devices have been approved for marketing as Class III devices since 1 July 2012 but can now be marketed as Class IIb devices.

#### **Human rights implications**

As the Amendment Regulation does not introduce any changes to the Principal Regulations other than to implement the change mentioned 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.

**Fiona Nash**

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