

## **EXPLANATORY STATEMENT**

### **Select Legislative Instrument No. 44, 2014**

#### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods (Medical Devices) Amendment (Joint Replacements) 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 purpose of the regulation is to amend the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Principal Regulations) to extend the current transitional period for the “up-classification” process involving implantable shoulder, hip or knee joint replacements, from 1 July 2014 to 1 July 2015.

On 1 July 2012, implantable medical devices intended by their manufacturer to be total or partial shoulder, hip or knee joint replacements were reclassified under the Principal Regulations from Class IIb medical devices to the higher risk classification of Class III, in order that they be subjected to an increased degree of pre-market scrutiny. This meant that any application for the inclusion of such devices in the Register after that date will have to satisfy the regulatory requirements for a Class III medical device rather than a Class IIb medical device.

A two year transition process was provided for in the *Therapeutic Goods (Medical Devices) Amendment Regulation 2012 (No. 1)* (the 2012 Regulation Amendments). As part of this process, sponsors of such devices which, as at 1 July 2012, were either already included in the Register as Class IIb devices or were the subject of an application for inclusion in the Register as Class IIb devices that had not been finally determined by the TGA, were given until 30 June 2014 to submit an application to the TGA to include their products in the Register as Class III devices.

If sponsors do not submit a Class III application by 30 June 2014, their Class IIb devices will be taken to be cancelled from the Register on 1 July 2014. If sponsors submit a Class III application by 30 June 2014, their relevant Class IIb entry will remain in the Register while their Class III application is being considered.

It has recently become apparent that more time is needed for affected sponsors to comply with this transition process. This is due to the unanticipated complexity arising from the fact that the majority of these joint replacement medical devices are imported into Australia and rely on European certifications to support their applications for marketing approval as Class III devices in Australia.

There is therefore a need to extend the transition process to ensure that the public continues to have access to the full range of these kinds of medical devices that satisfy relevant regulatory requirements.

Extending the up-classification process mentioned above from 1 July 2014 to 1 July 2015 gives sponsors greater time in this regard, and avoids unintended disruptions in supply of joint replacement devices.

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 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.

The TGA consulted with the key medical device peak body, the Medical Technology Association of Australia (the MTAA), about extending the transition period for joint replacements until 30 June 2015. The MTAA supports the proposal.

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

**ATTACHMENT****Details of the *Therapeutic Goods (Medical Devices) Amendment (Joint Replacements) Regulation 2014*****Section 1 – Name of regulation**

This section provides for the regulation to be referred to as the *Therapeutic Goods (Medical Devices) Amendment (Joint Replacements) Regulation 2014*.

**Section 2 – Commencement**

This section provides for the regulation to commence 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**

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*****Therapeutic Goods (Medical Devices) Regulations 2002*****Item 1 – Subregulations 11.1(3), (6) and (7)**

This item amends each of subregulations 11.1(3), (6) and (7), to replace references to the year 2014 in those subregulations with references to the year 2015.

These amendments, taken together, extend the current transition process for the up-classification of implantable medical devices intended by their manufacturer to be total or partial shoulder, hip or knee joint replacements, by 12 months – by providing for that process, or key elements that support that process, to end on 30 June 2015 rather than the current 30 June 2014.

Under this transition process, sponsors of such medical devices that, as at 1 July 2012, were included in the Australian Register of Therapeutic Goods (the Register) as Class IIb devices or were the subject of applications for inclusion in the Register as Class IIb devices that had not been finally determined, were given until 30 June 2014 to submit an application to include their products in the Register as Class III devices.

In relation to the subregulations mentioned above:

- subregulation 11.1(3) currently ensures that a sponsor of a device covered by the transition process outlined above who applies to include their product in the Register as a Class III device will not have to pay an annual charge for their Class III entry until after 30 June 2014 – these amendments extend this to 30 June 2015;
- subregulation 11.1(6) currently provides that Class IIb devices included in the Register that are covered by this transition process will be cancelled on 1 July 2014 except for those devices that are the subject of an application for inclusion in the Register as a

Class III device for which no decision has yet been made – these amendments extend this to 1 July 2015; and

- subregulation 11.1(7) currently has the effect of cancelling the inclusion in the Register of any Class IIb device that is the subject of an application for inclusion as a Class III device for which no decision has been made as at 1 July 2014 (and which is later decided to be unsuccessful) on the later of 1 July 2014 and the day the sponsor is notified that their application was unsuccessful – these amendments extend this to the later of 1 July 2015 and the day the sponsor is notified that their Class III application was unsuccessful.

**Item 2 – Subregulation 11.1(9)**

This item corrects a minor typographical error in subregulation 11.1(9).

## **Statement of Compatibility with Human Rights**

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

### ***Therapeutic Goods (Medical Devices) Amendment (Joint Replacements) 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 (Joints Replacements) Regulation 2014* (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 scrutiny proportionate to their risk.

Such products that, as at that date, had marketing approval from the Therapeutic Goods Administration (TGA) or were the subject of an application for marketing approval that had not been finally determined by the TGA, were given until 30 June 2014 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 purpose of the Amendment Regulation is to amend the Therapeutic Goods (Medical Devices) Regulations 2002 (the Principal Regulations) to extend this transition period for such sponsors for a further 12 months, from 30 June 2014 to 30 June 2015, to allow for consultation with industry on a range of matters relating to these products.

#### **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**

**Assistant Minister for Health**