

## **EXPLANATORY STATEMENT**

### **Select Legislative Instrument No. 38, 2014**

#### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods (Medical Devices) Amendment (Auditing Applications) 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.

Under the Act, the Secretary of the Department of Health is required to select for audit by the Secretary, applications for the inclusion of kinds of medical devices in the Australian Register of Therapeutic Goods (the Register) of a kind prescribed in the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Principal Regulations) (these include, for example, applications involving implantable intra-ocular lenses or implantable contraceptive devices), and also has a discretion to select for auditing any other applications to include a kind of medical device in the Register. An audit can involve a range of matters, including examining whether the kind of device complies with minimum technical requirements for safety and performance and whether they contain substances prohibited under the *Customs Act 1901*. For applications selected for audit, the Secretary must, under the Act, inform the applicant of that selection and require them to provide any information the Secretary is satisfied is relevant to the audit, either within 20 working days after the application was made or within such longer period as is prescribed for particular kinds of applications. There is currently no period prescribed for this purpose.

The purpose of the regulation is to amend the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Principal Regulations) to now prescribe such a longer period – 60 working days after the application was made – for applications known as “up-classification” applications.

“Up-classification” applications are applications for the inclusion in the Register of certain kinds of Class III implantable medical devices. They are devices intended by their manufacturer to be total or partial shoulder, hip or knee replacements and which, as at 1 July 2012, were included in the Register as Class IIb medical devices or were the subject of an application for inclusion as a Class IIb device that had not yet been finally determined at that time.

On 1 July 2012, these products were reclassified 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 products in the Register after that date 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 total or partial shoulder, hip or knee replacement medical devices which, as at 1 July 2012, were either already included in 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 the TGA to include their products in the Register as Class III devices. If sponsors do not submit a Class III application by that date, the inclusion of their Class IIb devices will be taken to be cancelled from the Register on 1 July 2014. The relevant Class IIb entry will remain in the Register while their Class III application is being considered.

Based on the TGA's experience, a large number of these applications are likely to be received within a relatively short timeframe in the lead-up to the 30 June 2014 deadline. The TGA expects that that around 900 up-classification applications will be submitted to the TGA between the start of March 2014 and 30 June 2014. This is equivalent to around 50 per cent of the total number of medical device applications the TGA usually receives annually.

Having 60 rather than 20 working days for the Secretary to inform applicants that their applications have been selected for audit will assist the TGA in managing all relevant applications efficiently and in a manner that does not divert resources unnecessarily from processing applications for other types of medical devices that are not involved in the up-classification process.

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.

### **Consultation**

Key medical devices peak bodies, including the Medical Technology Association of Australia and AusBiotech, were consulted about these amendments at the 6 February 2014 meeting of the Regulatory and Technical Consultative Forum for medical devices (the RegTech Forum).

The response at that meeting from the peak bodies in relation to these amendments and, in particular, to the new 60 working day timeframe for informing applicants of affected devices of their selection for audit, was positive. This support has since been confirmed in written responses to the TGA to an email sent to RegTech members on 24 February 2014 about the measures.

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

**Details of the *Therapeutic Goods (Medical Devices) Amendment (Auditing Applications) Regulation 2014*****Section 1 – Name of regulation**

This section provides for the regulation to be referred to as the *Therapeutic Goods (Medical Devices) Amendment (Auditing Applications) 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 – Regulation 5.3 (heading)**

This item makes a minor consequential amendment to replace the current heading of regulation 5.3 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Principal Regulations) with a new heading.

The current heading of regulation 5.3 refers to “*Applications to be selected for auditing (Act s41FH)*”. As item 2 below amends regulation 5.3 to also include information about the period of time within which the Secretary must advise applicants of certain kinds of medical device applications that their applications have been selected for auditing, item 1 introduces a new, broader, heading for subregulation 5.3 that reflects this.

**Item 2 – At the end of regulation 5.3**

This item introduces a new subregulation 5.3(3) to the Principal Regulations which prescribes, for the purposes of paragraph 41FH(3)(b) of the Act, a period of 60 working days (after the application was made) for the Secretary to advise applicants seeking inclusion of certain kinds of medical devices in the Register that their applications have been selected for auditing.

The kinds of applications to which this applies are those mentioned in subregulation 11.1(3) of the Principal Regulations that are submitted to the TGA before 1 July 2014.

Subregulation 11.1(3) refers to applications for inclusion in the Register as Class III medical devices involving products that are implantable medical devices intended by their manufacturer to be a total or partial shoulder, hip or knee joint replacement that were included in the Register on or after 1 July 2012 as Class IIb medical devices.

These implantable joint replacements were reclassified on 1 July 2012, under the Principal Regulations, from Class IIb medical devices to the higher risk classification of Class III – this reflected concerns to ensure that an increased degree of pre-market scrutiny be applied to such products, proportionate to their risk.

Under regulation 11.1 of the Principal Regulations, sponsors of such devices that, 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 that had not yet been finally determined, have until 30 June 2014 to apply to include their kind of device in the Register as a Class III medical device.

A large volume of these “up-classification” applications are expected to be lodged with the TGA in the lead-up to the 30 June 2014 deadline.

Under subsections 41FH(2) and (3) of the Act, if the Secretary selects an application to include a kind of medical device in the Register for auditing, the Secretary must, within 20 working days – or such other period as is prescribed – after the application is made, inform the applicant of that selection and require them to provide any information considered by the Secretary to be relevant to the audit.

The effect of the amendment in item 2 is to give the Secretary a longer period – 60 working days – after the receipt of one of these up-classification applications for the Secretary to advise the applicant of that fact and require them to provide any information relevant to completing the audit.

This assists the TGA to ensure that the expected volume of up-classification applications are able to managed efficiently in the lead-up to 30 June 2014, and in a manner that does not divert resources unnecessarily from processing applications for other types of medical devices that are not involved in the up-classification process.

**Item 3 – Subregulation 11.1(4)**

This item makes a minor editing change to subregulation 11.4 to reflect the introduction of a new subregulation 5.3(3) to the Principal Regulations by item 2 above.

## 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 (Auditing Applications) 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 (Auditing Applications) Regulation 2014* (the Amendment Regulation) is made under subsection 63(1) of the *Therapeutic Goods Act 1989* (the Act). Under the Act, when a person applies for marketing approval for a kind of medical device and the Secretary decides to audit the application, the Secretary has 20 working days – or such other period as is prescribed – to inform the applicant of that fact, and to request from the applicant information the Secretary considers to be relevant to completing the audit.

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 or were the subject of an application for marketing approval, were given until 30 June 2014 to apply for marketing approval for their products as Class III medical devices. A large number of these applications are expected before that deadline.

The purpose of the Amendment Regulation is to amend the Therapeutic Goods (Medical Devices) Regulations 2002 (the Principal Regulations) to prescribe a longer period – 60 working days – than the 20 working day period mentioned above for informing applicants of their selection for audit and for requesting supporting information – to assist with the management of those applications in that relatively short timeframe.

#### **Human rights implications**

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

**Senator the Hon Fiona Nash**  
**Assistant Minister for Health**