

EXPLANATORY STATEMENT

Select Legislative Instrument 2012 No. 142

Therapeutic Goods Act 1989

Therapeutic Goods Amendment Regulation 2012 (No. 1)

Therapeutic Goods (Medical Devices) Amendment Regulation 2012 (No. 1)

The object of the *Therapeutic Goods Act 1989* (the Act) is to establish and maintain a national system of controls for the quality, safety and 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 and Ageing, 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 regulations is, principally, to amend the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to reclassify implantable medical devices that are intended by their manufacturer to be total or partial hip, knee or shoulder joint replacements, from the current Class IIb classification to Class III.

The regulatory framework for medical devices classifies devices within a four level risk-based scale, designating medical devices as either Class I (lowest risk), IIa, IIb or III (highest risk) depending on the intended purpose of the device and the potential risk associated with its use. The extent of pre-market scrutiny applied to a medical device is commensurate with the risk classification of the kind of device.

Reclassifying these joint replacements as Class III medical devices reflects the fact that concerns have arisen in relation to the safety of these products, and will increase the rigour of pre-market assessment of such medical devices before they are included on the Australian Register of Therapeutic Goods (the Register) and are therefore generally available for use in Australia.

The regulations also provide for the transitioning, over a two year period, of affected joint replacement devices that are included in the Register as Class IIb medical devices as at 1 July 2012 (or which, at that time, are the subject of an application for inclusion in the Register as a Class IIb device), from Class IIb to Class III. Sponsors of such existing Class IIb devices have until 30 June 2014 to apply for the inclusion of their products in the Register as Class III devices.

The regulations also amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) in relation to a small number of minor, separate matters, including:

- permitting the Complaints Resolution Panel to deal with a complaint about an advertisement or generic information relating to a therapeutic good if court proceedings have begun in relation to the subject matter of the complaint or if such proceedings begin after the making of a complaint to the Panel; and

- enabling sponsors of therapeutic goods granted an exemption from paying an annual charge in financial years 2009-10 or 2010-11 on the basis that the turnover of their goods was of low value, but who did not give the Secretary of the Department of Health and Ageing the information required under the TG Regulations to substantiate the low value of their turnover, to provide that information within a further specified period. If they do so, affected sponsors then avoid liability to pay the relevant charge.

Details of the amendments to the TG Regulations are set out in Attachment A, and details of the amendments to the MD Regulations are set out in Attachment B.

The Complaints Resolution Panel chair was consulted in relation to the changes made to the Panel's ability to deal with a complaint if court proceedings have begun, and the Australian Society for Bioregulatory Medicine was consulted in relation to the change of name of that organisation in Schedule 1 to the Therapeutic Goods Regulations 1990. Consultation was not undertaken in relation to the amendments relating to low value exemptions for financial years 2009-10 and 2010-11, as these measures are considered to be minor and machinery in nature.

In relation to the reclassification of implantable total or partial hip, knee or shoulder joint replacements, extensive consultation occurred in 2009 and 2010, including as part of the Government's Review of Health Technology Assessment in Australia (the HTA Review) and a subsequent discussion paper issued by the TGA in October 2010 (titled *Reforms in the Medical Devices Regulatory Framework*). The report relating to the HTA Review, and the 2009 and 2010 TGA papers, are available from the TGA's website (www.tga.gov.au). In addition, in 2011 the reclassification of these products was considered by the Senate Community Affairs Committee in the context of its Inquiry in relation to *The regulatory standards for the approval of medical devices in Australia* (the Committee's report of the same name, dated November 2011, is available from www.aph.gov.au). Industry has been broadly, although not universally, supportive of the reclassification of these products.

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

The regulations are legislative instruments for the purposes of the *Legislative Instruments Act 2003*.

The *Therapeutic Goods Amendment Regulation 2012 (No. 1)* commences on the day after it is registered, and the *Therapeutic Goods (Medical Devices) Amendment Regulation 2012 (No. 1)* commences on 1 July 2012.

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

ATTACHMENT A**Details of the *Therapeutic Goods Amendment Regulation 2012 (No. 1)*****Section 1 – Name of Regulation**

This section provides for the regulation to be referred to as the *Therapeutic Goods Amendment Regulation 2012 (No. 1)*.

Section 2 – Commencement

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

Section 3 – Amendment of *Therapeutic Goods Regulations 1990*

This section provides for Schedule 1 to amend the *Therapeutic Goods Regulations 1990* (the Principal Regulations).

Schedule 1 – Amendments**Item [1] – Regulation 42ZCAA, before definition of *complaint***

The Complaints Resolution Panel (the Panel) is a committee established under regulation 42R of the Principal Regulations. The Panel's functions are to receive and consider complaints about advertisements and generic information relating to therapeutic goods, to make requests of persons responsible for advertisements and generic information, and to make recommendations to the Secretary of the Department of Health and Ageing, about such advertisements or generic information, in accordance with its powers as set out in Subdivision 2 of Division 3 of Part 6 of the Principal Regulations.

Under subregulation 42ZCAGA of the Principal Regulations, if the Panel is satisfied that the subject matter of a complaint, or the advertisement or generic information to which a complaint relates, could be more effectively or conveniently dealt with by another authority, and if the complaint could have been made directly to that other authority, then the Panel may (in writing) refer the matter to the authority.

Item [1] makes a minor amendment to regulation 42ZCAA of the Principal Regulations for clarification purposes by including a definition of “another authority”, specifying that that term includes the Therapeutic Goods Administration (the TGA). The purpose of this amendment is to remove any doubt that the TGA is an authority to which the Panel can refer matters involving complaints, in accordance with regulation 42ZCAGA.

Items [2], [3] and [4] – Amendments to regulation 42ZCAJ regarding dealing with complaints by the Complaints Resolution Panel in the event of court proceedings

Under subregulation 42ZCAJ(1) of the Principal Regulations, the Panel cannot deal with a complaint about an advertisement or generic information relating to a therapeutic good if a court proceeding has begun about the subject matter of the complaint, and the proceeding has not been finally disposed of.

Under subregulation 42ZCAJ(2) of the Principal Regulations, the Panel cannot deal with such a complaint if, after a complaint has been made to the Panel, a court proceeding begins about the subject matter of the complaint, and that proceeding has not been finally disposed of.

Item [4] amends regulation 42ZCAJ with the effect that, notwithstanding subregulations 42ZCAJ(1) and (2), the Panel can decide to deal with a complaint in either of the circumstances mentioned in those provisions, after taking into account certain matters.

Those matters are:

- whether either the person making the complaint (if that person is known to the Panel), or the person apparently responsible for the advertisement or generic information, will be unreasonably disadvantaged if the Panel were to deal with the complaint before the court proceeding had been completed;
- whether the complaint could be referred to another authority under regulation 42ZCAGA of the Principal Regulations;
- the public interest; and
- any other matter the Panel thinks relevant.

The Panel will have to notify the person making the complaint (if known) and the “person apparently responsible” (i.e. the person who appears to be responsible for the advertisement or generic information) about any decision to deal with the complaint.

Item [2] replaces the current wording of the title of regulation 42ZCAJ to reflect these amendments.

Item [3] makes a minor, grammatical change to subregulations 42ZCAJ(1) and (2) by replacing references in those provisions to “cannot” with “must not”.

Item [5] – After subregulation 43AAE(3)

Subdivision 2 of Division 1 of Part 7 of the Principal Regulations sets out a regime for the exempting of sponsors of therapeutic goods (other than biologicals) from the requirement to pay an annual charge in respect of their goods for a financial year, if they are able to demonstrate that the turnover of their goods was of low value. Low value is defined regulation 43AAB of the Principal Regulations as a turnover of not more than 15 times the relevant annual registration, listing or inclusion charge payable for a financial year.

When a sponsor applies for a low value exemption, the application must be accompanied by a statement of the estimated turnover of the relevant therapeutic goods for the current financial year. Upon receipt of an application from a sponsor for a low value exemption, the Secretary is required under regulation 43AAD to decide within 21 days whether to grant the exemption or refuse the request.

Under subregulation 43AAE(1) of the Principal Regulations, if the Secretary has granted a low value exemption for a financial year with respect to a new entry in the Register, the sponsor has until 1 September of the following financial year to provide (in writing, in a form approved by the Secretary) details of the *actual* turnover of their goods for the financial year for which the exemption was granted, as well as a statement of that actual turnover signed by a qualified accountant.

Under subregulation 43AAE(3), if a sponsor does not provide this information to the Secretary as required, the exemption is taken to be cancelled on 30 September of the financial year following the financial year for which the exemption was granted, and the charge must then be paid by 31 October.

For financial years 2009-10 and 2010-11 (the first years in which this low value regime was in operation), none of the sponsors to whom low value exemptions were granted provided the details of their actual turnover, or a signed statement from an accountant in relation to their actual turnover, as required under regulation 43AAE, apparently because they were not aware of their obligation to do so.

All of those sponsors were, therefore, under subregulation 43AAE(3) of the Principal Regulations required to pay the full annual charge which they had been previously exempted from having to pay, by 31 October of the following financial year (although no such sponsors have done so).

The amendments set out in item [5] amend regulation 43AAE so that subregulations 43AAE(1) to (3) do not apply to sponsors who were granted low value exemptions for financial years 2009-10 or 2010-11 and who did not provide information about their actual turnover for those periods as required. The amendment permits those sponsors a further period (of not less than two months) within which to submit that information to the Secretary. If a sponsor does not provide the information to the Secretary within the period, then the exemption is taken to be cancelled on the day after the day specified in the notice, and the relevant charge must be paid within two months after the day specified in the notice.

Items [6] and [7] – Subregulation 43AAF(1) and paragraph 43AAF(2)(b)

Subregulation 43AAF(1) of the Principal Regulations requires that when a sponsor who has been granted a low value exemption submits the information about the actual turnover of their goods required under subregulation 43AAE(1), the Secretary must, within 21 days of receiving that information, decide whether the actual turnover of the sponsor's goods was of low value or not, and notify the sponsor of that decision.

Item [6] makes a minor amendment to subregulation 43AAF(1) to include a reference to new subregulation 43AAE(5) in paragraph 43AAF(1)(a), with the effect that the Secretary is required to undertake these steps when a sponsor, in accordance with the amendments set out in item [6], submits the information about their actual turnover for financial years 2009-10 or 2010-11.

Item [6] also ensures that if the Secretary decides that a sponsor's actual turnover for financial years 2009-10 or 2010-11 was not of low value, the sponsor could appeal to the Administrative Appeals Tribunal for a review of that decision, under subregulation 43AAI(a) of the Principal Regulations.

Item [7] makes a minor amendment to paragraph 43AAF(2)(b) with the effect that where a sponsor submits the information about their actual turnover for financial years 2009-10 or 2010-11 and the Secretary finds, on the basis of that information, that the turnover was *not* of low value, the sponsor must pay the charge within two months of being notified by the Secretary under subregulation 43AAF(1)(b).

Item [8] – Schedule 1, item 26AA

Item [8] replaces the reference to the “Australian Association of Homotoxicology Incorporated” in item 26AA of Schedule 1 to the Principal Regulations with a reference to “Australian Society for Bioregulatory Medicine Incorporated”, to reflect a recent change in the name of that organisation.

ATTACHMENT B**Details of the *Therapeutic Goods (Medical Devices) Amendment Regulation 2012 (No. 1)*****Section 1 – Name of Regulation**

This section provides for the regulation to be referred to as the *Therapeutic Goods (Medical Devices) Amendment Regulation 2012 (No. 1)*.

Section 2 - Commencement

This section provides for the regulation to commence on 1 July 2012.

Section 3 – Amendment of *Therapeutic Goods (Medical Devices) Regulations 2002*

This section provides for Schedule 1 to amend the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Principal Regulations).

Schedule 1 – Amendments**Item [1] – Transitional arrangements relating to 2012 Amendment Regulation**

This item provides for transitional arrangements relating to implantable medical devices that are intended by their manufacturer to be total or partial hip, knee or shoulder joint replacements and that are, as at 1 July 2012, either included on the Australian Register of Therapeutic Goods (the Register) as a Class IIb medical device, or are the subject of an application for inclusion on the Register as a Class IIb device and are later included on the Register as a result of that application.

These transitional arrangements, principally, put in place a two year transition, from the commencement of the Regulation until 30 June 2014, for the reclassification of hip, knee and shoulder joint replacement medical devices from Class IIb medical devices to Class III.

Item [1] sets out these transitional arrangements in a new Part 11 of the Principal Regulations.

Subregulation 11.1(2) requires that if an application is made before 1 July 2012 for the inclusion of a total or partial hip, knee or shoulder joint replacement as a Class IIb medical device and it has not been finally determined by that date, the product is to be included on the Register as a Class IIb medical device, provided the application is successful.

‘Finally determined’ is defined as when a decision has been made on whether to grant an application and there is no longer any possibility of a change in the outcome of the decision in terms of the granting of approval for the inclusion of the relevant device on the Register. For the purposes of determining when there is no longer any possibility of a change in the outcome of a decision, the exercise of a discretion (for instance by a court) to extend a period for seeking review by a court or tribunal of the decision or for starting other proceedings (including appeals) arising out of the application, after that period has ended, is not to be considered. In other words, if a court exercises a discretion after the period in which an application to appeal against a decision has elapsed to allow an application to be made, that matter will not be taken into account in determining whether there is no longer any possibility of a change in the outcome of the decision.

New subregulation 11.1(3) applies if a total or partial hip, knee or shoulder joint replacement is included on the Register as a Class IIb medical device as at 1 July 2012, or is included as a

Class IIb device after that date because it was the subject of an application for inclusion as a Class IIb device as at 1 July 2012 and, in either case, if an application is then also made during the transition period for the device to be included as a Class III medical device.

The effect of subregulation 11.1(3) is that, in the circumstances outlined above, no annual charge will be payable in relation to the inclusion of the relevant joint replacement as a Class III medical device for the transition period, i.e. the financial years 2012-13 and 2013-14.

Subregulation 11.1(4) is intended to make it clear that such applications are not subject to mandatory auditing under Subdivision B of Division 1 of Part 4-5 of the *Therapeutic Goods Act 1989*. They could however be selected for auditing under that Subdivision.

Subregulation 11.1(5) is intended to make clear that no application fee applies in such circumstances provided the application for inclusion of the relevant device as a Class III medical device is made before 1 July 2013, respectively.

Under subregulation 12.1(6), any total or partial hip, knee or shoulder joint replacement still included in the Register as a Class IIb device as at 1 July 2014 will be cancelled from the Register on that date, *unless* an application has been made before 1 July 2014 to have the product included in the Register as a Class III medical device and the Secretary has not, as at that date, decided whether or not to grant that application.

If such an application was unsuccessful then, under new subregulation 12.1(7), the relevant Class IIb entry will be cancelled from the Register either on 1 July 2014 or the date when the notice (advising that the application for inclusion of the product as a Class III was unsuccessful) was given to the applicant whichever was the later.

Subregulation 11.1(8) sets out when an application is ‘finally determined’ for the purposes of the transitional provisions, explaining that this is taken to be the first time when both a decision has been made as to whether or not to grant an application, and there is no longer any possibility of a change in the outcome of that decision.

Subregulation 11.1(9) clarifies the definition of ‘finally determined’ in subregulation 11.1(8). Subregulation 11.1(9) explains that the meaning of that term does not include the possibility of a court or tribunal exercising a discretion to extend the period of time for seeking review of the decision or for starting other proceedings (including appeals) arising out of the application, decision or review.

Item [2] – Schedule 2, paragraph 3.4(4)(e)

This item makes a minor, formatting change to subclause 3.4(4) of Schedule 2 to the Principal Regulations in order to accommodate item [3].

Item [3] – Schedule 2, after paragraph 3.4(4)(e)

Item [3] amends subclause 3.4(4) of Schedule 2 to the Principal Regulations to add a new paragraph 3.4(4)(f), which refers to total or partial shoulder, hip or knee joint replacements.

The effect of new paragraph 3.4(4)(f) makes it clear that implantable medical devices that are total or partial hip, knee or shoulder joint replacements will be classified as Class III medical devices upon the commencement of the new Regulation, i.e. 1 July 2012.

The regulatory framework for medical devices classifies devices within a four level risk-based scale, designating medical devices as either Class I, IIa, IIb or III depending on the intended purpose of the device and the potential risk associated with its use.

The extent of pre-market scrutiny applied to a medical device is commensurate with the risk classification of the kind of device.

The change in the classification of implantable medical devices that are total or partial hip, knee or shoulder joint replacements from Class IIb to Class III is intended to recognise the concerns that have arisen in the community in relation to the safety and performance of these kinds of medical devices, and to increase the level of pre-market scrutiny associated with applications for inclusion in the Register for such products.

Statement of Compatibility with Human Rights

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

Therapeutic Goods Amendment Regulation 2012 (No. 1)

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 Amendment Regulation 2012 (No. 1)* (the Amendment Regulation) is made under subsection 63(1) of the *Therapeutic Goods Act 1989* (the TG Act).

The purpose of the Amendment Regulation is to amend the *Therapeutic Goods Regulations 1990* to make a small number of changes including enabling the Complaints Resolution Panel to deal with a complaint about an advertisement or generic information for a therapeutic good if court proceedings are underway in relation to the subject matter of the complaint, and permitting sponsors granted an exemption from paying an annual charge for financial years 2009-10 or 2010-11 on the basis that the turnover of their goods was of low value, but who have not given the Secretary of the Department of Health and Ageing information about the actual turnover of their goods as required under the *Therapeutic Goods Regulations 1990*, to provide that information within a further specified period.

Human rights implications

This legislative instrument 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.

Catherine King

Parliamentary Secretary for Health and Ageing