EXPLANATORY STATEMENT

Select Legislative Instruments 2012 No. 144

Therapeutic Goods (Charges) Act 1989

Therapeutic Goods (Charges) Amendment Regulation 2012 (No. 1)

The *Therapeutic Goods (Charges) Act 1989* (the Act) imposes annual charges on the registration, listing and inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (the Register), and on the licensing of manufacturers of therapeutic goods. The Therapeutic Goods Administration (the TGA) is responsible for administering the Act.

Section 4 of the Act provides that annual charges of such amounts as are set out in regulations are payable in respect of entries of therapeutic goods in the Register, and of manufacturing licences that are in force at any time within a financial year.

Subsection 5(1) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing the amounts of charges. Subsection 5(2) of the Act enables the Governor-General to prescribe different levels of charges for different classes of goods or, in the case of annual licensing charges, for different steps in the manufacture of therapeutic goods.

The purpose of the regulation is to amend the *Therapeutic Goods (Charges) Regulations 1990* (the Principal Regulations) to make a small number of minor amendments, principally in order to ensure that manufacturers who manufacture only biologicals are not required to pay an annual charge arising from the fact they hold a manufacturing licence.

A 'biological' is defined in subsection 32A(1) of the *Therapeutic Goods Act 1989* as a thing that either comprises, contains or is derived from, human cells or tissues or that is specified by the Secretary of the Department of Health and Ageing as being a biological in a legislative instrument under subsection 32BA(2) of that Act. Examples of biologicals include human cardiovascular tissues such as heart valves and human musculoskeletal tissue such as muscles, ligaments and bones.

Measures setting out that such manufacturers are not required to pay an annual licence charge were inadvertently not included in amendments to the Principal Regulations in 2011 that commenced on 31 May 2011 (the *Therapeutic Goods (Charges) Amendment Regulations 2011 (No.1)*). The regulation therefore removes the existing obligation for affected manufacturers to pay an annual manufacturing licence charge.

This change is taken to have commenced from 31 May 2011, in order to ensure that affected manufacturers will not be regarded as having been liable to pay such a charge for financial year 2010-11 (or for subsequent financial years).

As this measure entails a benefit by removing the existing obligation on affected manufacturers to pay annual licence charges, it is not considered that there will be any disadvantage or liability for any person as a result of this retrospectivity.

Details of the regulation are set out in the Attachment.

The removal of the requirement for manufacturers of only biologicals to pay an annual licence charge was not the subject of separate industry consultation. However, this measure reflects the overall policy relating to the establishment and implementation of the regulatory framework for biologicals that was introduced in May 2011. This policy was set out in the Cost Recovery Impact Statement for the Regulation of Biologicals (Human Cell and Tissue Therapy Products), which was released for consultation between October and November 2010.

The Act specifies no 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 is taken to have commenced on 31 May 2011. The retrospective nature of the amendments do not disadvantage any person or impose a liability on any person other than the Commonwealth, therefore subsection 12(2) of the *Legislative Instruments Act 2003* does not prevent the retrospective amendments from taking effect.

Authority: Subsection 5(1) of the *Therapeutic Goods (Charges) Act 1989*

ATTACHMENT

Details of the *Therapeutic Goods (Charges) Amendment Regulation 2012 (No. 1)*

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

Section 2 - Commencement
This section provides for the regulation to be taken to have commenced on 31 May 2011.

Section 3 – Amendment of *Therapeutic Goods (Charges) Regulations 1990*
This section provides for Schedule 1 to amend the *Therapeutic Goods (Charges) Regulations 1990* (the Principal Regulations).

Schedule 1 - Amendments

Item [1] – Paragraph 3(2)(l)

Item [1] makes a minor formatting change to paragraph 3(2)(l) of the Principal Regulations in order to accommodate item [2].

Item [2] – After paragraph 3(2)(l)

Item [2] inserts a new paragraph 3(2)(m) in the Principal Regulations, which specifies that, despite paragraphs 3(2)(a) to (l) of the Principal Regulations, the annual charge for a licence for the manufacture of a biological only is nil.

The intended effect of new paragraph 3(2)(m) is that where the only products manufactured by a licence holder, or in relation to which a licence holder engages in a step in manufacture, are biologicals (and not other therapeutic goods), the applicable annual licence charge will be nil.

Amendments were made to the *Therapeutic Goods Act 1989* by the *Therapeutic Goods Amendment (2009 Measures No.3) Act 2010* to establish a new regulatory framework for biologicals. These amendments commenced on 31 May 2011.

Amendments, commencing on the same day, were also made to the Principal Regulations, the *Therapeutic Goods Regulations 1990* and the *Therapeutic Goods (Medical Devices) Regulations 2002* to implement many of the details of the new framework.

However, this measure was inadvertently not included in the abovementioned amendments to the Principal Regulations that commenced on 31 May 2011 and, as such, annual licence charges have remained in place in relation to relevant manufacturers of biologicals.

Item [2] therefore addresses that inadvertent omission.

Item [3] – Subregulation 3(3)

Subregulation 3(3) of the Principal Regulations currently sets out that if, but for that subregulation, more than one of the annual charges listed in subregulation 3(2) will otherwise apply to a manufacturing licence holder for a financial year in relation to the registration or listing of particular therapeutic goods or for a particular manufacturing licence, the licence holder need only pay the greatest such charge.

Subregulation 3(3) is in place because paragraphs 3(2)(a) to (l) of the Principal Regulations list a number of annual charges relating the manufacture of different kinds of products, and a manufacturer who manufactures across those categories will otherwise be liable to pay a number of annual charges in relation to the same manufacturing licence.

As explained above, item [2] makes it clear that where a licence holder only manufactures biologicals, the applicable annual licence charge is nil.

A licence holder who manufactures, or who engages in a step in the manufacture of, both biologicals and other therapeutic goods could not rely on new paragraph 3(2)(m), because in such circumstances they could not be said to be manufacturing *only* biologicals.

As such, a situation could occur where:

- a licence holder:
    - manufactures biologicals and other therapeutic goods under a manufacturing licence; and
    - manufactures in such a manner that they will, but for subregulation 3(3), be required to pay more than one of the annual charges set out in paragraphs 3(2)(a) to (l) in relation to that licence; and
- in relation to the greatest such charge, the licence holder only manufactures, or only engages in a step in the manufacture of, biologicals.

For example, if a manufacturer:

- produces sterile goods that are all biologicals, which would result in an annual charge of $10,300 under paragraph 3(2)(a); and
- produces ingredients, being ingredients that are not biologicals, which would result in an annual charge of $5,300 under paragraph 3(2)(c).

In such a situation, the manufacturer could not, as explained above, rely on new paragraph 3(2)(m) because they would not be producing solely biologicals.

Further, in this situation the manufacturer would, through the operation of subregulation 3(3), be required to pay the *higher* annual charge of $10,300 notwithstanding that the only goods produced by the manufacturer in relation to that charge were biologicals.

As it is not intended that a manufacturer should pay a higher charge in relation to a licence by reason of manufacturing biologicals, an amendment is made to subregulation 3(3) to ensure this cannot happen.

Item [3] is intended to address this possibility by amending subregulation 3(3) of the Principal Regulations to provide that, when determining under that provision which of a number of annual licence charges is the greater, a charge payable only because biologicals are manufactured is not to be considered.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Charges) 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 (Charges) Amendment Regulation 2012 (No. 1)* (the Amendment Regulations) is made under subsection 5(1) of the *Therapeutic Goods (Charges) Act 1989* (the Charges Act).

The purpose of the Amendment Regulation is to amend the *Therapeutic Goods (Charges) Regulations 1990* to, principally, specify that manufacturers who manufacture solely biologicals are not required to pay an annual charge for their manufacturing licence. This measure was inadvertently not included in amending regulations which implemented many of the details of the new regulatory framework for biologicals which came into effect on 31 May 2011.

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.

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