EXPLANATORY STATEMENT

Select Legislative Instrument 2012 No. 145

Therapeutic Goods (Charges) Act 1989

Therapeutic Goods (Charges) Amendment Regulation 2012 (No. 2)

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), which is part of the Department of Health and Ageing, is responsible for administering the Act.

Section 4 of the Act provides that annual charges of such amounts as are prescribed are payable in respect of entries of therapeutic goods (including medical devices) in the Register, as well as in respect of licences that are in force at any time within a financial year. Under subsection 4(1A) of the Act, where one or more therapeutic goods are "grouped" and each of the "grouped" therapeutic goods is covered by a single registration or listing number, then a single annual charge as prescribed will apply for maintaining all the registered or listed goods covered under the same group.

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 increase all annual charges relating to the registration, listing or inclusion of therapeutic goods on the Register, and all annual charges relating to manufacturing licences, by 5.6 per cent.

The 5.6 per cent increase reflects both a 3.6 per cent increase of TGA fees and charges based on a formula agreed with industry associations (comprised of 50 per cent of the Labour Price Index to September 2011 and 50 per cent of the Consumer Price Index to September 2011), and an additional increase of two per cent. The additional two per cent increase reflects the need to fund the implementation of a number of recommendations arising from several recent reviews into key areas of the regulation of therapeutic goods, and to improve TGA's capacity to conduct post market surveillance of therapeutic goods.

These reviews and recommendations are outlined in the TGA document *TGA reforms: A Blueprint for TGA's future*, dated December 2011 and include measures relating to the improvement of regulatory transparency (such as the development of consultation principles, and the release of a wider range of information relating to the regulation of therapeutic goods), complementary medicines (including updating guidelines relating to the levels and kinds of evidence supporting therapeutic claims made about those products that should be held by sponsors), medical devices (including the reclassification of certain kinds of joint replacement devices) and advertising of therapeutic products.

In applying these increases, the following rounding policy has been applied:

a) for amounts that are less than $140, up to the nearest $10;
b) for amounts between $141 and $10,000, to the nearest $10; and
c) for amounts over $10,000, to the nearest $100.

The amendments to the Principal Regulations, when taken together with related amendments to the *Therapeutic Goods Regulations 1990* and the *Therapeutic Goods (Medical Devices) Regulations 2002*, are expected to increase the fees and charges collected by the TGA by $2.6 million (to $120.50 million) over the 2012-13 financial year.

The increase in charges enable the TGA to recover its costs in administering the *Therapeutic Goods Act 1989* and continue to meet the Government's Cost Recovery Guidelines, and support the implementation of the reforms process and improvements mentioned above.

Consultations with industry associations, including in relation to the proposal to increase TGA fees and charges by 5.6 per cent, were held at sectoral bilateral meetings convened between 21 and 24 February 2012. Industry was not supportive of an increase of 5.6 per cent, as it exceeded the 3.6 percent increase that would be made based solely on the indexation model relating to annual increases of TGA fees and charges agreed between industry and the TGA.

Details of the regulation are set out in the Attachment.

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 commences on 1 July 2012.

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

ATTACHMENT

Details of the *Therapeutic Goods (Charges) Amendment Regulation 2012 (No. 2)*

Section 1 – Name of regulation
This section provides for the regulation to be referred to as the *Therapeutic Goods (Charges) Amendment Regulation 2012 (No. 2).*

Section 2 – Commencement
This section provides for the regulation to commence on 1 July 2012.

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] – Subregulation 3(3), note

The note to subregulation 3(3) of the Principal Regulations refers to the fact that under regulation 43AAJ of the *Therapeutic Goods Regulations 1990* (the TG Regulations), the annual charge for a manufacturing licence under Part 3-3 of the *Therapeutic Goods Act 1989* (other than a licence for the manufacture of human blood and blood components) payable by a person whose wholesale turnover of therapeutic goods in a financial year is not more than $81 300, is half the amount mentioned in subregulation 3(2) for that person. Subregulation 3(2) of the Principal Regulations lists annual charges for manufacturing licences.

Item [1] replaces the reference in the note to the amount of $81 300 with a reference to the amount of $85 900.

This ensures consistency with changes to the TG Regulations, which include an amendment to regulation 43AAJ of the TG Regulations to increase that turnover threshold from $81 300 to $85 900.

Item [2] – Further amendments

This item increases all annual charges for therapeutic goods and manufacturing licences set out in the Principal Regulations by 5.6 per cent, subject to the TGA's rounding policy.

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. 2)

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. 2)* (the Amendment Regulation) is made under subsection 5(1) of the *Therapeutic Goods (Charges) Act 1989*.

The purpose of the Amendment Regulation is to amend the *Therapeutic Goods (Charges) Regulations 1990* to increase all annual charges relating to the registration, listing or inclusion of therapeutic goods on the Australian Register of Therapeutic Goods, and all annual charges relating to manufacturing licences, by 5.6 per cent, subject to the Therapeutic Goods Administration's rounding policy.

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

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