EXPLANATORY STATEMENT

Therapeutic Goods (Charges) Act 1989

Therapeutic Goods (Charges) Amendment (2016 Measures No. 1) Regulation 2016

The *Therapeutic Goods (Charges) Act 1989* (the Charges 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 (TGA), which is part of the Department of Health, is responsible for administering the Charges Act.

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

Subsection 5(1) of the Charges Act provides that the Governor-General may make regulations, not inconsistent with the Charges Act, prescribing the amounts of charges. Under subsection 5(2) of the Charges Act, the Governor-General may 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 *Therapeutic Goods (Charges) Amendment (2016 Measures No. 1) Regulation* 2016 (the Regulation) is to amend the Therapeutic Goods (Charges) Regulations 1990 (the Charges Regulations) to increase annual charges by 2.25 per cent for the financial year 2016-17.

The increase applies to annual charges relating to the registration, listing or inclusion of therapeutic goods in the Register - this encompasses registered goods, listed goods, biologicals and medical devices – and to annual charges for manufacturing licences.

The 2.25 per cent figure for the increase is based on an indexation formula used to calculate adjustments to TGA fees and charges in most previous years, and is based on the Australian Bureau of Statistics' Wage Price Index (50 per cent) (in this case, for the year to September 2015) and Consumer Price Index (50 per cent)) (also for the year to September 2015).

This increase ensures that the TGA is able to continue to recover its costs of administering the *Therapeutic Goods Act 1989*.

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

- for charge items that are less than $10,000 - to the nearest $5; and
- for charge items that are greater than or equal to $10,000 - to the nearest $100.

Details of the Regulation are set out in the Attachment.

The Charges Act does not specify conditions that need to be met before the power under that Act to make the Regulation may be exercised.

The Regulation is a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulation commences on 1 July 2016.

Consultation

Consultation on the proposal to increase TGA fees and charges by 2.25 per cent was undertaken at bilateral meetings with industry representative groups in February and March 2016. The representative groups – who included Medicines Australia, the Generic and Biosimilar Medicines Association (GBMA), AusBiotech, the Medical Technology Association of Australia (MTAA), IVD Australia, the Australian Dental Industry Association (ADIA), the Australian Self-Medical Industry (ASMI), Complementary Medicines Australia and Accord Australasia – did not object to the proposal.

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

ATTACHMENT

Details of the *Therapeutic Goods (Charges) Amendment (2016 Measures No. 1) Regulation 2016*

Section 1 – Name of Regulation
This section provides that the title of the Regulation is the *Therapeutic Goods (Charges) Amendment (2016 Measures No. 1) Regulation 2016.*

Section 2 – Commencement
This section provides for the Regulation to commence on 1 July 2016.

Section 3 – Authority
This section provides that the Regulation is made under the *Therapeutic Goods (Charges) Act 1989*.

Section 4 – Schedule
This section provides that each instrument that is specified in a Schedule to the Regulation is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Regulation has effect according to its terms.

Schedule 1 – Annual charges for 2016-17

Item 1 - Table of amendments to the Therapeutic Goods (Charges) Regulations 1990
Item 1 sets out a table of amendments to provisions of the *Therapeutic Goods (Charges) Regulations 1990* (the Charges Regulations).

The effect of these amendments is to increase all annual charges for therapeutic goods and manufacturing licences by 2.25 per cent, subject to the TGA's rounding policy, from 1 July 2016.

Item 26 of the table makes an amendment to the note to subregulation 3(3) of the Charges Regulations.

This note 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 to manufacture human blood and blood components) that is payable by a person whose wholesale turnover of goods in a financial year is not more than $92 400, is half the amount mentioned in subregulation 3(2) of the Charges Regulations. Subregulation 3(2) of the Charges Regulations lists annual charges for manufacturing licences.

Item 26 of the table replaces the current reference in this note to the amount of $92 400 with a reference to the updated amount of $94 500, for 2016-17. This ensures consistency with changes to the TG Regulations that also commence on 1 July 2016, which include an amendment to regulation 43AAJ of the TG Regulations to increase the wholesale turnover threshold mentioned above, from $92 400 to $94 500.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Charges) Amendment (2016 Measures No.1) Regulation 2016

The *Therapeutic Goods (Charges) Amendment (2016 Measures No.1) Regulation 2016* (the Amendment Regulation) 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 Amendment Regulation is made under subsection 5(1) of the *Therapeutic Goods (Charges) Act 1989* (the Charges Act). It amends the *Therapeutic Goods (Charges) Regulations 1990* (the Charges Regulations) to increase annual charges for therapeutic goods and manufacturing licences by 2.25 per cent for the 2016-17 financial year (i.e. from 1 July 2016). This increase ensures that the TGA is able to continue to recover its costs of administering the *Therapeutic Goods Act 1989*.

The increase applies to annual charges relating to the registration, listing or inclusion of therapeutic goods in the Australian Register of Therapeutic Goods - this encompasses registered goods, listed goods, biologicals and medical devices – and to annual charges for manufacturing licences.

The 2.25 per cent figure is based on an indexation formula used to calculate TGA fees and charges increases in most previous years, and is based on the Australian Bureau of Statistics' Wage Price Index (50 per cent) and Consumer Price Index (50 per cent)) – in both cases, for the year to September 2015.

Human rights implications

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

Sussan Ley, Minister for Health