EXPLANATORY STATEMENT

Select Legislative Instrument No. 61, 2014

Therapeutic Goods (Charges) Act 1989

Therapeutic Goods (Charges) Amendment (2014 Measures No. 1) Regulation 2014

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 (therapeutic goods are, principally, goods that are, or are presented to be for a therapeutic use such as diagnosing, curing or alleviating a disease or ailment (e.g. a medicine or medical device)). The Therapeutic Goods Administration (the 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 entries of therapeutic goods in the Register, as well as in respect of licences to manufacture, or to undertake a step in the manufacture, of therapeutic goods, 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 or listing number, a single annual charge as is prescribed will apply for maintaining all the registered or listed 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 Regulation is to amend the *Therapeutic Goods (Charges) Regulations 1990* (the Charges Regulations) to increase annual charges by 2.4 per cent.

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 annual charges relating to manufacturing licences.

The 2.4 per cent increase is comprised of 50 per cent of the Australian Bureau of Statistics' (ABS) Wage Price Index (WPI) for the 12 month period to September 2013, and 50 per cent of the Consumer Price Index (CPI) for the same period. This reflects a formula previously agreed with industry for the calculation of increases to TGA fees and charges, with the substitution, however, of the WPI for the previously used Labour Price Index (LPI), following the discontinuation by the ABS of the LPI.

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

(a) for current fee items that are less than $10,000, to the nearest $5;

(b) for current fee items that are greater than or equal to $10,000, to the nearest $100.

The amendments to the Charges 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 $3.0 million (to $135.7 million) over the 2014-15 financial year.

The increase in fees and charges enables the TGA to continue to recover its costs in administering the *Therapeutic Goods Act 1989* and the Charges Act.

Details of the Regulation are set out in the Attachment.

The Charges Act specifies no conditions that would 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 2014.

Consultations in relation to the proposal to increase TGA fees and charges by 2.4 per cent for the financial year 2014-15 were held with industry associations at sectoral bilateral meetings convened between 12 February 2014 and 4 March 2014. The industry associations present were Accord Australasia Ltd (Accord), the Generic Medicines Industry Association of Australia, the Australian Self Medication Industry Inc., the Australian Dental Industry Association, Ausbiotech, IVD Australia, the Medical Technology Association of Australia, Medicines Australia and the Complementary Healthcare Council of Australia.

Predominantly, the industry associations did not oppose the increase. Accord indicated that it was unable to support the increase because of its general objection to cost recovered government entities (such as the TGA) increasing fees and charges on an annual basis, and recommended that in the current budget economic climate, TGA fees and charges be maintained at current levels.

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

ATTACHMENT

Details of the *Therapeutic Goods (Charges) Amendment (2014 Measures No.1) Regulation 2014*

Section 1 – Name of regulation
This section provides for the regulation to be referred to as the *Therapeutic Goods (Charges) Amendment (2014 Measures No.1) Regulation 2014*.

Section 2 – Commencement
This section provides for the regulation to commence on 1 July 2014.

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

Section 4 – Schedule
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 (Charges) Regulations 1990

Item 1 – Amendment of listed provisions

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 (with the exception of the amendment in item 28 in the table) is to increase all annual charges for therapeutic goods and manufacturing licences set out in the Charges Regulations by 2.4 per cent, subject to the TGA's rounding policy.

Item 28 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 TG Act (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 $88 400, is half the amount mentioned in subregulation 3(2) of the Charges Regulations for the licence. Subregulation 3(2) of the Charges Regulations lists annual charges for manufacturing licences.

Item 28 of the table replaces the current reference in this note to the amount of $88 400 with a reference to the amount of $90 500. This ensures consistency with the changes to the TG Regulations, which include an amendment to regulation 43AAJ of the TG Regulations to increase the wholesale turnover threshold mentioned above, from $88 400 to $90 500.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Charges) Amendment (2014 Measures No.1) 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 (Charges) Amendment (2014 Measures No.1) Regulation 2014* (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* (the Charges Regulations) to increase annual charges relating to the regulation of therapeutic goods by 2.4 per cent, subject to the Therapeutic Goods Administration's rounding policy. This increase applies to annual charges relating to the registration, listing or inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (including medicines, therapeutic devices, biologicals and medical devices), and annual charges relating to manufacturing licences. These amendments, when taken together with related amendments to the *Therapeutic Goods Regulations 1990* and the *Therapeutic Goods (Medical Devices) Regulations 2002*, will enable the TGA to continue to recover its costs of administering the *Therapeutic Goods Act 1989*.

Human rights implications

As the Amendment Regulation does not introduce changes to the Charges Regulations other than in relation to implementing a 2.4 per cent increase of annual charges for therapeutic goods and licences to manufacture therapeutic goods, 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.

Fiona Nash

Assistant Minister for Health