EXPLANATORY STATEMENT

**Select Legislative Instrument 2013 No. 94**

*Therapeutic Goods (Charges) Act 1989*

*Therapeutic Goods Act 1989*

*Therapeutic Goods Legislation Amendment (Fees and Charges) Regulation 2013*

The object of the *Therapeutic Goods Act 1989* (the TG Act) is to establish and maintain a national system of controls for the quality, safety, efficacy 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 TG Act.

Subsection 63(1) of the TG Act provides that the Governor-General may make regulations, not inconsistent with the TG Act, prescribing matters required or permitted to be prescribed by the TG Act or necessary or convenient to be prescribed for carrying out or giving effect to the TG Act.

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 TGA is also 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 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 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 each of the *Therapeutic Goods (Charges) Regulations 1990* (the Charges Regulations), the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to increase the fees and charges set out in those respective regulations by

2.9 per cent (the Charges Regulations are made under the Charges Act, and each of the TG Regulations and the MD Regulations are made under the TG Act).

The fee increases relating to the TG Regulations apply to application fees for registration or listing in the Register, application fees for manufacturing licences, evaluation fees, clinical trial notification fees, application fees for export certificates and inspection fees for manufacturing premises.

The fee increases relating to the MD Regulations apply to fees relating to conformity assessments and abridged conformity assessments of medical devices, applications for the inclusion of medical devices in the Register and applications for conformity assessment certificates for medical devices.

The increases relating to the Charges Regulations apply 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 2.9 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 2012, 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 fees and charges for therapeutic goods, with the substitution, however, of the WPI for the previously used Labour Price Index (LPI), as the ABS has discontinued its LPI.

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

1. for amounts that are $180 or less, up to the nearest $10;
2. for amounts between $181 and $10 000, to the nearest $10; and
3. for amounts over $10 000, to the nearest $100.

The amendments to the TG Regulations, the MD Regulations and the Charges Regulations, taken together, are expected to increase the fees and charges collected by the TGA by $3.9 million (to $132.2 million) over the 2013-14 financial year.

The increase in fees and charges enable the TGA to recover its costs in administering the TG Act and the Charges Act, and to continue to meet the Government’s Cost Recovery Guidelines.

Details of the regulation are set out in the Attachment.

Neither the TG Act nor the Charges Act specify conditions that need to be met before the respective powers under those Acts 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 2013.

Consultations in relation to the proposal to increase TGA fees and charges by 2.9 per cent for financial year 2013-14 were held with industry associations at sectoral bilateral meetings convened between 19 and 21 February 2013. The industry associations present were Accord, the Generic Medicines Industry Association, the Australian Self Medication Industry, the Australian Dental Industry Association, Ausbiotech, IVD Australia, the Medical Technology Association of Australia, Medicines Australia and the Complementary Healthcare Council of Australia. The industry associations did not oppose the increase.

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

Subsection 5(1) of the

*Therapeutic Goods (Charges) Act 1989*

**ATTACHMENT**

**Details of the *Therapeutic Goods Legislation Amendment (Fees and Charges) Regulation 2013***

Section 1 – Name of regulation

This section provides for the regulation to be referred to as the *Therapeutic Goods Legislation Amendment (Fees and Charges) Regulation 2013.*

Section 2 – Commencement

This section provides for the regulation to commence on 1 July 2013.

Section 3 – Authority

This section provides that the regulation is made under the *Therapeutic Goods (Charges) Act 1989* and the *Therapeutic Goods Act 1989* (the TG Act).

# Section 4 – Schedule

# Each instrument that is specified in a schedule to this instrument is amended or repeals 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) Regulation 1990***

**Item 1 – Amendment of listed provisions—charges**

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 29 in the table) is to increase all annual charges for therapeutic goods and manufacturing licences set out in the Charges Regulations by 2.9 per cent, subject to the TGA’s rounding policy.

Item 29 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 $85 900, 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 29 of the table replaces the current reference in this note to the amount of $85 900 with a reference to the amount of $88 400.

This ensures consistency with the changes to the TG Regulations in item 3, which includes an amendment to regulation 43AAJ of the TG Regulations to increase the wholesale turnover threshold mentioned above, from $85 900 to $88 400.

***Therapeutic Goods (Medical Devices) Regulations 2002***

**Item 2 – Amendments of listed provisions—fees**

Item 2 sets out a table of amendments to provisions of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations).

The effect of these amendments is to increase the fee for an abridged conformity assessment in paragraph 9.4(2)(b) of the MD Regulations, and the fees for all relevant items in Schedule 5 to the MD Regulations, by 2.9 per cent, subject to the TGA’s rounding policy.

***Therapeutic Goods Regulations 1990***

**Item 3 – Amendments of listed provisions—charges and fees**

Item 3 sets out a table of amendments to provisions of the TG Regulations.

The effect of these amendments (with the exception of the amendment in item 9 of the table) is to increase various fees specified in paragraph 43AAJ(1)(b) and subregulations 45(4A), 45(9) and 45(11) of the TG Regulations, and in Part 2 of Schedule 9 and Part 2 of Schedule 9A to the TG Regulations, by 2.9 per cent, subject to the TGA’s rounding policy.

Item 9 of the table makes an amendment to regulation 45A of the TG Regulations.

Regulation 45A currently limits the total amount payable by a person for applications under regulation 43AAC for exemptions from liability to pay an annual registration, listing or inclusion charge on the basis that the turnover of the person’s goods was of low value, to $14 000. If the cost to a person of such applications in a financial year exceeds $14 000, the person is not required to pay any further amounts above that level for such applications in the financial year.

This threshold amount is based on the value of 100 units of the relevant application fee, being the fee at item 3AB of Schedule 9 to the TG Regulations.

This fee is currently $140, but is increased to $150 as part of these amendments (item 48 of the table refers).

As this fee of $140 is increased to $150 as part of these amendments, item 9 of the table therefore amends regulation 45A to increase the threshold amount in that provision from the current $14 000 to $15 000, to reflect the related fee increase of item 3AB of Schedule 9.

**Statement of Compatibility with Human Rights**

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

**Therapeutic Goods Legislation Amendment (Fees and Charges) Regulation 2013**

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 Legislation Amendment (Fees and Charges) Regulation 2013* (the Amendment Regulation) is made under subsection 63(1) of the *Therapeutic Goods Act 1989* and subsection 5(1) of the *Therapeutic Goods (Charges) Act 1989*.

The purpose of the Amendment Regulation is to amend each of the *Therapeutic Goods Regulations 1990*, the *Therapeutic Goods (Medical Devices) Regulations 2002* and the *Therapeutic Goods (Charges) Regulations 1990* to increase fees and charges relating to the regulation of therapeutic goods, by 2.9 per cent (subject to the Therapeutic Goods Administration’s rounding policy). The increase in fees applies to application fees for registration, listing or inclusion in the Australian Register of Therapeutic Goods (the Register), application fees for manufacturing licences, evaluation fees, clinical trial notification fees, application fees for export certificates and inspection fees for manufacturing premises. The increase in charges applies to annual charges relating to the registration, listing or inclusion of therapeutic goods in the Register, and annual charges relating to manufacturing licences.

**Human rights implications**

As the Amendment Regulation does not introduce any changes to the regulations mentioned above other than to effect a 2.9 per cent increase of a range of existing fees and charges relating to 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.

**Shayne Neumann**

**Parliamentary Secretary for Health and Ageing**