EXPLANATORY STATEMENT

**Select Legislative Instrument No. 62, 2014**

*Therapeutic Goods Act 1989*

*Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulation 2014*

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/performance 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, is responsible for administering the TG Act.

Subsection 63(1) of the TG Acovides 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 purpose of the Regulation is to amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to increase the fees set out in those respective regulations by 2.4 per cent.

The fee increases apply, for example, to application fees for the registration, listing or inclusion of therapeutic goods (including medicines, therapeutic devices, biologicals and medical devices) in the Australian Register of Therapeutic Goods (the Register), application fees for licences to manufacture, or to undertake a step in the manufacture of, therapeutic goods, fees relating to the evaluation of therapeutic goods for marketing approval, clinical trial notification fees, application fees for export certificates and inspection fees for manufacturing premises.

The increases also apply to fees relating to conformity assessments and abridged conformity assessments of medical devices (these are assessments of the quality of a medical device manufacturer’s manufacturing process, and of the product design of a medical device), application fees for the inclusion of medical devices in the Register and application fees for conformity assessment certificates for medical devices.

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:

1. for current fee items that are less than $10,000, to the nearest $5; and
2. for current fee items that are greater than or equal to $10,000, to the nearest $100.

The amendments to the TG Regulations and the MD Regulations, when taken together with amendments to the *Therapeutic Goods (Charges) Regulations 1990* (these are contained in the separate Therapeutic Goods (Charges) Amendment (2014 Measures No.1) Regulation 2014), 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 TG Act and the *Therapeutic Goods (Charges) Act 1989*.

Details of the Regulation are set out in the Attachment.

The TG Act does not specify 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 63(1) of the *Therapeutic Goods Act 1989*

**ATTACHMENT**

**Details of the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulation 2014***

Section 1 – Name of regulation

This section provides for the Regulation to be referred to as the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) 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 Act 1989* (the TG Act).

# 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 (Medical Devices) Regulations 2002***

**Item 1 – Amendments of listed provisions**

Item 1 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 2.4 per cent, subject to the TGA’s rounding policy.

***Therapeutic Goods Regulations 1990***

**Item 2 – Amendments of listed provisions**

Item 2 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 2.4 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 $15 000. This 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 $150, but is increased to $155 as part of these amendments (item 48 of the table refers). Item 9 of the table therefore makes a corresponding amendment to regulation 45A to increase the maximum amount in that provision from the current $15 000 to $15 500, 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 Other Measures) 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 Legislation Amendment (Fees and Other Measures) Regulation 2014* (the Amendment Regulation) is made under subsection 63(1) of the *Therapeutic Goods Act 1989*.

The purpose of the Amendment Regulation is to amend the *Therapeutic Goods Regulations 1990* andthe *Therapeutic Goods (Medical Devices) Regulations 2002* to increase fees relating to the regulation of therapeutic goods by 2.4 per cent, subject to the Therapeutic Goods Administration’s rounding policy. The increase in fees applies, for example, to application fees for the registration, listing or inclusion of therapeutic goods (including medicines, therapeutic devices, biologicals and medical devices) in the Australian Register of Therapeutic Goods, application fees for manufacturing licences, evaluation fees, clinical trial notification fees, application fees for export certificates and inspection fees relating to manufacturing premises. These amendments, when taken together with related amendments to the *Therapeutic Goods (Charges) Regulations 1990*, 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 regulations mentioned above, other than in relation to implementing a 2.4 per cent increase to a range of existing fees relating to 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**