EXPLANATORY STATEMENT

*Therapeutic Goods (Charges) Act 1989*

*Therapeutic Goods (Charges) Amendment Regulations 2019*

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 (the Department), is responsible for administering the Act.

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 provides in part that the regulations may prescribe different charges in relation to different classes of goods (including medical devices) or, in the case of annual licensing charges, for different steps in the manufacture of therapeutic goods.

Section 4 of the 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 and conformity assessment body determinations, that are in force at any time within a financial year. In addition, 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, a single annual charge as is prescribed will apply for maintaining all the registered or listed goods covered under the same group.

The purpose of the *Therapeutic Goods (Charges) Amendment Regulations 2019* (the Regulations) is to amend the *Therapeutic Goods (Charges) Regulations 2018* to increase the annual charges set out in those regulations by 2.05 per cent, for the financial year 2019-20.

The increase applies to annual charges relating to the registration, listing or inclusion of therapeutic goods in the Register. This encompasses registered goods (including provisionally registered medicines), listed goods, biologicals and medical devices.

The 2.05 per cent 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’ Wages Price Index (50 per cent) (in this case, for the year to September 2018) and Consumer Price Index (50 per cent) (also for the same period).

This increase is in line with the TGA’s cost recovery model. In applying this increase, the following rounding policy has been applied:

* for fee items that are less than $10,000 – to the nearest $10; and
* for fee items that are greater than or equal to $10,000 – to the nearest $100.

Details of the Regulations are set out in the Attachment.

The Act specifies no conditions that need to be satisfied before the power to make the Regulations may be exercised.

The Regulations are a legislative instrument for the purposes of the *Legislation* *Act 2003*.

The Regulations commence on 1 July 2019.

**Consultation**

The TGA held bilateral meetings with 13 key industry representative bodies in December 2018 to discuss proposals to update TGA fees and charges for 2019-20, including for example with Medicines Australia, the Generic and Biosimilar Medicines Association, AusBiotech, the Medical Technology Association of Australia, the Australian Self Medication Industry (ASMI) and Accord Australasia. The bodies noted the proposed 2.05 per cent increase was consistent with past practice and were broadly supportive. The TGA also undertook public consultation to obtain broader stakeholder feedback, with a consultation paper released on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) and submissions sought from 21 December 2018 to 8 February 2019.

13 submissions on the proposed increase were received, of which 7 supported the proposed increase. 6 were in favour of no increase, particularly in light of the inclusion in that proposed increase of application fees for Class I medical devices (an application fee of $530 was introduced for most such devices for the first time on 1 July 2018 by the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2018*, and the proposed *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2019*, which complement the proposed Regulations, would increase this fee to $540). 2 submissions expressed concern that some lower annual charges – in particular, those under $200, would increase as a result of the proposed Regulations. However, due to the TGA’s rounding policy, such annual charges (e.g. the current annual charge of $90 for Class 1 medical devices other than those that are required to be supplied in a sterile state or that have a measuring function) will not change under the Regulations.

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

**ATTACHMENT**

**Details of the *Therapeutic Goods (Charges) Amendment Regulations 2019***

Section 1 – Name

This section provides for the Regulations to be referred to as the *Therapeutic Goods (Charges) Amendment Regulations 2019.*

Section 2 – Commencement

This section provides for the commencement of the Regulations on 1 July 2019.

Section 3 – Authority

This section provides that the Regulations are made under the *Therapeutic Goods (Charges) Act 1989* (the Act).

# Section 4 – Schedules

# This section provides that 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 the Regulations has effect according to its terms.

Schedule 1 – Amendments

***Therapeutic Goods (Charges) Regulations 2018***

**Items 1–32**

These items amend each of the amounts of annual charges prescribed in the *Therapeutic Goods (Charges) Regulations 2018* by 2.05 per cent, from 1 July 2019, 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 Regulations 2019***

The *Therapeutic Goods (Charges) Amendment Regulations 2019* (the Regulations) are 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 Regulations are made under subsection 5(1) of the *Therapeutic Goods (Charges) Act 1989* (the Act), and amend the *Therapeutic Goods (Charges) Regulations 2018* (the Charges Regulations) to increase the annual charges set out in the Charges Regulations by 2.05 per cent, for the financial year 2019-20.

The increase applies to annual charges relating to the registration, listing or inclusion of therapeutic goods in the Register. This encompasses registered goods (including provisionally registered medicines), listed goods, biologicals and medical devices.

The 2.05 per cent 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’ Wages Price Index (50 per cent) (in this case, for the year to September 2018) and Consumer Price Index (50 per cent) (also for the same period).

This increase is in line with the TGA’s cost recovery model. In applying this increase, the following rounding policy has been applied:

* for fee items that are less than $10,000 – to the nearest $10; and
* for fee items that are greater than or equal to $10,000 – to the nearest $100.

**Human rights implications**

As the Regulations do not introduce any changes to the Charges Regulations other than to implement the changes to implement the 2.05 per cent increase to annual charges outlined above, they do not engage any of the applicable rights or freedoms.

**Conclusion**

The Regulations are compatible with human rights as they do not raise any human rights issues.