

EXPLANATORY STATEMENT

Therapeutic Goods (Charges) Act 1989

Therapeutic Goods (Charges) Regulations 2018

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 (TGA), which is part of the Department of Health, 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, 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 *Therapeutic Goods (Charges) Regulations 1990* (the Charges Regulations) are due to sunset on 1 October 2018 pursuant to the *Legislation Act 2003*. The purpose of the *Therapeutic Goods (Charges) Regulations 2018* (the Regulations) is to repeal and replace the Charges Regulations before this date.

The Regulations incorporate measures to increase annual charges for most therapeutic goods and manufacturing licences by 1.9 per cent for the financial year 2018-19, from 1 July 2018. A small number of other changes are also included. These are to:

- increase the annual charge for listed complementary medicines by \$80, to reflect a greater allocation of post-market monitoring resources for these products;
- reduce annual licence charges for manufacturers of medicines and their active ingredients, following a recent review of the costs relating to the regulation of therapeutic goods manufacturers; and
- introduce annual charge amounts for provisionally registered medicines (these are a new category of promising new prescription medicines, introduced by the *Therapeutic Goods Amendment (2017 Measures No.1) Act 2018*).

The 1.9 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 2017) and Consumer Price Index (50 per cent) (for the same period).

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

- for charge items that are less than \$10,000 - to the nearest \$10 with a minimum increase of \$10; and
- for charge 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 principally commence on 1 July 2018 (sections 1 to 4 commence the day after it is registered on the Federal Register of Legislation, with the new charges commencing 1 July 2018).

Consultation

Preliminary consultation on possible changes to increase annual charges for 2018-19 was undertaken at bilateral meetings with industry representative bodies (Medicines Australia, the Generic and Biosimilar Medicines Association, AusBiotech, the Medical Technology Association of Australia, IVD Australia, the Australian Dental Industry Association (ADIA), the Australian Self-Medical Industry, Complementary Medicines Australia and Accord Australasia) in December 2017. Further consultation on the proposal to increase most charges by 1.9 per cent, increase the charge for listed complementary medicines by \$80 and introduce charges for provisionally registered prescription medicines, from 1 July 2018, was undertaken at bilateral meetings with the same bodies in February 2018. The bodies did not object to the proposals.

A consultation paper on proposed changes to annual charges (and fees) for manufacturing licences (*‘Review of GMP Fees & Charges’*) was released on the TGA’s website on 9 February 2018, and closed on 5 March 2018. A number of ‘roadshows’ were also held in February 2018 in Sydney, Melbourne and Brisbane, enabling industry body representatives, sponsors and manufacturers to provide direct feedback. Follow-up discussions were held with some industry bodies after 5 March 2018, and the proposed changes were discussed at the TGA Industry Working Group on Good Manufacturing Practice (TIWGG) meeting on 15 March 2018. No objections were raised in relation to the proposed changes to annual charges for manufacturing licences.

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

Details of the *Therapeutic Goods (Charges) Regulations 2018*

Section 1 – Name

This section provides that the title of the Regulations is the *Therapeutic Goods (Charges) Regulations 2018*.

Section 2 – Commencement

This section provides for sections 1 to 4 of the Regulations to commence the day after the Regulations are registered on the Federal Register of Legislation, and for sections 5 and 6, Part 2, and Schedule 1 of the Regulations to commence on 1 July 2018.

Section 3 – Authority

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

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the Regulations 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.

Section 5 – Definitions

This section outlines the definitions that apply to the Regulations – in particular, a number of terms referred to in the Regulations (e.g. ‘biological’, ‘current Poisons Standard’ and ‘grouped therapeutic goods’) have the same meaning as in the *Therapeutic Goods Act 1989*, and ‘biologic’ has the same meaning as in the *Therapeutic Goods (Charges) Regulations 1990* (principally, this term refers to a prescription medicine with an active ingredient of biological origin).

Section 6 – Classes of medical devices and biologicals

This section explains that a reference to a medical device of a particular class is a reference to a medical device classified as that class under Division 3.1 of the *Therapeutic Goods (Medical Devices) Regulations 2002*, and a reference to a biological of a particular class is a reference to a biological of that class within the meaning of the *Therapeutic Goods Regulations 1990*.

Part 2 – Charges

Section 7 – Annual charges for biologics and some other goods

This section sets out applicable annual charges for therapeutic goods that are registered and listed in the Australian Register of Therapeutic Goods (the Register) other than (principally) when such goods are grouped (subsection 7(1)), registered and listed grouped therapeutic goods (subsection 7(2)), biologicals (subsection 7(3)) and medical devices (subsection 7(4)) and licences (subsection 7(5)). The charges are generally payable when a product is entered in the Register, or when a manufacturing licence is in force, at any time during a financial year. In some circumstances where more than one charge applies, only the highest applicable charge applies.

Subregulation 7(5) outlines the charges for licences. Each licence will incur one charge regardless of the number of steps in the manufacture of the therapeutic goods to which the licence relates. The fee outlined in paragraph 7(5)(a) is payable, unless another paragraph applies.

Section 8 – Annual charges for goods that are no biologics

This section sets out applicable annual charges for prescription medicines that are not biologics – i.e. prescription medicines with an active ingredient that is not of biological origin (principally, these are chemically based prescription medicines). The amount payable depends on whether the conditions outlined in subsections 8(2) – (10) apply.

A higher annual charge (specified in paragraph 8(2)(a)) is payable in the circumstances outlined in subsections 8(3) – (10), which reflects the need for the TGA to commit greater resources to the post-market monitoring of these types of medicines (e.g. those containing thalidomide – paragraph 8(3)(a) refers). A lower annual charge (specified in paragraph 8(2)(b)) is payable if none of the circumstances in subsections 8(3) – (10) apply.

Section 9 – Annual charges for provisionally registered medicines

This section provides for the annual charges for provisionally registered medicines where the provisional registration of a medicine is in force at any time during the charge year. Subregulation 9(2) has the effect that if a provisionally registered medicine is registered later in the same charge year, the annual charges for the registration of the medicine do not apply.

Schedule 1 – Repeals

Therapeutic Goods (Charges) Regulations 1990

Item 1 – The whole of the instrument

Item 1 provides for the repeal of the *Therapeutic Goods (Charges) Regulations 1990* which would, otherwise, be subject to the sunset (i.e. automatic repeal) provisions of the *Legislation Act 2003* on 1 October 2018. The Regulations effectively replace the Charges Regulations.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Charges) Regulations 2018

The *Therapeutic Goods (Charges) Regulations 2018* (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 *Therapeutic Goods (Charges) Regulations 1990* (the Charges Regulations) is due to sunset on 1 October 2018 pursuant to the *Legislation Act 2003*. The purpose of the *Therapeutic Goods (Charges) Regulations 2018* (the Regulations) is to repeal and replace the Charges Regulations before this date and, in so doing, to also incorporate measures to increase annual charges for most therapeutic goods and manufacturing licences by 1.9 per cent for the financial year 2018-19, from 1 July 2018.

The 1.9 per cent figure is based on a 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 2017) and Consumer Price Index (50 per cent) (for the same period). This increase is designed to ensure that the TGA is able to continue to recover its costs of administering the *Therapeutic Goods Act 1989*.

The Regulations also:

- increase the annual charge for listed complementary medicines by \$80, to reflect a greater allocation of post-market monitoring resources for these products;
- reduce annual licence charges for manufacturers of medicines and their active ingredients, following a recent review of the costs relating to the regulation of therapeutic goods manufacturers; and
- introduce annual charge amounts for provisionally registered medicines (these are a new category of promising new prescription medicines, introduced by the *Therapeutic Goods Amendment (2017 Measures No.1) Act 2018*).

Human rights implications

As the Regulations do not introduce any changes compared to the Charges Regulations other than to implement the changes outlined 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.

Greg Hunt, Minister for Health