

EXPLANATORY STATEMENT

Therapeutic Goods (Charges) Act 1989

Therapeutic Goods (Charges) Amendment (2020 Measures No.1) Regulations 2020

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 main purpose of the *Therapeutic Goods (Charges) Amendment (2020 Measures No.1) Regulations 2020* (the Regulations) is to amend the *Therapeutic Goods (Charges) Regulations 2018* (the Charges Regulations) to increase the annual charges set out in those regulations for most products by 1.95 per cent, for the financial year 2020-21.

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.

However, the increase does not apply to annual charges for the inclusion of Class IIa, IIb, III or AIMD medical devices that are listed prostheses as defined in the *Private Health Insurance (Prostheses) Rules (No.1) 2020*, made by the Minister under item 4 of the table in section 333-20 of the *Private Health Insurance Act 2007* (examples of such products include implantable defibrillators, cardiac pacemakers and Cochlear implants). The Regulations reduce the annual charges for these higher risk devices for 2020-21 by 50 per cent of the amount that would otherwise have applied to them under the proposed 1.95 per cent increase, to alleviate the impact of reductions in elective surgeries as a result of the impact of the public health emergency caused by the disease known as coronavirus (COVID-19).

The 1.95 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 2019) 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.

The Regulations also amend the Charges Regulations to remove a small number of inadvertent errors and an annual charge for a licence to manufacture therapeutic devices. 'Therapeutic device' has been a superseded product category for quite some time, following the introduction of a specific regulatory regime for such products as medical devices by the *Therapeutic Goods Amendment (Medical Devices) Act 2002* and the conclusion in 2007 of that Act's transitional arrangements.

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 2020.

Consultation

In relation to consultation, the TGA held bilateral meetings with 13 key industry representative bodies in December 2019 to consult on the proposed revision of TGA fees and charges for 2020-21. The industry bodies included Medicines Australia (MA), the Generic and Biosimilar Medicines Association (GBMA), AusBiotech, the Medical Technology Association of Australia (MTAA), Consumer Healthcare Products Australia (CHPA), Complementary Medicines Australia (CMA) and Accord Australasia. A majority of the bodies indicated their support for the proposed 1.95 per cent increase. The TGA also undertook public consultation to obtain broader stakeholder feedback, with a consultation paper released on the TGA website (www.tga.gov.au) and submissions sought from 20 January 2020 to 28 February 2020. 8 submissions on the proposed increase were received (6 from industry representative bodies and 2 from sponsors), of which 4 indicated support for the proposed increase. CMA, and 2 industry representative bodies in the medical devices sector (Assistive Technology Suppliers Australia and Pathology Technology Australia), did not support the increase, in light (respectively) of the likely impact of COVID-19 on business and the economy, and increasing costs of doing business in the device sector. The Australasian Leukaemia and Lymphoma Group, a not for profit organisation that sponsors clinical trials, did not support the increase and requested that fee increases not apply to not for profit organisations.

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

Details of the *Therapeutic Goods (Charges) Amendment (2020 Measures No.1) Regulations 2020*

Section 1 – Name

This section provides for the Regulations to be referred to as the *Therapeutic Goods (Charges) Amendment (2020 Measures No.1) Regulations 2020*.

Section 2 – Commencement

This section provides for the commencement of the Regulations on 1 July 2020.

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, 3-5, 7-8, 10-12, 14-20, 22 and 24-33

These items amend each of the amounts of annual charges prescribed in the *Therapeutic Goods (Charges) Regulations 2018* (the Charges Regulations) by 1.95 per cent, from 1 July 2020, subject to the TGA's rounding policy, other than those charges that would be reduced by item 21 below.

Items 2, 6, 9 and 13

These items remove a small number of errors from the Charges Regulations, in relation to annual charges which are referred to as charges relating to the registration or listing of medical devices.

Medical devices are included in the Australian Register of Therapeutic Goods (the Register), rather than being registered or listed, and the correct fees that apply for the inclusion of kinds of medical devices in the Register are set out separately, in subregulation 7(4) of the Charges Regulations.

As such, items 2, 6, 9 and 13 remove the subparagraphs containing these errors (subparagraphs 7(1)(a)(ii), 7(1)(c)(ii), 7(2)(a)(ii) and 7(2)(c)(ii)) from the Charges Regulations. As these charge items have not been applied, no one has been disadvantaged by these errors.

Item 21

This item amends the Charges Regulations to introduce new annual charge amounts for the inclusion of kinds of medical devices that are Class IIa, IIb, III and AIMD medical devices

for the 2020-21 financial year, if the kinds of devices are a listed prosthesis within the meaning of the instrument made by the Minister under item 4 of the table in section 333-20 of the Private Health Insurance Act 2007 (currently this is the *Private Health Insurance (Prostheses) Rules (No.1) 2020*), as in force on 8 April 2020.

Examples of affected kinds of devices include implantable defibrillators, spinal cord electrical stimulators, Cochlear implants and cardiac pacemakers (Class AIMD), joint implants, breast implants and medicated orthopaedic cement (Class III) and dental implants (Class IIb).

The annual charges for these higher risk devices for 2020-21 introduced for 2020-21 by this item would reflect 50 per cent of the amount that would otherwise have applied to such devices under the 1.95 per cent increase.

This is designed to alleviate the impact of reductions in elective surgeries as a result of the impact of the public health emergency caused by the disease known as coronavirus (COVID-19).

This item only applies the reduction for the 2020-21 financial year.

Item 23

Paragraph 7(5)(d) of the Charges Regulations sets out an annual charge for a licence for the manufacture of sterile or non-sterile single types of therapeutic devices.

‘Therapeutic device’ has been a superseded product category for quite some time, as it reflects that the products that are now known as medical devices were regulated as therapeutic devices, before Chapter 4 was added to the *Therapeutic Goods Act 1989* in 2002 by the *Therapeutic Goods Amendment (Medical Devices) Act 2002* (the 2002 Amendment Act) to introduce a specific regulatory regime for such products. The transitional arrangements associated with the 2002 Amendment Act ended in 2007.

As such, this item repeals paragraph 7(5)(d) of 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) Amendment (2020 Measures No.1) Regulations 2020

The *Therapeutic Goods (Charges) Amendment (2020 Measures No.1) Regulations 2020* (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).

The purpose of the Regulations is to amend the *Therapeutic Goods (Charges) Regulations 2018* (the Charges Regulations) to increase the annual charges set out in the Charges Regulations by 1.95 per cent, for the financial year 2020-21.

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

The 1.95 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 2019) 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.

The Regulations also amend the Charges Regulations to remove a small number of inadvertent errors and an annual charge for a licence to manufacture therapeutic devices.

'Therapeutic device' has been a superseded product category for quite some time, following the introduction of a specific regulatory regime for such products as medical devices by the *Therapeutic Goods Amendment (Medical Devices) Act 2002* and the conclusion in 2007 of that Act's transitional arrangements.

Human rights implications

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

Greg Hunt, Minister for Health