EXPLANATORY STATEMENT

Therapeutic Goods (Charges) Act 1989

Therapeutic Goods (Charges) Amendment (2021 Measures No. 1) Regulations 2021

The proposed instrument would increase annual charges for therapeutic goods to support cost recovery.

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 (other than medical devices). 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 (2021 Measures No. 1) Regulations 2021* (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 1.05 per cent, for the financial year 2021-22. The Regulations complement the *Therapeutic Goods Legislation Amendment (Fees) Regulations 2021*, which increase fees for therapeutic goods for 2021-22 by the same rate.

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 1.05 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 2020) 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 charges that are less than $10,000 – to the nearest $10; and
- for charges that are equal to or greater than $10,000 – to the nearest $100.

The Regulations also make a minor amendment to the Charges Regulations to repeal a spent provision that only applied in relation to the 2020-21 financial year.

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 2021.

Consultation

The TGA held bilateral meetings with 13 key industry representative bodies in December 2020 to consult on the proposed revision of both TGA fees and charges for 2021-22. The industry bodies included Medicines Australia, the Generic and Biosimilar Medicines Association, AusBiotech, the Medical Technology Association of Australia, Consumer Healthcare Products Australia (CHPA), Complementary Medicines Australia (CMA) and Accord Australasia. A majority of the bodies indicated their support for the proposed 1.05 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 4 February 2021 to 17 March 2021. 23 submissions were received, including from industry representative bodies, sponsors or manufacturers and professional bodies. Of these, 14 indicated support for the proposed increase, 6 (including industry representative bodies Assistive Technology Suppliers Australia, Optical Distributors and Manufacturers Association and Pathology Technology Australia) were not supportive, principally due to the impact of COVID-19 on business and the economy and increasing costs of doing business, 1 did not oppose the proposed increase and 2 did not indicate a preference.

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

ATTACHMENT

Details of the *Therapeutic Goods (Charges) Amendment (2021 Measures No. 1) Regulations 2021*

Section 1 – Name
This section provides for the Regulations to be referred to as the *Therapeutic Goods (Charges) Amendment (2021 Measures No. 1) Regulations 2021.*

Section 2 – Commencement
This section provides for the commencement of the Regulations on 1 July 2021.

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 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 to 16 and 18 to 27
These items amend each of the amounts of annual charges prescribed in the *Therapeutic Goods (Charges) Regulations 2018* (the Charges Regulations) by 1.05 per cent, from 1 July 2021, subject to the TGA's rounding policy.

Item 17 – Subsection 7(4A)
This item makes a minor amendment to the Charges Regulations to repeal subsection 7(4A), to reflect that subsection 7(4A) imposed annual charges for certain higher risk kinds of medical devices only for the financial year 2020-21 and as such this provision will be spent after 30 June 2021.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Charges) Amendment (2021 Measures No. 1) Regulations 2021

The *Therapeutic Goods (Charges) Legislation (2021 Measures No. 1) Regulations 2021* (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 main purpose of the *Therapeutic Goods (Charges) Amendment (2021 Measures No. 1) Regulations 2021* (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 1.05 per cent, for the financial year 2021-22. The Regulations complement the Therapeutic Goods Legislation Amendment (Fees) Regulations 2021 which increase fees for therapeutic goods for 2021-22 by the same rate.

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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 and Aged Care