EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Legislation Amendment (Fees) Regulations 2021

The instrument increases fees relating to therapeutic goods to support cost recovery.

The object of the *Therapeutic Goods Act 1989* (the Act) is to establish and maintain a national system of controls for the quality, safety, efficacy 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 (the Department), is responsible for administering the Act.

Subsection 63(1) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing matters required or permitted to be prescribed by the Act or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Amongst other matters, the regulations may prescribe fees in respect of matters under the Act or the regulations made under the Act.

The purpose of the *Therapeutic Goods Legislation Amendment (Fees) Regulations 2021* (the Regulations) is, principally, 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 1.05 per cent for the financial year 2021-22. The Regulations complement the *Therapeutic Goods (Charges) Amendment (2021 Measures No. 1) Regulations 2021,* which increase annual charges for therapeutic goods and licences to manufacture therapeutic goods for 2021-22 by the same rate.

The increase applies, for example, to application fees for the registration, listing or inclusion of therapeutic goods (including medicines, 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.

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), and application fees for conformity assessment certificates for medical devices, are also covered by the increase.

These fees are designed to reflect recovery of the costs of administering the Act, consistent with the Australian Government Cost Recovery Guidelines.

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).

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 equal to or greater than $10,000 – to the nearest $100.

The Regulations also make a minor amendment to the TG Regulations to introduce a fee for the evaluation, from a safety perspective, of a disinfectant for which an application for listing in the Register is made, where such an evaluation is needed. The fee is based on the effort required for officers of the TGA's Medical Devices Authorisation Branch, and Laboratories Branch, to assess the safety profiles of such products.

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, Complementary Medicines Australia 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 63(1) of the *Therapeutic Goods Act 1989*

ATTACHMENT

Details of the *Therapeutic Goods Legislation Amendment (Fees) Regulations 2021*

Section 1 – Name
This section provides for the Regulations to be referred to as the *Therapeutic Goods Legislation Amendment (Fees) 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 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

Part 1 – Fees

Therapeutic Goods (Medical Devices) Regulations 2002

Item 1– Amendments of listed provisions
This item sets out a table of amendments to listed provisions of the *Therapeutic Goods (Medical Devices) Regulations 2002*.

The effect of these amendments is to increase the fees for all relevant items by 1.05 per cent from 1 July 2021, subject to the TGA's rounding policy.

Therapeutic Goods Regulations 1990

Item 2 – Clause 3 of Schedule 9 (after table item 9AD)
This item amends the table in clause 3 of Schedule 9 to the *Therapeutic Goods Regulations 1990* (the TG Regulations) to introduce an evaluation fee for assessing, where necessary, the safety profile of a disinfectant for which an application for listing in the Australian Register of Therapeutic Goods (the Register) is made, for the purposes of paragraph 26(1)(d) of the Act.

The effect of this amendment is that the fee will be payable where an evaluation is necessary in order for the Secretary to come to a view as to whether the grounds in paragraph 26(1)(d) of the Act for refusing to list therapeutic goods in the Register under section 26 of the Act – being, that the Secretary is satisfied that the goods are not safe for the purposes for which they are to be used – may apply.

The fee is in the amount of $19,200. This amount reflects the effort that would be involved for officers of the TGA's Medical Devices Authorisation Branch, and Laboratories Branch, to assess such products and associated supporting documentation to determine if the grounds for refusal in paragraph 26(1)(d) may apply.

An evaluation will generally only be required where a disinfectant presents particular potential safety concerns. Examples include, but are not limited to, a new ingredient type, a different concentration of an ingredient type compared to existing disinfectants with marketing approval, or where novel claims are made about such a disinfectant.

An evaluation fee for this purpose was previously included in the then item 9B of Schedule 9 to the TG Regulations, in respect of therapeutic devices, but was removed from 1 July 2020 as part of measures to reflect that therapeutic devices had been a superseded product category for quite some time. There is, however, a continuing need for a fee of this nature, to ensure appropriate cost recovery for the evaluation of new disinfectants that present particular potential safety concerns.

Item 3 – Amendments of listed provisions
This item sets out a table of amendments to listed provisions of the TG Regulations.

The effect of these amendments is to increase the fees for all relevant items by 1.05 per cent from 1 July 2021, 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 Legislation Amendment (Fees) Regulations 2021

The *Therapeutic Goods Legislation Amendment (Fees) 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 63(1) of the *Therapeutic Goods Act 1989* (the Act).

The purpose of the *Therapeutic Goods Legislation Amendment (Fees) Regulations 2021* (the Regulations) is, principally, 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 1.05 per cent for the financial year 2021-22. The Regulations complement the *Therapeutic Goods (Charges) Amendment (2021 Measures No. 1) Regulations 2021*, which increases annual charges for therapeutic goods and licences to manufacture therapeutic goods for 2021-22 by the same rate.

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These fees are designed to reflect recovery of the costs of administering the Act, consistent with the Australian Government Cost Recovery Guidelines.

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).

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The Regulations also make a minor amendment to the TG Regulations to introduce a fee for the evaluation, from a safety perspective, of a disinfectant for which an application for listing in the Register is made, where such an evaluation is needed. Such an evaluation will generally only be required where a disinfectant presents particular potential safety concerns. Examples include, but are not limited to, a new ingredient type, a different concentration of an ingredient type compared to existing disinfectants with marketing approval, or where novel claims are made about such a disinfectant.

The fee is based on the effort required for officers of the TGA's Medical Devices Authorisation Branch, and Laboratories Branch, to assess the safety profiles of such products.

Human rights implications

As the Regulations do not introduce any changes to the TG Regulations or MD 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