EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2022

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 and Other Measures) Regulations 2022* (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 2.6 per cent for the financial year 2022-23. The Regulations complement the *Therapeutic Goods (Charges) Amendment (2022 Measures No. 1) Regulations 2022*, which increase annual charges for therapeutic goods and licences to manufacture therapeutic goods for 2022-23 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 2.6 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 2021) and Consumer Price Index (50 per cent) (also for the same period).

The Regulations also make a small number of other, minor amendments to the TG Regulations and MD Regulations to:

- introduce fees for requests to vary an approval, or to vary conditions of an approval, for the import, supply or export of unapproved medicines, biologicals or medical devices for use solely for experimental purposes in humans (i.e. clinical trials); and
- correct an inadvertent error in subregulation 4A.6(2) of the MD Regulations in relation to the circumstances in which the Secretary may decide to make a conformity assessment body determination to allow an Australian corporation to assess the manufacture of medical devices.

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 2022.

Consultation

In relation to consultation, the TGA held bilateral meetings with 13 key industry representative bodies in December 2021 to consult on the proposed revision of TGA fees and charges for 2022-23. 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 2.6 per cent increase.

The TGA also undertook public consultation to obtain broader stakeholder feedback, with a consultation paper released on the TGA website and submissions sought from 25 January 2022 to 7 March 2022. 14 submissions were received, including ten from industry representative bodies, two from sponsors or manufacturers, one from a professional body and one from an individual. Of these:

- nine (including seven industry bodies) confirmed their support for the proposed increase;
- three (including two industry bodies, the Optical Distributors & Manufacturers Association of Australia Ltd and Assistive Technology Suppliers Australia) did not support the proposed increase, for a number of reasons including in particular the impact of COVID-19 and the impact on the costs of doing business;
- one did not object to the proposed increase; and
- one proposed a higher (3.6 per cent) increase.

Authority: Subsection 63(1) of the *Therapeutic Goods Act 1989*

ATTACHMENT

Details of the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2022*

Section 1 – Name
This section provides for the Regulations to be referred to as the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2022*.

Section 2 – Commencement
This section provides for the commencement of the Regulations on 1 July 2022.

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 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.

Schedule 1 – Amendments

Therapeutic Goods (Medical Devices) Regulations 2002

The MD Regulations provide for a number of matters in relation to the regulation of medical devices, including, relevantly, a schedule of fees relating to applications or requests under the Act in connection with medical devices (e.g. applications for marketing approval).

Item [1] – Subregulation 4A.6(2)
Subregulation 4A.6(1) of the MD Regulations has the effect of requiring that if an Australian corporation applies for a conformity assessment body determination (to become an Australian conformity assessment body, able to assess the manufacture of medical devices), and the application is in accordance with the requirements of regulation 4A.2, the Secretary must decide whether to make the conformity assessment body determination (or to refuse to do so).

Subregulation 4A.6(2) of the MD Regulations provides that the Secretary must not decide to make the determination unless he or she is satisfied that it is likely that the Australian corporation will be able to comply with the requirements of Schedule 3AA to the MD Regulations throughout the period specified in the determination as mentioned in paragraph 4A.8(2)(b) of the MD Regulations.

The problem is that at the point that the Secretary is required to decide whether to make (or refuse to make) the conformity assessment body determination, there is no determination in place to which the Secretary could refer to identify this period for the purposes of subregulation 4A.6(2).

Paragraph 4A.8(2)(b) of the MD Regulations provides that a conformity assessment body determination has effect at all times until the end of the period specified in the determination,

but this step necessarily occurs after a decision has been made under subregulation 4A.6(1) to make the determination.

To correct this error, and remove any risk of confusion, this item amends subregulation 4A.6(2) to make it clear that the Secretary must not decide to make a determination unless satisfied that it is likely that the Australian corporation will be able to comply with the requirements of Schedule 3AA, without reference to a particular period, with the intended effect to require the Secretary to just consider the question of an Australian corporation's ability to comply with Schedule 3AA as at the time that the Secretary is considering the application.

Item [2] – Part 1 of Schedule 5 (after table item 1.7)
Under subsection 41HB(1) of the Act, the Secretary may grant a written approval to a person for the import, export or supply of a specified (unapproved) medical device or kind of medical device for, relevantly, use solely for experimental purposes in humans (i.e. clinical trials). Such an approval may be given subject to conditions (subsection 41HB(2) of the Act refers).

Under subsection 41HB(8) of the Act, a person to whom such an approval is given may request that the Secretary vary the medical device or kind of medical device specified in the approval, or vary the conditions imposed on the approval under subsection 41HB(2), if the steps listed in paragraphs 41HB(8)(c)-(e) are met.

These include, at paragraph 41HB(8)(e), that the request is accompanied by the fee prescribed in the regulations.

This item amends Part 1 of Schedule 5 to the MD Regulations to introduce a fee for the purposes of paragraph 41HB(8)(e) of the Act, in the amount of $5,376. This amount has been calculated to reflect the effort expected to be involved for officers of the Therapeutic Goods Administration's Medical Devices Authorisation Branch to assess such requests.

Items [3] and [4] – Paragraph 2.1(b) of Part 2 of Schedule 5 and amendments of listed provisions – Part 1 of Schedule 5
Clause 2.1 of Part 2 of Schedule 5 to the MD Regulations provides that in addition to the assessment fee mentioned in certain items of Part 1 of Schedule 5 for an assessment of an application for a conformity assessment certificate or an application to include a kind of medical device in the Australian Register of Therapeutic Goods, certain additional amounts are also payable.

These include, relevantly, an amount of $440 per hour for each assessor for an assessment that is required to be conducted outside Australia.

Item 3 amends the reference to $440 in paragraph 2.1(b) to update this amount to $451, reflecting a proposed increase of 2.6 per cent, from 1 July 2022.

Item 4 sets out a table of amendments to listed provisions of the MD Regulations.

The effect of these amendments is to increase the fees for all relevant items by 2.6 per cent from 1 July 2022.

Therapeutic Goods Regulations 1990

The *Therapeutic Goods Regulations 1990* (the TG Regulations) provide for a number of matters relating to the regulation of therapeutic goods other than medical devices (in practice, principally medicines and biologicals), including, relevantly, a schedule of fees relating to applications or requests under the Act in connection with such goods (e.g. applications for marketing approval).

Item [5] – Amendments of listed provisions
This item sets out a table of amendments to listed provisions of the TG Regulations, in relation to regulations 43AAJ, 43AC, 43ACA and 45 of the TG Regulations.

The effect of these amendments is to increase the fees for all relevant items by 2.6 per cent from 1 July 2022.

Item [6] – Clause 3 of Schedule 9 (after table item 1)
Under paragraph 19(1)(b) of the Act, the Secretary may grant a written approval to a person for the import, export or supply of specified (unapproved) therapeutic goods (in practice, principally medicines) for use solely for experimental purposes in humans (i.e. clinical trials). Such an approval may be given subject to conditions (subsection 19(1A) of the Act refers).

Under subsection 19(4B) of the Act, a person to whom such an approval is given may request that the Secretary vary the therapeutic goods specified in the approval, or vary the conditions imposed on the approval under subsection 19(1A), if the steps listed in paragraphs 19(4B)(c)-(e) are met.

These include, at paragraph 19(4B)(e), that the request is accompanied by the fee prescribed in the regulations.

This item amends the table in clause 3 of Schedule 9 to the TG Regulations to introduce two fees for the purposes of paragraph 19(4B)(e) of the Act, in the amounts of:

- $510 if the therapeutic goods are a medicine and if paragraph (a) of item 1 of the table in clause 3 of Schedule 9 to the TG Regulations applied to the evaluation of the initial approval of the use of the medicine in the clinical trial (item 1 relates to where the evaluation consisted of the consideration of a summary of chemical, pharmaceutical and biological information about the goods, descriptive information about the proposed clinical trial, information about adverse events associated with the use of the goods and information about the goods provided to the relevant ethics committee related to the clinical trial); and
- $6,300 if the therapeutic goods are a medicine and if paragraph (b) of item 1 of the table in clause 3 of Schedule 9 to the TG Regulations applied to the evaluation of the initial approval of the use of the medicine in the clinical trial.

These amounts have been calculated to reflect the effort expected to be involved for officers of the Therapeutic Goods Administration's Pharmacovigilance Branch to assess such requests.

Items [7]-[9], and [11] – Amendments of listed provisions – clause 3 of Schedule 9, clause 4 of Schedule 9, clause 5 of Schedule 9, and Part 2 of Schedule 9A
These items set 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 2.6 per cent from 1 July 2022.

Item [10] – Part 2 of Schedule 9A (after table item 16)
Under paragraph 32CK(1)(e) of the Act, the Secretary may grant a written approval to a person for the import, export or supply of specified (unapproved) biologicals for use solely for experimental purposes in humans (i.e. clinical trials). Such an approval may be given subject to conditions (subsection 32CK(6) of the Act refers).

Under subsection 32CK(9A) of the Act, a person to whom such an approval is given may request that the Secretary vary the biological specified in the approval, or vary the conditions imposed on the approval under subsection 32CK(6), if the steps listed in paragraphs 32CK(9A)(c)-(e) are met.

These include, at paragraph 32CK(9A)(e), that the request is accompanied by the fee prescribed in the regulations.

This item amends the table in Part 2 of Schedule 9A to the TG Regulations to introduce a new fee for the purposes of paragraph 32CK(9A)(e), in the amount of $7,670.

This amount has been calculated to reflect the effort expected to be involved for officers of the Therapeutic Goods Administration's Pharmacovigilance Branch to assess such requests.

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 and Other Measures) Regulations 2022

The *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2022* (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 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 2.6 per cent for the financial year 2022-23. The Regulations complement the *Therapeutic Goods (Charges) Amendment (2022 Measures No. 1) Regulations 2022*, which increases annual charges for therapeutic goods and licences to manufacture therapeutic goods for 2022-23 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 2.6 per cent increase is based on an indexation formula used to calculate adjustments to Therapeutic Goods Administration 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 2021) and Consumer Price Index (50 per cent) (also for the same period).

The Regulations also make a small number of other, minor amendments to the TG Regulations and MD Regulations to:

- introduce fees for requests to vary an approval, or to vary conditions of an approval, for the import, supply or export of unapproved medicines, biologicals or medical devices for use solely for experimental purposes in humans (i.e. clinical trials); and
- correct an inadvertent error in subregulation 4A.6(2) of the MD Regulations in relation to the circumstances in which the Secretary may decide to make a conformity

assessment body determination to allow an Australian corporation to assess the manufacture of medical devices.

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