EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2019

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 2019* (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 2.05 per cent, for the financial year 2019-20.

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.

The 2.05 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 2018) 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 would also include a small number of other, minor changes, including in particular to:

- reduce the application fee for *in vitro* diagnostic (IVD) medical devices that are intended by their manufacturer to be for export only, to reflect that less information is needed to be verified as part of the processing of such applications than for other IVD medical devices, and better automation of the processing of these applications through the modification of the TGA's existing e-BS software; and
- introduce a small number of deadlines within which the Secretary of the Department of Health must complete certain actions in relation to medicines for which listing in the Register under the new pathway for assessed listed medicines is sought, or where variations to an entry in the Register for such medicines are requested; and to introduce a small number of related fees and definitions.

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*.

Sections 1 – 4 of the Regulations commence the day after the Regulations are registered on the Federal Register of Legislation, Parts 1 and 2 of Schedule 1 commence on 1 July 2019 and Part 3 of Schedule 1 commences immediately after the commencement of Part 3 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2018* (on 1 July 2019).

Consultation

The TGA held bilateral meetings with 13 key industry representative bodies in December 2018 to discuss proposals to update TGA fees and charges for 2019-20, including for example with Medicines Australia, the Generic and Biosimilar Medicines Association, AusBiotech, the Medical Technology Association of Australia, the Australian Self Medication Industry (ASMI) and Accord Australasia. The bodies noted the proposed 2.05 per cent increase was consistent with past practice and were broadly supportive. 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 21 December 2018 to 8 February 2019. 13 submissions on the proposed increase were received, of which 7 supported the proposed increase. 6 were in favour of no fee increase, particularly in light of the inclusion in that proposed increase of application fees for Class I medical devices (an application fee of $530 was introduced for most such devices for the first time on 1 July 2018 by the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2018*, and the Regulations increase this fee to $540).

The TGA undertook targeted consultation on the proposed measures relating to assessed listed medicines with ASMI, Accord and Complementary Medicines Australia between 17 January and 8 February 2019. The bodies were broadly supportive of the intention of the framework including the new fee structure and time periods, but expect that these will be reviewed on an ongoing basis.

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

ATTACHMENT

Details of the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2019*

Section 1 – Name
This section provides for the Regulations to be referred to as the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2019.*

Section 2 – Commencement
This section provides for the commencement of sections 1 – 4 of the Regulations on the day after the Regulations are registered on the Federal Register of Legislation, Parts 1 and 2 of Schedule 1 to the Regulations on 1 July 2019 and Part 3 of Schedule 1 to the Regulations immediately after the commencement of Part 3 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2018* (on 1 July 2019).

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– Part 1 of Schedule 5 (table item 1.5, column headed "Matter", paragraph (h))
This item makes a minor amendment to paragraph (h) of column 2 of item 1.5 of Schedule 5 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations), to make it clear that the current application fee of $1,020 for applications to include an *in vitro* diagnostic (IVD) medical device in the Australian Register of Therapeutic Goods (the Register) would not, in light of the amendment made by item 2 below, apply to IVD medical devices that are intended by their manufacturer to be for export only.

Item 2 – Part 1 of Schedule 5 (at the end of table item 1.5)
This item amends item 1.5 of Schedule 5 to the TG Regulations, to introduce a new, lower application fee of $90 for applications to include an IVD medical device in the Register that is intended by its manufacturer to be for export only.

This fee, which is considerably lower than the current application fee for other IVD medical devices of $1,020, principally reflects that less information is needed to be verified as part of the processing of such applications compared to the situation for other IVD medical devices (as the processing of such applications only requires verification by the Department of Health's Medical Devices Branch that applicants use the correct application form, and pay

the required application fee, resulting in a reduced effort than required for IVD medical devices other than those that are for export only), and better automation of the processing of these applications through the modification of the TGA's existing e-BS software.

In that regard, this measure complements the measure to reduce application fees for medical devices other than IVD medical devices that are for export only that was introduced by Part 1 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2018 Measures No.3) Regulations 2018*.

The new, lower fee of $90 also incorporates amortisation costs associated with the modification of the TGA's e-BS software in respect of entries in the Register for export only IVD medical devices.

This amendment does not involve the introduction of any fees other than the new $90 fee outlined above.

Item 3 – Amendments of listed provisions
This item 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 2.05 per cent, subject to the TGA's rounding policy.

Therapeutic Goods Regulations 1990

Item 4 – Regulation 2
This item amends regulation 2 of the *Therapeutic Goods Regulations 1990* (the TG Regulations) to introduce a number of definitions relating to medicines that are listed in the Register under the new pathway for assessed listed complementary medicines (section 26AE of the Act refers).

These are medicines that are lower risk medicines that (unlike most other listed medicines) are evaluated by the Secretary as part of the process for obtaining marketing approval.

Items 10-20 below amend the TG Regulations to, in particular, introduce specific fees, and periods within which the Secretary of the Department of Health (the Secretary) must complete certain actions, for these medicines (along with a number of related matters). As these fees and periods vary depending on the precise circumstances for such medicines, the definitions support these new measures by identifying the different circumstances in which they will apply.

For example, this item introduces a definition for an L(A)C1 (section 9D) request, which is principally a request made by a sponsor of an assessed listed medicine to vary the entry in the Register for the medicine that is of a kind specified in the changes table as an L(A)C1 (section 9D) level change. The changes table is defined in regulation 2 of the TG Regulations as the table published by the Department's website (in practice, this is published on the TGA's website, www.tga.gov.au) for the purposes of that definition, as in force from time to time.

Items 5 – 8 – Regulation 2 (definitions of RCMC1, RCMC2, RCMC3 and RCMC4 (section 23 applications)
These items make minor amendments to replace paragraphs (a) – (c) of each of the definitions of RCMC1, RCMC2, RCMC3 and RCMC4 (section 23) applications in regulation 2 of the TG Regulations with revised paragraphs (a) – (c) in each definition.

The revised paragraphs do not alter the meaning or effect of any of these definitions. Rather, they are designed to make it clearer that these definitions relate to applications for the registration of complementary medicines that would (if registered) form part of the same gazetted therapeutic goods group as another complementary medicine that is already registered in the Register, but would be separate and distinct from that existing medicine (subsection 16(1A) of the Act and regulation 11 of the TG Regulations explain the circumstances in which listed medicines are taken to be separate and distinct from one another).

Item 9 – After paragraph 10AA(1)(d)
This item amends subregulation 10AA(1) of the TG Regulations for the purposes of subparagraph 9D(7)(b)(ii) of the Act to prescribe each of the new categories of section 9D request that are introduced by item 4 above (L(A)C1, L(A)C2 and L(A)CN).

This has the effect that where a sponsor of an assessed listed medicine makes any of these kinds of requests to vary the entry in the Register for their medicine and does not do so in accordance with the steps outlined for such requests in paragraphs 9D(7)(c) – (g) of the Act (e.g. that they pay the relevant prescribed application fee), then the request will not be effective under subsection 9D(7) of the Act.

Item 10 – Subregulation 16GG(2) (before table item 1)
Regulation 16GG of the TG Regulations sets out periods of time within which the Secretary must notify a sponsor of a registered complementary medicine who requests a variation to the entry in the Register for their medicine that the request is effective. Regulation 16GG also sets out periods of time within which the Secretary must make a decision on such requests.

This item amends regulation 16GG of the TG Regulations to also prescribe periods of time for these same steps in relation to assessed listed medicines for which an L(A)C1 or L(A)C2 (section 9D) request is made.

Item 11 – Subregulation 16GH(1) (after table item 3)
Regulation 16GH of the TG Regulations sets out periods of time within which the Secretary must notify a person who applies under section 23 of the Act to register a complementary medicine in the Register, or to list certain kinds of medicine in the Register under section 26AE of the Act (these are assessed listed medicines covered by the existing application categories defined in regulation 2 - L(A)1, L(A)2 and L(A)3 applications) that their application has passed preliminary assessment (the preliminary assessment requirements are set out in subsection 23B(2) of the Act). Regulation 16GH also sets out periods of time within which the Secretary must complete an evaluation of such applications.

This item amends regulation 16GH of the TG Regulations to also prescribe periods of time for these same steps in relation to assessed listable medicines for which an L(A)C1 or L(A)C2 or (section 23) application is made.

Items 12 – 15 – Regulation 43ACA
Regulation 43ACA of the TG Regulations requires the Secretary to refund specified amounts to sponsors of registered complementary medicines for which certain kinds of requests are made under section 9D of the Act to vary an entry in the Register for such a medicine, if an evaluation of the supporting documentation for such a request is not undertaken.

These items principally amend regulation 43ACA to also require the Secretary to refund specified amounts in such circumstances, to sponsors of assessed listed medicines for which an L(A)C1 or L(A)C2 (section 9D) request is made.

These items also make a minor change to the heading of regulation 43ACA to make it clear that, with these amendments, it will no longer be limited to registered complementary medicines.

Items 16 and 17 – Regulation 43AF
Regulation 43AF of the TG Regulations requires that if a sponsor of a registered complementary medicine makes a request to vary the entry in the Register for their medicine that is of a kind mentioned in paragraph 43AF(b) and the Secretary makes a decision on the request but not within the period prescribed in regulation 16GG of the TG Regulations within which the Secretary must make such decisions, then 25 per cent of the application fee relating to the request must be repaid to the sponsor.

Item 17 amends regulation 43AF with the effect that the same refund requirement will also apply for sponsors of assessed listed medicines who make an L(A)C1 or L(A)C2 (section 9D) request in relation to their medicines. This amendment complements the effect of the amendment to be made by item 10 above, in relation to the introduction of periods of time within which the Secretary must make a decision on such requests.

Item 16 makes a minor amendment to the heading of regulation 43AF to make it clear that, with these amendments, it will not be limited to registered complementary medicines.

Items 18 and 19 – Clause 2 of Schedule 9
These items make minor amendments to clause 2 of Part 1 of Schedule 9 to the TG Regulations and the heading of clause 2, to make it clear that the fees prescribed in Part 2 of Schedule 9 do not apply in relation to applications, evaluations or requests covered by Part 3 or Part 4 of Schedule 9.

Item 20 – Clause 5 of Schedule 9 (before table item 1)
This item amends the table in Part 4 of Schedule 9 to the TG Regulations to introduce a number of new fees that would be specific to assessed listed medicines, or medicines for which listing in the Register under the new pathway for such medicines is sought.

The new fees relate to:

- paragraph 9D(7)(f) of the Act in relation to requests to vary an entry in the Register for an assessed listed medicine that already has marketing approval;
- paragraph 23B(2)(b) of the Act in relation to the application fee for applications to list such a medicine in the Register; and
- subsection 26AC(2) of the Act in relation to the evaluation of an application to listed such a medicine in the Register that has passed preliminary assessment.

In each instance, the specified amounts are based on the effort involved for staff of the Department's Complementary and Over the Counter Medicines Branch to process and (in relation to the L(A)C1 and L(A)C2 (section 9D) requests and the L(A)C1 and L(A)C2 (section 23 applications)) evaluate such requests and applications.

Item 21 – Amendment 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 2.05 per cent, subject to the TGA's rounding policy.

Part 2 – Other measures

Therapeutic Goods Regulations 1990

Items 22-24 – Schedule 4 (table items 3, 4A and 8)
Schedule 4 to the TG Regulations identifies those therapeutic goods that are required to be entered in the part of the Register for listed therapeutic goods, for the purposes of paragraph 10(b) of the TG Regulations and paragraph 9A(4)(a) of the Act.

Items 3, 4A and 8 of Schedule 4 provide for the eligibility for listing in the Register of certain medicines and homoeopathic preparations, in specified circumstances.

These circumstances include, for each of these items, that the medicines or homoeopathic preparations do not contain any ingredients that are included in a Schedule to, or Appendix C of, the Poisons Standard (other than, for homoeopathic preparations covered by item 4A of Schedule 4, an ingredient that is more than a 1,000 fold dilution of a mother tincture) (paragraphs 3(c)(i), 4A(e) and 8(c)(i) of Schedule 4 refer).

Concerns have arisen that the reference to 'ingredient' in each of these items in this context may cause confusion and may be misinterpreted as only referring to things that are intentionally added to a medicine or homoeopathic preparation as part of its formulation.

This is not the intention in relation to this requirement – rather, the intention is to require that these products do not contain substances such as contaminants or impurities in raw materials or as a result of the manufacturing process, which may be inappropriate for a listed medicine or potentially harmful. For example, arsenic can be a naturally occurring environmental contaminant of green-lipped mussels, and if arsenic is present in a listed medicine containing green-lipped mussel at a concentration identified in the Poisons Standard, it would not be eligible for listing.

Items 22-24 address this concern by amending table items 3, 4A and 8 of Schedule 4, to make each clearer that, in order to be eligible, the medicines or homoeopathic preparations covered by those items must not contain a substance that is included in a Schedule to the Poisons Standard (except, in the case of a homoeopathic preparation covered by item 4A that is more than a 1,000 fold dilution of a mother tincture).

These items do not refer to Appendix C to the Poisons Standard, to reflect that this Appendix C has been replaced by new Schedule 10 to the Poisons Standard in the most recent *Poisons Standard February 2019* (noting that the term 'Poisons Standard' is defined in

regulation 2 of the TG Regulations as having the same meaning as the term 'current Poisons Standard', with the latter term defined in subsection 52A(1) of the Act as the first Poisons Standard or the document last prepared under paragraph 52D(2)(b) of the Act).

Part 3 – Amendments commencing after Part 3 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2018*

Therapeutic Goods Regulations 1990

Items 25 and 26 – Clause 3 of Schedule 9 (table items 6AA and 6ABA)
In 2018, Part 3 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2018* (the 2018 Amendment Regulations) amended each of table items 6AA and 6ABA of Part 2 of Schedule 9 to the TG Regulations, to increase the fee in table item 6AA from $400 to $640, and to increase the fee in table item 6ABA from $2,070 to $2,430. However, under the 2018 Amendment Regulations these amendments commence on 1 July 2019.

As such, items 19 and 20 commence immediately after the commencement of Part 3 of Schedule 1 to the Amendment Regulations, to increase the updated amounts of each of those fees by 2.05 per cent for the 2019-20 financial year, in accordance with the indexation formula based increase to other TGA fees and charges.

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 2019

The *Therapeutic Goods Amendment (Fees and Other Measures) Regulations 2019* (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), and amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to increase the fees in those respective regulations by 2.05 per cent, for the financial year 2019-20.

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.

The 2.05 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 2018) 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 include a small number of other, minor changes, to:

- reduce the application fee for *in vitro* diagnostic (IVD) medical devices that are intended by their manufacturer to be for export only, to reflect that less information is needed to be verified as part of the processing of such applications than for other IVD medical devices, and better automation of the processing of these applications through the modification of the TGA's existing e-BS software; and
- introduce a small number of deadlines within which the Secretary of the Department of Health must complete certain actions in relation to medicines for which listing in the Register under the new pathway for assessed listed medicines is sought, or where

variations to an entry in the Register for such medicines are requested; and to introduce a small number of related fees and definitions for such medicines; and

- make it clearer that in order to be eligible for listing in the Register (as opposed to registration), medicines and homoeopathic preparations must not contain substances that are included in a schedule to the Poisons Standard that may be inappropriate for low risk listed medicines, or harmful to users.

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.