EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2024

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 or performance, 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 and Aged Care (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. Relevantly, the regulations may prescribe fees in respect of matters under the Act, or the regulations made under the Act.

The main purpose of the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2024* (the Regulations) is 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 4.7 per cent for the 2024-25 financial year. It also introduces some new fees to appropriately cost recover for the administration of the therapeutic goods regulatory scheme.

The 4.7 per cent indexation increase was calculated using the same formula used in most previous years to calculate adjustments to TGA fees and charges. The formula is comprised of the Australian Bureau of Statistics' Consumer Price Index (50 per cent) and Wage Price Index (50 per cent), (both for the year to September 2023). This increase is in line with the TGA's cost recovery model and complements the *Therapeutic Goods (Charges) Amendment (2024 Measures No. 1) Regulations 2024*, which increase therapeutic goods charges for 2024-25.

The fees that are prescribed, and that have had indexation applied, are based on the effort involved in processing or undertaking the relevant related service, (such as evaluating an application for marketing approval), in order to reflect the recovery of the costs of administering the Act, consistent with the Australian Government Cost Recovery Guidelines. The Regulations apply increases to a range of fees, for example, to: application fees for the registration; listing or inclusion of medicines and biologicals 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 other than medical devices; 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.

The Regulations also make other fee-related amendments to the TG Regulations and MD Regulations, principally to:

- introduce a fee for the assessment of a request for consent to import, supply or export an unapproved therapeutic good that does not comply with an applicable standard –

this fee complements the existing fee for approved therapeutic goods (i.e. those that are included in the Register);
- introduce a fee for requests made to the Secretary by sponsors of medicines or biologicals for the Secretary to vary or remove a condition of entry of their product in the Register, for the purposes of subsections 28(3A) and 32EE(2) of the Act (to apply from 1 January 2025 to allow sufficient time to implement fee changes);
- introduce a new, reduced fee for the auditing of an application to include a kind of medical device in the Register that is a Class 3 or 4 in vitro diagnostic (IVD) medical device, where no laboratory testing is undertaken as part of the audit;
- prescribe a clinical trial notification fee for each additional site for a clinical trial involving unapproved medical devices; and
- make other minor consequential or editorial amendments.

Details of the Regulations are set out in the Attachment A. The Amendment Specification is compatible with human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in Attachment B.

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 as follows:
- Sections 1 to 4 and Schedule 1 commence on 1 July 2024; and
- Schedule 2 commences on 1 January 2025.

Consultation

In relation to consultation, the TGA held bilateral meetings with 13 key industry representative bodies in November-December 2023 on changes to TGA fees and charges for 2024-25. The industry bodies included Medicines Australia, Accord Australasia, the Generic and Biosimilar Medicines Association, AusBiotech, the Medical Technology Association of Australia, Consumer Healthcare Products Australia and Complementary Medicines Australia. Most of the bodies indicated their support for the 4.7 per cent indexation increase to TGA fees.

The TGA also undertook public consultation to obtain broader stakeholder feedback, with a consultation paper released on the TGA website and submissions sought over a four-week period to 23 February 2024. The TGA received 15 submissions from this public consultation – 10 from industry representative bodies and 5 from sponsors or manufacturers of therapeutic goods. Twelve respondents did not raise concerns in relation to the indexation increase, with 3 submissions not supporting the indexation increase. No significant concerns were raised in relation to the small number of other fees and charges changes. After considering the submissions against indexation, the Regulations introduce the indexation increase because it is consistent with the Australian Government Cost Recovery Guidelines and critical to achieving full cost recovery given rising costs, without reducing service delivery to industry and supporting the efficient operation of the TGA's activities.

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

Details of the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2024*

Section 1 – Name
This section provides that the title of the Regulations is the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2024.*

Section 2 – Commencement
This section provides that the Regulations commence as follows:

- Sections 1 to 4 and Schedule 1 commence on 1 July 2024; and
- Schedule 2 commences on 1 January 2025.

The majority of the amendments to the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) commence on 1 July 2024.

However, the provisions in the Regulations, which seek to introduce fees for requests from sponsors to vary conditions of registration, listing or inclusion of therapeutic goods in the Register, are to commence on 1 January 2025. The delayed commencement of these provisions would allow sufficient time for the implementation of these fee changes.

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 instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule to the instrument has effect according to its terms.

Schedule 1 – Amendments commencing 1 July 2024

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.

Items [1] and [2] – Subsection 9.1AA(1) and Subsection 9.1AA(2) (method statement, step 2)
Items 1 and 2 amend subsection 9.1AA(1) and step 2 of the method statement in subsection 9.1AA(2) of the MD Regulations to update the fee prescribed from "$30" to "$31". These amendments simply reflect the application of the 4.7 per cent indexation increase to these fee amounts (rounded to the nearest dollar) for consent to import, supply or export implantable medical devices.

Item [3] – Paragraph 9.7(1)(d)
Item 3 makes a consequential amendment to paragraph 9.7(1)(d) of the MD Regulations to include a reference to the new table item 1.14AA, after table item 1.14A, in Part 1 of Schedule 5.

Item [4] – In the appropriate position in Part 11
Item 4 inserts a new application provision in Part 11 of the MD Regulations, relating to the application audit assessment fees for IVD medical devices.

The new application provision makes it clear that table items 1.14A, 1.14AA and 1.14B of Part 1 of Schedule 5 to the MD Regulations, as amended by these Regulations, only apply in relation to applications made on or after 1 July 2024 and in relation to which an application audit assessment fees is payable under subsection 41LA(3) of the Act.

Item [5] – Part 2 of Schedule 4 (table item 2.3, column headed "Conditions", paragraph (b))
Item 5 makes a consequential amendment to paragraph (b) in the second column of table item 2.3 in Part 2 of Schedule 4 to the MD Regulations to precisely refer to paragraph (a) of item 1.8.

Item [6] – Part 2 of Schedule 4 (table item 2.3, column headed "Conditions", after paragraph (h))
Item 6 introduces paragraph (ha) in the second column of table item 2.3 in Part 2 of Schedule 4 to the MD Regulations to provide that a notification must be accompanied by the notification fee specified in paragraph (b) of item 1.8 of Schedule 5.

Item [7] – Part 1 of Schedule 5 (table item 1.4, column headed "Amount ($)")
Item 7 amends the fourth column of table item 1.4 in Part 1 of Schedule 5 to the MD Regulations, to include a reference to items 1.14AA, 1.14B and 1.14C. The application audit assessment fee in relation to a suspension of a conformity assessment certificate referred to in table item 1.4 applies to all IVD medical devices. This amendment corrects a previous omission in table item 1.4 by including references to the other table items in Part 1 of Schedule 5 which prescribe a fee for an application audit assessment for IVD medical devices.

Item [8] – Part 1 of Schedule 5 (table item 1.8)
Item 8 replaces the existing table item 1.8 in Part 1 of Schedule 5 to the MD Regulations, to prescribe a clinical trial notification fee of $429 for any additional site for a clinical trial involving unapproved medical devices.

Fees are currently prescribed for notifying the TGA of an additional clinical trial site for unapproved medicines and biologicals. However, there is currently no fee for notification of an additional site for medical devices in the MD Regulations. This item addresses this gap by prescribing a clinical trial notification fee of $429 for each additional site for a clinical trial involving unapproved medical devices.

This amendment implements a clinical trial notification fee involving unapproved medical devices to make it consistent with the existing fee for an additional clinical trial site for a clinical trial involving an unapproved medicine or biological, prescribed in table item 14 in Part 2 of Schedule 9 and table item 17 in Part 2 of Schedule 9A to the TG Regulations (respectively).

Item [9] – Part 1 of Schedule 5 (at the end of paragraph (b) of table item 1.14A)
Item 9 amends paragraph (b) of table item 1.14A in Part 1 of Schedule 5 to the MD Regulations, to effectively provide that this item does not apply to devices to which new item 1.14AA applies. This item carves out devices to which the new table item 1.14AA applies, being Class 3 IVD medical devices or Class 4 IVD medical devices (other than devices to which paragraph (d) of item 1.14A or item 1.14C applies).

Item [10] – Part 1 of Schedule 5 (subparagraph (c)(ii) of table item 1.14A))
Item 10 makes a consequential amendment to subparagraph (c)(ii) of table item 1.14A in Part 1 of Schedule 5 to include reference to new item 1.14AA.

Item [11] – Part 1 of Schedule 5 (after table item 1.14A)
Item 11 amends Part 1 of Schedule 5 to introduce new table item 1.14AA to provide a fee of $14,865 for an application audit assessment for a Class 3 or 4 IVD medical device (other than devices to which other relevant items apply) where the device is not subject to laboratory testing as part of the auditing of the application.

Items 1.14A(b) and (c) in Part 1 of Schedule 5 to the MD Regulations currently prescribe an application audit assessment fee of $22,387 for Class 3 and Class 4 IVD medical devices. This fee was costed on the basis that laboratory testing is required for all these devices.

However, a review of these applications found that not all Class 3 and 4 IVD medical device application audit assessments require laboratory testing. The new item 1.14AA introduces a lower fee of $14,865 for an application audit assessment for both classes of IVD medical devices where no laboratory testing is undertaken.

Item [12] – Part 1 of Schedule 5 (table item 1.14B, column headed "Matter")
Item 12 makes a consequential amendment to the second column of table item 1.14B in Part 1 of Schedule 5 to the MD Regulations, to include a reference to new item 1.14AA.

Item [13] – Paragraph 2.1(b) of Schedule 5
Item 13 amends paragraph 2.1(b) of Schedule 5 to the MD Regulations, to update the fee which applies to an assessment that is required to be conducted outside Australia from an hourly rate of $474 to $496, to reflect the 4.7 per cent indexation-based increase.

Item [14] – Amendments of listed provisions—Part 1 of Schedule 5
Item 14 sets out a table of amendments to listed provisions of Part 1 of Schedule 5 to the MD Regulations.

The effect of these amendments is to increase the fees for all relevant items by the indexation rate of 4.7 per cent from 1 July 2024.

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, schedules of fees relating to applications or requests under the Act in connection with such goods.

Item [15] – Clause 3 of Schedule 9 (table item 1A)
Item 15 replaces item 1A in Part 2 of Schedule 9 to the TG Regulations, with the only change being to introduce an application fee for processing an application for consent under section

14 or 14A of the Act for an application relating to goods to which no entry in the Register relates. The item otherwise remains the same except for the application of the 4.7 per cent indexation increase for fees specified in this item.

Item 1A in Part 2 of Schedule 9 to the TG Regulations currently prescribes fees for processing an application for consent (to non-compliance with a standard) for therapeutic goods to which an entry in the Register relates. A fee is prescribed for goods to which a single entry in the Register relates, while a reduced fee is prescribed for each entry where there are separate entries in the Register in relation to the goods and the non-conformance with the standard is the same for all the goods.

There is currently no applicable fee associated with recovering the costs of assessing consent applications, made pursuant to sections 14 or 14A of the TG Act, relating to therapeutic goods which are not included in the Register. This item addresses this gap and introduce a new fee of $3,712 for processing an application for consent for the purposes of section 14 or 14A of the Act.

Item [16] – Part 2 of Schedule 9A (table, heading to column headed "Fee")
Item 16 makes a minor editorial amendment to replace the existing heading in the third column of the table in Part 2 of Schedule 9A to the TG Regulations with "Fee $".

Items [17]-[21] – 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
Items 17 to 21 set out tables of amendments to listed provisions of the TG Regulations.

The effect of these amendments is to increase the fees for all relevant items by the indexation rate of 4.7 per cent from 1 July 2024.

Schedule 2 – Amendments commencing 1 January 2025

Therapeutic Goods Regulations 1990

Item [1] – Clause 3 of Schedule 9 (after table item 1AF)
Item 1 introduces a new item 1AFA in the table in Part 2 of Schedule 9, to introduce fees for requests from sponsors to vary or remove conditions of registration or listing of certain therapeutic goods in the Register, for the purposes of subsection 28(3A) of the Act. The fees prescribed are as follows:

- for therapeutic goods that are specified in Part 1 of Schedule 10 to the TG Regulations (i.e. those goods evaluated by the Prescription Medicines Authorisation Branch in the Department) – $2,879.
- for all other therapeutic goods – $1,790.

The fees are based on staff effort and efficiency costs in relation to the associated activities for the relevant application types.

Item [2] – Part 2 of Schedule 9A (after table item 2A)
Item 2 introduces a new item 2B in the table in Part 2 of Schedule 9A, to introduce a fee of $2,010 for requests from sponsors to vary or remove conditions of inclusion of biologicals in the Register, for the purposes of subsection 32EE(2) of the Act. The fee if based on staff effort and efficiency costs in relation to the associated activities for the relevant application types.

ATTACHMENT B

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 2024

This disallowable legislative instrument is 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 object of the *Therapeutic Goods Act 1989* (the Act) is to establish and maintain a national system of controls for the quality, safety, efficacy or performance, 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 and Aged Care (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. Relevantly, the regulations may prescribe fees in respect of matters under the Act, or the regulations made under the Act.

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The fees that are prescribed, and that have had indexation applied, are based on the effort involved in processing or undertaking the relevant related service, (such as evaluating an application for marketing approval), in order to reflect the recovery of the costs of administering the Act, consistent with the Australian Government Cost Recovery Guidelines. The Regulations apply increases to a range of fees, for example, to: application fees for the registration; listing or inclusion of medicines and biologicals 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 other than medical devices; 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.

The Regulations also make other fee-related amendments to the TG Regulations and MD Regulations, principally to:

- introduce a fee for the assessment of a request for consent to import, supply or export an unapproved therapeutic good that does not comply with an applicable standard – this fee complements the existing fee for approved therapeutic goods (i.e. those that are included in the Register);
- introduce a fee for requests made to the Secretary by sponsors of medicines or biologicals for the Secretary to vary or remove a condition of entry of their product in the Register, for the purposes of subsections 28(3A) and 32EE(2) of the Act (to apply from 1 January 2025 to allow sufficient time to implement fee changes);
- introduce a new, reduced fee for the auditing of an application to include a kind of medical device in the Register that is a Class 3 or 4 in vitro diagnostic (IVD) medical device, where no laboratory testing is undertaken as part of the audit;
- prescribe a clinical trial notification fee for each additional site for a clinical trial involving unapproved medical devices; and
- make other minor consequential or editorial amendments.

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.

Mark Butler, Minister for Health and Aged Care