

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2023

The instrument amends fees for therapeutic goods in accordance with the annual indexation of fees, and revises a number of fees relating to medical devices to more appropriately give effect to cost recovery arrangements.

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 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 purpose of the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2023* (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 most of the fees set out in those respective regulations by 5.2 per cent for the 2023-24 financial year.

The 5.2 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) for the year to September (this was 3.1 per cent for the year to September 2022), and Consumer Price Index (50 per cent) for the year to September (this was 7.3 per cent for the year to September 2022). This increase is in line with the TGA's cost recovery model and complements the *Therapeutic Goods (Charges) Amendment (2023 Measures No. 1) Regulations 2023*, which increases therapeutic goods charges for 2023-24 by these (and in some cases other) rates of increase.

The increase applies, 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 amend a small number of medical device-related fees by more than 5.2 per cent to more accurately reflect the cost of undertaking level 2 audits in relation to assessing certain kinds of applications to include medical devices in the Register, the evaluation of applications for the inclusion of some disinfectants and certain fees relating to in vitro diagnostic (IVD) medical devices. A small number of medical device fees are also reduced to reflect efficiencies and streamlined assessment processes identified in 2022. Separately, most fees relating to medical device conformity assessment certificates are not subject to any change in 2023-24 (including not being subject to the 5.2 per cent increase), to

reflect that these fees are to be reviewed as part of an examination of the full cost recovery of conformity assessment fees.

The Regulations also introduce a waiver mechanism to reflect that, in connection with updates to the legislative instruments that underpin the Prostheses List (which sets out prostheses that private health insurers must pay benefits for if a patient is covered, and the benefit amount), there may be a need for sponsors of medical devices affected by reclassification reforms introduced by the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019* to maintain two entries in the Register for a period of time - both their pre-reclassification entry and their reclassification entry, while updates to those instruments are being progressed. The waiver ensures that affected sponsors are only subject to one annual charge, rather than two, in connection with these updates.

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 2023.

Consultation

In relation to consultation, the TGA held bilateral meetings with 13 key industry representative bodies in December 2022 to consult on the proposed revision of TGA fees and charges for 2023-24. 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 5.2 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 in February 2023 and submissions sought over a four-week period to 21 March 2023. Thirty-six submissions were received, including 11 from industry representative bodies, 22 from sponsors or manufacturers, and 3 from other respondents. Of these:

- twenty-eight submissions, including from peak industry bodies and major sponsors supported the proposed 5.2 per cent indexation increase; and
- the medical device industry raised concerns about the proposed increases to specific medical device fees for assessing applications (in particular, Level 2 application audit assessments for medical devices other than in-vitro diagnostic medical devices, disinfectants and diagnostic tests).

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

Details of the Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2023

Section 1 – Name

This section provides that the title of the Regulations is the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2023*.

Section 2 – Commencement

This section provides for the commencement of the Regulations on 1 July 2023.

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

Therapeutic Goods (Medical Devices) Regulations 2002

Item [1] – After Part 8

Under reforms introduced by the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019* (the reclassification reforms), a number of specified kinds of medical devices were reclassified to support the harmonisation, where possible, of the regulation of medical devices in Australia with that of the European Union. For example, certain spinal implantable medical devices (SIMDs) were up-classified from Class IIb to Class III medical devices. The effect of these reforms included that sponsors of affected medical devices that were already in the Register were required to re-apply to include their products in the Register at a higher classification level.

Separately, a number of devices that are subject to the reclassification reforms are also included in the legislative instrument underpinning the Prostheses List (PL) that is made under the *Private Health Insurance Act 2007* (the PHI Act) (currently, the *Private Health Insurance (Prostheses) Rules (No. 1) 2023*). The PL is itself the subject of a number of reforms, although these are not aligned with or connected to the medical device reclassification reforms.

This item introduces a waiver (and related refund) mechanism to reflect that, in connection with updates to the legislative instruments that underpin the Prostheses List (which sets out prostheses that private health insurers must pay benefits for if a patient is covered, and the benefit amount), there may be a need for sponsors of medical devices affected by reclassification reforms to maintain two entries in the Register for a period of time - both their pre-reclassification entry and their reclassification entry, while Prostheses List updates

are being progressed. The waiver is designed to ensure that affected sponsors are only subject to one annual charge, rather than two, while this is the case.

New regulation 8A.1 identifies that the kinds of medical devices that may be eligible for the waiver or refund are those kinds of devices to which the reclassification reforms applied, where:

- the medical device was, immediately before 25 November 2021, included in the Register and classified as a class of medical device mentioned in column 2 of that item; or
- on 25 November 2021, the medical device was the subject of a class of application mentioned in column 2 of the item for inclusion in the Register, and the application had not been finally determined.

New regulation 8A.1 also defines the term ‘*charge year*’ as having the same meaning as in the *Therapeutic Goods (Charges) Regulations 2018* (that is, that it means the financial year to which the charge relates).

New regulation 8A.2 requires the Secretary, on application, to waive the annual charge that relates to the transitional, i.e. pre-reclassification, entry in the Register where the Secretary is satisfied that certain criteria are met:

- the medical device is a transitional medical device; and
- the entry for the kind of medical device in the Register does not include any medical device that is not a transitional medical device (this means that entries that contain devices that are subject to the reclassification reforms and devices that are not subject to the reclassification reforms are not eligible for the waiver); and
- there is both an entry in the Register for the medical device at the pre-reclassification level and an entry in the Register for the medical device at the reclassification level; and
- the same kind of medical device is also listed in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules, made under the PHI Act, as in force from time to time.

New regulation 8A.3 complements the waiver by introducing a related refund mechanism that requires the Secretary, on application, to refund an amount equal to the annual charge for the transitional, i.e. pre-reclassification, entry in the Register where satisfied that the above criteria are met and the sponsor has already paid that annual charge. This may happen for instance if sponsors have automated systems to effect payment of annual charges, or may, for other reasons, only identify that they were eligible for the waiver after they have paid the relevant charge.

Item [2] – Before paragraph 10.7(1A)(a)

This item makes decisions to refuse a waiver or refund under the new mechanism merits reviewable.

Under subregulation 10.7(3) of the MD Regulations, a person whose interests are affected by an initial decision of the Secretary may, by notice in writing given to the Minister within 90 days after the decision first comes to the person’s notice, request the Minister to reconsider the decision.

Subregulation 10.7(4) provides that the Minister must reconsider the initial decision as soon as practicable after receiving a request under subregulation (3), and may confirm or revoke the initial decision, or revoke the initial decision and make a decision in substitution for the initial decision.

The term ‘*initial decision*’ is defined in subregulation 10.7(1) of the MD Regulations as meaning a decision made under any of the provisions that are specified within the definition. However, new subregulation (1A), which was inserted into regulation 10.7 by the *Therapeutic Goods Legislation Amendment (2023 Measures No. 1) Regulations 2023*, reflects that a number of refusal decisions of the Secretary that are not specified in subregulation (1) are also initial decisions for the purposes of regulation 10.7.

This item also amends subregulation 10.7(1A) to provide that a refusal decision under subregulation 8A.2(2) or 8A.3(2) is an initial decision, with the effect that a person who applies for a waiver or refund under the new mechanism may apply for merits review if the Secretary refuses to grant a waiver or refund if not satisfied that the application meets the criteria.

Item [3] – Part 1 of Schedule 5 (table item 1.10A)

Under subsection 41LA(1) of the Act, a conformity assessment fee specified in or determined in accordance with the regulations is payable by a person in respect of consideration of an application for a conformity assessment certificate in Part 4-4 of the Act.

Relevantly, paragraph 41LA(2)(c) provides that the regulations may prescribe different levels of conformity assessment fees in relation to different parts of the conformity assessment procedures that are considered in relation to an application for a conformity assessment certificate under Part 4-4. The conformity assessment procedures are listed in Schedule 3 to the MD Regulations.

For the purposes of subsection 41LA(1) and paragraph 41LA(2)(c), item 1.10A in the table in Part 1 of Schedule 5 to the MD Regulations prescribes the fees in respect of the consideration of an application for a conformity assessment certificate under Part 4-4 of the Act, where the assessment is required because of changes, or changes, to an in-vitro diagnostic (IVD) medical device or quality management system applying to that device.

However, table item 1.10A does not specify the amounts that apply in relation to each conformity assessment procedure. Rather, it prescribes the relevant fee as being calculated on the basis of 60 per cent of the corresponding fee under table item 1.9A (which specifies the fees payable in relation to each conformity assessment procedure as part of an initial conformity assessment). Some industry participants have raised concerns about the readability of this table item.

To address such concerns, this item replaces table item 1.10A with a list of each of the conformity assessment procedures contained in Schedule 3 to the MD Regulations, and the fee that corresponds to each procedure. This is to better assist manufacturers and sponsors of IVD medical devices in understanding the fee structure that applies to conformity assessments of IVD medical devices, without the need to refer to item 1.9A or apply a calculation.

Consistent with the current fee structure for these assessments, the fee specified in new table item 1.10A for each conformity assessment procedure is calculated at 60 per cent of the corresponding fee in table item 1.9A.

Item [4] – Part 1 of Schedule 5 (table items 1.14, 1.14A and 1.14B)

Under subsection 41LA(3) of the Act, an application audit assessment fee specified in or determined in accordance with the regulations is payable by a person in respect of the auditing of an application for the inclusion of a kind of medical device in the Register under Part 4-5 of the Act, if paragraph 41FH(1)(a) required the Secretary to select the application for audit. Paragraph 41LA(4)(c) of the Act provides that the regulations may prescribe different levels of application audit assessment fees in relation to different levels of assessments of kinds of medical devices.

This item replaces table items 1.14, 1.14A, and 1.14B, and introduces an amended fee structure so that a fee is prescribed for application audit assessments that are conducted in respect of all kinds of medical devices. This item also introduces a stand-alone fee for application audit assessments in respect of Class 3 IVD medical devices.

Specifically this item:

- replaces the current fee in item 1.14 of Part 1 of Schedule 5 to the MD Regulations of \$7,582 for Level 1 activities and review of evidence of conformity associated with a Level 2 application audit assessment, with a fee of \$16,000 for Class III medical devices other than IVD medical devices, and a fee of \$4,000 for all other medical devices (other than IVD medical devices), to better reflect the work required in undertaking such assessments for these different classes of device;
- replaces the current fee in item 1.14A of Part 1 of Schedule 5 to the MD Regulations of \$7,387 for an application audit assessment for Class 1, Class 2 and Class 3 IVD medical devices with a fee of \$22,387 for Class 3 IVD medical devices, a fee of \$22,387 for Class 4 IVD medical devices other than Class 4 IVD medical devices that are immunohaematology reagent IVD medical devices or Class 4 IVD medical devices to which item 1.14B or 1.14C applies, and a fee of \$16,621 for Class 4 IVD medical devices that are immunohaematology reagent IVD medical devices (the fee for Class 1 and Class 2 IVD medical devices remains \$7,387). These amendments better reflect the work required in undertaking such assessments for these different classes and kinds of device, and also introduce assessment fees for Class 4 IVD medical devices and Class 4 IVD medical devices that is an immunohaematology reagent (none of these table items currently specify a fee for application audit assessments in respect of commercial class 4 IVD medical devices, as opposed to Class 4 *in-house* IVD medical devices which are covered in current items 1.14B and 1.14C).

Table item 1.14C, which specifies a fee of \$16,621 for application audit assessments in respect of Class 4 in-house IVD medical devices that are immunohaematology reagent IVD medical devices, is unaffected by this item (and is not subject to the 5.2 per cent indexation rate).

In each case the new (or preserved) fee is designed to reflect the effort involved for officers of the TGA's Medical Devices Authorisation Branch to undertake and complete these assessments.

Item [5] – Paragraph 2.1(b) of Part 2 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 table items in 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 Register, certain additional amounts are also payable.

These include, relevantly, an amount of \$451 per hour for each assessor involved in an assessment that is required to be conducted outside Australia.

This item amends the reference to \$451 in item 2.1, paragraph (b), to update this amount to \$474, reflecting the indexation increase of 5.2 per cent, from 1 July 2023.

Item [6] – Amendments of listed provisions—Part 1 of Schedule 5

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 the indexation rate of 5.2 per cent from 1 July 2023. Table items that are not included in the table of amendments are not subject to the 5.2 per cent indexation rate as they are being reviewed during 2023-24.

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 [7] – Part 2 of Schedule 9 (table items 2A and 2AB)

Under section 9D of the Act the Secretary may, on the Secretary's own initiative or following a request by a person to whom therapeutic goods are entered on the Register, vary the entry in the Register in relation to those goods.

Item 2A in the table in Part 2 of Schedule 9 to the TG Regulations prescribes the fees for varying an entry in the Register (not including evaluation of data) under section 9D of the Act (other than subsection 9D(2C)) for specified kinds of therapeutic goods, including certain registered medicines, listed medicines, disinfectants, medical devices, and, separately, certain medical devices that are of a kind '*affected by the EU transition*' (within the meaning of subregulation 9.1AA(3) of the MD Regulations).

Item 2AB in the table in Part 2 of Schedule 9 to the TG Regulations specifies, for the purposes of subsection 9D(1) of the Act, the application fee for the variation of an entry of a kind of IVD medical device in the Register because the entry contains incomplete or incorrect information.

This item replaces table item 2A to amend the fee structure for variations that are made to entries for specified kinds of therapeutic goods in the Register. In some cases, the variation fee for certain kinds of therapeutic goods is increased by a rate higher than the 5.2 per cent indexation rate (e.g. the variation fee for disinfectants). In relation to other kinds of therapeutic goods, however, the variation fee is unaffected by this item, or the indexation rate

(e.g. the variation fee for certain kinds of medical devices) as those fees are currently under review.

The purpose of these amendments is to better ensure that the fees for varying an entry in the Register are commensurate with the time and effort required of TGA officers to process those variations. In particular, the item addresses under-recovery of fees relating to variations that are made to entries of disinfectants and medical devices in the Register (with the fee structure for the latter having been replaced).

This item also repeals table item 2AB, on the basis that it is not used in practice, and, in any case, a variation of the kind described in that table item would, as appropriate, attract the relevant fee mentioned in new table item 2A.

Item [8] – Part 2 of Schedule 9 (table item 9B)

Subsection 26(1) of the Act provides that, where an application is made for the listing of therapeutic goods (other than goods which may be listed under sections 26A or 26AE) in relation to a person under section 23 of the Act, and the requirements specified in paragraphs 26(1)(aaa) to (b) are satisfied, the Secretary is not to refuse to list the goods in relation to the person, except where the Secretary is satisfied of certain matters.

Relevantly, paragraph 26(1)(d) provides that, where the Secretary is satisfied that the goods are not safe for the purposes for which they are to be used, the Secretary may refuse to list the goods in relation to the person.

For the purposes of paragraph 26(1)(d) of the Act, item 9B in the table in Part 2 of Schedule 9 to the TG Regulations specifies an evaluation fee of \$19,699 for assessing whether a disinfectant is not safe for the purposes for which it is to be used.

This item repeals this fee for disinfectants in table item 9B, on the basis that this fee is not needed. This is because the nature and safety profiles of disinfectants are well known. Accordingly, an evaluation of the kind mentioned in item 9B is not necessary to ensure that such products are safe for use if approved. Rather, the fees for an application for listing of a disinfectant in the Register, or a variation of an entry in the Register for a disinfectant, are increased in item 10 in Schedule 1 to the Regulations to better reflect the work involved in the processing of applications for the listing of disinfectants in the Register.

Item [9] – 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, with the effect of increasing the fees for all listed provisions by the indexation rate of 5.2 per cent, from 1 July 2023.

Items [10] to [13] – Amendments of listed provisions — clauses 3 to 5 of Schedule 9, and Part 2 of Schedule 9A

These items set out tables of amendments to listed provisions of the TG Regulations.

The effect of these amendments is to increase the fees for most listed items by the indexation rate of 5.2 per cent, from 1 July 2023.

However, the application fee for the listing of disinfectants in the Register, which is prescribed by table item 3, paragraph (a), in clause 3 of Schedule 9 to the TG Regulations, is increased by a rate higher than the indexation rate of 5.2 per cent.

The purpose of this amendment is to better ensure that the recovery of fees relating to the processing of applications for the listing of disinfectants in the Register are commensurate with the time and effort required of TGA officers to process those applications.

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 2023

The *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2023* (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 purpose of the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2023* (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 most of the fees set out in those respective regulations by 5.2 per cent for the 2023-24 financial year.

The 5.2 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) for the year to September (this was 3.1 per cent for the year to September 2022), and Consumer Price Index (50 per cent) for the year to September (this was 7.3 per cent for the year to September 2022). This increase is in line with the TGA's cost recovery model and complements the *Therapeutic Goods (Charges) Amendment (2023 Measures No. 1) Regulations 2023*, which increases therapeutic goods charges for 2023-24 by these (and in some cases other) rates of increase.

The increase applies, 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 amend a small number of medical device-related fees by more than 5.2 per cent to more accurately reflect the cost of undertaking level 2 audits in relation to assessing certain kinds of applications to include medical devices in the Register, the evaluation of applications for the inclusion of some disinfectants and certain fees relating to in vitro diagnostic (IVD) medical devices. A small number of medical device fees are also reduced to reflect efficiencies and streamlined assessment processes identified in 2022. Separately, most fees relating to medical device conformity assessment certificates are not subject to any change in 2023-24 (including not being subject to the 5.2 per cent increase), to reflect that these fees are to be reviewed as part of an examination of the full cost recovery of conformity assessment fees.

The Regulations also introduce a waiver mechanism to reflect that, in connection with updates to the legislative instruments that underpin the Prostheses List (which sets out prostheses that private health insurers must pay benefits for if a patient is covered, and the benefit amount), there may be a need for sponsors of medical devices affected by

reclassification reforms introduced by the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019* to maintain two entries in the Register for a period of time - both their pre-reclassification entry and their reclassification entry, while updates to those instruments are being progressed. The waiver ensures that affected sponsors are only subject to one annual charge, rather than two, in connection with these updates.

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