EXPLANATORY STATEMENT

Therapeutic Goods (Charges) Act 1989

Therapeutic Goods (Charges) Amendment (2024 Measures No. 1) Regulations 2024

The instrument increases annual charges for therapeutic goods to support cost recovery.

The *Therapeutic Goods (Charges) Act 1989* (the Act) imposes annual charges on the registration, listing and inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (the Register), and on the licensing of manufacturers of therapeutic goods other than medical devices. The Therapeutic Goods Administration (the TGA), which is part of the Department of Health and Aged Care, is responsible for administering the Act.

Subsection 5(1) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing the amounts of charges. Subsection 5(2) of the Act provides that the regulations may prescribe different charges in relation to different classes of goods or, in the case of annual licensing charges, for different steps in the manufacture of therapeutic goods. Paragraph 5(2)(c) also permits the regulations to prescribe different charges for different kinds of conformity assessment body determinations. These determinations specify that an Australian corporation is an Australian conformity assessment body responsible for monitoring the compliance of Australian and overseas manufacturers of medical devices with conformity assessment procedures set out in Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Section 4 of the Act provides that annual charges of prescribed amounts are payable in respect of therapeutic goods on the Register, manufacturing licences, and conformity assessment body determinations that are in force at any time within a financial year. In addition, under subsection 4(1A) of the Act, where one or more therapeutic goods are "grouped" and each of the "grouped" therapeutic goods is covered by a single registration or listing number, a prescribed single annual charge will apply for maintaining all the registered or listed goods covered under the same group.

The main purpose of the *Therapeutic Goods (Charges) Amendment (2024 Measures No. 1) Regulations 2024* (the Regulations) is to amend the *Therapeutic Goods (Charges) Regulations 2018* (the Charges Regulations) to increase the annual charges that are set out in those regulations for the 2024-25 financial year by 4.7 per cent. In addition to this indexation-based increase of 4.7 per cent, the Regulations also implement an additional increase of up to 4.43 per cent to certain annual charges to support the cost recovery of costs associated with digital transformation and the development and implementation of the Unique Device Identification (UDI) scheme to improve the traceability and identification of problems with medical devices in Australia.

The 4.7 per cent increase is based on an indexation formula used to calculate adjustments to TGA fees and charges in most previous years. The formula comprises the Australian Bureau of Statistics' Consumer Price Index (50 per cent) and Wage Price Index (50 per cent) (in this case, for the year to September 2023). These increases are in line with the TGA's cost recovery model. The additional increase for certain charges of up to 4.43 per cent is based on calculations for cost recovery of the Government's $23.3 million investment in digital transformation and the development and implementation of the UDI scheme over 5 financial years from FY 2023-24 to FY 2027-28.

The Regulations complement the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2024* which, among other things, increase most fees for therapeutic goods for 2024-25 by the 4.7 per cent indexation rate. The Regulations also reduce the annual charges for certain types of prescription medicines (containing thalidomide, leflunomide, lenalidomide, mifdepristone, clozapine and isotretinoin), to better reflect decreases in the costs of regulatory activities for these goods.

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 on 1 July 2024.

Consultation

In relation to consultation, the TGA held bilateral meetings with 13 key industry representative bodies in November-December 2023 on the 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 but did not support additional increases to TGA charges to facilitate cost recovery of the TGA's digital transformation and business systems or the implementation of the UDI scheme. Industry also maintained the concerns it raised last year in respect of the cost recovery of the $23.3 million investment in the TGA's digital and business and UDI systems.

The TGA also undertook public consultation, releasing a consultation paper on the TGA website for a month seeking submissions by 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.

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 5(1) of the *Therapeutic Goods (Charges) Act 1989*

ATTACHMENT A

Details of the *Therapeutic Goods (Charges) Amendment (2024 Measures No. 1) Regulations 2024*

Section 1 – Name
This section provides that the title of the Regulations is the *Therapeutic Goods (Charges) Amendment (2024 Measures No. 1) Regulations 2024*.

Section 2 – Commencement
This section provides that the Regulations commence on 1 July 2024.

Section 3 – Authority
This section provides that the Regulations are made under the *Therapeutic Goods (Charges) Act 1989*.

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 (Charges) Regulations 2018

The Regulations increase all annual charges relating to the inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (the Register), and licences to manufacture therapeutic goods, that are prescribed by the *Therapeutic Goods (Charges) Regulations 2018* (the Charges Regulations) for the 2024-25 financial year. The total rate of increase that is applied to each annual charge depends on the kind of therapeutic good or licence to which the charge relates. This is because the overall increase to annual charges for the 2024-25 financial year consists of multiple components, not all of which apply uniformly to all annual charges.

The first component, which applies to all annual charges, is an increase of 4.7 per cent, based on a composite indexation formula that has been used to calculate adjustments to the Therapeutic Goods Administration (TGA) fees and charges in previous years. The formula combines the Australian Bureau of Statistics' Wages Price Index (WPI) (50 per cent) (in this case, for the year to September 2023) and Consumer Price Index (CPI) (50 per cent) (also for the same period).

The second component is an increase of up to 4.43 per cent which applies to annual charges for cost recovery of the costs associated with digital transformation and the implementation of the Unique Device Identification (UDI) scheme. A different percentage increase applies to different annual charges, and the rates are as follows:

- Medicines and biologicals – 2.01 per cent;
- Medical devices other than in vitro diagnostic (IVD) medical devices - Class IIa and above (including implantable medical devices) – 4.43 per cent;
- Medical devices - Class I (including measuring and sterile devices), and all classes of IVD medical devices – 2.68 per cent; and

- Other annual charges – 1.60 per cent.

An increase of 1.75 per cent was applied to charges for Class II and above medical devices to recover the costs of implementing the UDI scheme which relates to such devices. To cost recover for digital transformation, an increase of 2.01 per cent was applied to charges for medicines and biologicals, an increase of 2.68 per cent was applied to medical devices and an increase of 1.60 per cent was applied to other charges.

Items [1]-[23], [25]-[26] and [28]-[29]
These items amend each of the amounts of annual charges prescribed in the Charges Regulations, in relation to inclusion of therapeutic goods in the Register and in relation to manufacturing licences, from 1 July 2024. An increase of 4.7 per cent applies to all annual charges, based on a composite indexation formula (combining CPI and WPI for the year to September). An additional increase of up to 4.43 percent applies to certain charges for cost recovery of the costs associated with digital transformation and the development and implementation of the UDI scheme.

Items [24] and [27]
These items repeal subsection 8(3) in the Charges Regulations to reflect that the higher charge amount is no longer be payable where the condition contained in the subsection is met, and to make consequential editorial amendments.

The higher annual charge is currently prescribed for specified medicines as there are significant risk management activities associated with these medicines. However, risk minimisation programs for these medicines are now well established and require less regulatory oversight. Therefore, a reduced annual charge is provided.

The reduced charge applies to goods containing one or more of the following ingredients, subject to other conditions prescribed in subsections 8(4) to (10) of the Charges Regulations:

- Thalidomide.
- Leflunomide.
- Lenalidomide.
- Mifepristone.
- Clozapine.
- Isotretinoin.

ATTACHMENT B

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Therapeutic Goods (Charges) Amendment (2024 Measures No. 1) 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 legislative instrument

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The main purpose of the *Therapeutic Goods (Charges) Amendment (2024 Measures No. 1) Regulations 2024* (the Regulations) is to amend the *Therapeutic Goods (Charges) Regulations 2018* (the Charges Regulations) to increase the annual charges that are set out in those regulations for the 2024-25 financial year by 4.7 per cent. In addition to this indexation-based increase of 4.7 per cent, the Regulations also implement an additional increase of up to 4.43 per cent to certain annual charges to support the cost recovery of costs associated with digital transformation and the development and implementation of the Unique Device Identification (UDI) scheme to improve the traceability and identification of problems with medical devices in Australia.

The 4.7 per cent increase is based on an indexation formula used to calculate adjustments to TGA fees and charges in most previous years. The formula is comprised of the Australian

Bureau of Statistics' Consumer Price Index (50 per cent) and Wage Price Index (50 per cent) (in this case, for the year to September 2023). These increases are in line with the TGA's cost recovery model. The additional increase for certain charges of up to 4.43 per cent is based on calculations for cost recovery of the Government's $23.3 million investment in digital transformation and the development and implementation of the UDI scheme over 5 financial years from FY 2023-24 to FY 2027-28.

The Regulations complement the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2024* which, among other things, increase most fees for therapeutic goods for 2024-25 by the 4.7 per cent indexation rate. The Regulations also reduce the annual charges for certain types of prescription medicines (containing thalidomide, leflunomide, lenalidomide, mifdepristone, clozapine and isotretinoin), to better reflect decreases in the costs of regulatory activities for these goods.

Human rights implications

As the Regulations do not introduce any changes to the Charges 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