

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods (Charges) Act 1989*

#### *Therapeutic Goods (Charges) Amendment (2022 Measures No. 1) Regulations 2022*

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 (the Department), 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 in part that the regulations may prescribe different charges in relation to different classes of goods (including medical devices) or, in the case of annual licensing charges, for different steps in the manufacture of therapeutic goods.

Section 4 of the Act provides that annual charges of such amounts as are prescribed are payable in respect of therapeutic goods on the Register, as well as in respect of 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 single annual charge as is prescribed will apply for maintaining all the registered or listed goods covered under the same group.

The main purpose of the *Therapeutic Goods (Charges) Amendment (2022 Measures No. 1) Regulations 2022* (the Regulations) is to amend the *Therapeutic Goods (Charges) Regulations 2018* (the Charges Regulations) to increase the annual charges set out in those regulations for most products by 2.6 per cent, for the financial year 2022-23. The Regulations complement the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2022* which increase fees for therapeutic goods for 2022-23 by the same rate. The implementation of the proposed increase through two separate instruments reflects that the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2022* amends the *Therapeutic Goods Regulations 1990* and the *Therapeutic Goods (Medical Devices) Regulations 2002*, which are made under the *Therapeutic Goods Act 1989* and, relevantly, impose fees for services, while the Charges Regulations are made under the *Therapeutic Goods (Charges) Act 1989* (and impose taxes).

The increase applies to annual charges relating to the registration, listing or inclusion of therapeutic goods in the Register. This encompasses registered goods (including provisionally registered medicines), listed goods, biologicals and medical devices.

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). This increase is in line with the TGA’s cost recovery model.

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

**Details of the *Therapeutic Goods (Charges) Amendment (2022 Measures No. 1) Regulations 2022***

**Section 1 – Name**

This section provides for the Regulations to be referred to as the *Therapeutic Goods (Charges) Amendment (2022 Measures No. 1) 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 (Charges) Act 1989*.

**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 (Charges) Regulations 2018***

**Items [1]-[27]**

These items amend each of the amounts of annual charges prescribed in the *Therapeutic Goods (Charges) Regulations 2018* (the Charges Regulations) by 2.6 per cent, from 1 July 2022.

## Statement of Compatibility with Human Rights

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

### ***Therapeutic Goods (Charges) Amendment (2022 Measures No. 1) Regulations 2022***

The *Therapeutic Goods (Charges) Amendment (2022 Measures No. 1) 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 5(1) of the *Therapeutic Goods (Charges) Act 1989* (the Act). The main purpose of the Regulations is to amend the *Therapeutic Goods (Charges) Regulations 2018* (the Charges Regulations) to increase the annual charges set out in those regulations for most products by 2.6 per cent, for the financial year 2022-23. The Regulations complement the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2022*, which increase fees for therapeutic goods for 2022-23 by the same rate.

The increase applies in particular to annual charges relating to the registration, listing or inclusion of therapeutic goods in the Australian Register of Therapeutic Goods. This encompasses registered goods (including provisionally registered medicines), listed goods, biologicals and medical devices.

The 2.6 per cent increase is based on an indexation formula used to calculate adjustments to Therapeutic Goods Administration (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). This increase is in line with the TGA's cost recovery model.

#### **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.

**Greg Hunt, Minister for Health and Aged Care**