EXPLANATORY STATEMENT

Therapeutic Goods (Charges) Act 1989

Therapeutic Goods (Charges) Amendment (2017 Measures No. 1) Regulations 2017

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. The Therapeutic Goods Administration (TGA), which is part of the Department of Health, is responsible for administering the Act.

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, 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 number, a single annual charge as is prescribed will apply for maintaining all the registered goods covered under the same group.

Subsection 5(1) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing the amounts of charges. Under subsection 5(2) of the Act, the Governor-General may prescribe different levels of charges for different classes of goods or, in the case of annual licensing charges, for different steps in the manufacture of therapeutic goods.

The purpose of the *Therapeutic Goods (Charges) Amendment (2017 Measures No. 1) Regulations* 2017 (the Regulations) is, principally, to amend the *Therapeutic Goods (Charges) Regulations 1990* (the Charges Regulations) to increase annual charges by 1.65 per cent for the financial year 2017-18, with some exceptions, and also to introduce an annual charge for certain in-vitro diagnostic medical devices (IVDs) from 1 July 2017.

The increase applies to annual charges relating to the registration, listing or inclusion of therapeutic goods in the Register. This encompasses registered goods, listed goods, biologicals and Class 1 medical devices. The Regulations, however, reduce annual charges for medical devices other than some Class I medical devices, in recognition that annual charges revenue from medical devices has been higher than expected following the introduction of the Annual Charges Exemption (ACE) scheme on 1 July 2015. Annual charges for manufacturing licences are also covered by the increase of 1.65 per cent.

The 1.65 per cent figure for the 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' Wage Price Index (50 per cent) (in this case, for the year to September 2016) and Consumer Price Index (50 per cent)) (also for the year to September 2016).

This increase ensures that the TGA is able to continue to recover its costs of administering the *Therapeutic Goods Act 1989*.

In applying these increases, the following rounding policy has been applied:

- for charge items that are less than $10,000 - to the nearest $10; and
- for charge items that are greater than or equal to $10,000 - to the nearest $100.

Details of the Regulations are set out in the Attachment.

The Act does not specify conditions that need to be met before the powers under the Act 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 2017.

Consultation

Consultation on the proposals to increase TGA charges by 1.65 per cent, reduce charges for medical devices other than Class 1 devices by 4.96 per cent and introduce an annual charge for IVD medical devices from 1 July 2017 was undertaken at bilateral meetings with industry representative bodies in February 2017. The representative bodies - Medicines Australia, the Generic and Biosimilar Medicines Association, AusBiotech, the Medical Technology Association of Australia, IVD Australia, the Australian Dental Industry Association (ADIA), the Australian Self-Medical Industry, Complementary Medicines Australia and Accord Australasia - did not object to the proposal. ADIA advised that the decrease in annual charges for some medical devices, when coupled with the previous 5 percent reduction in charges for medical devices classified as Class IIa and above that was introduced on 1 July 2015, would result in minimal residual impact associated with the introduction of the TGA's ACE scheme on 1 July 2015.

Authority: Subsection 5(1) of the *Therapeutic Goods (Charges) Act 1989*.

ATTACHMENT

Details of the *Therapeutic Goods (Charges) Amendment (2017 Measures No. 1) Regulations 2017*

Section 1 – Name
This section provides that the title of the Regulations is the *Therapeutic Goods (Charges) Amendment (2017 Measures No. 1) Regulations 2017.*

Section 2 – Commencement
This section provides for the Regulations to commence on 1 July 2017.

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 1990

Item 1 – Paragraph 3(1B)(e)
Item 1 provides for an annual charge of $660 for all classes of in-vitro diagnostic medical devices (IVDs) required to be included in the Register, except for Class 4 in-house IVDs.

A new framework for the regulation of IVDs was introduced in 2010. As part of the transitional arrangements for the introduction of this new framework, it was determined that annual charges for IVDs would not commence until after the end of the transition period on 30 June 2017. As such, there is now a need to introduce an appropriate annual charge – in the amount of $660 - for all classes of IVDs required to be included in the Register, except for Class 4 in-house IVDs.

This charge reflects the expected staff effort of personnel in the Medical Devices and Laboratories Branches, and the Advertising Unit, of the Department's Health Products Regulation Group that are likely to be involved in monitoring the numbers of relevant entries in the Register for these products.

Class 4 in-house IVDs will not attract an annual charge, as they will be exempt under the Annual Charges Exemption scheme (ACE scheme) because they are for in-house use by laboratories only and are not for sale, whereas under the ACE scheme a sponsor's liability for annual charges is, principally, based on the turnover of their products.

Item 2 - Amendments of listed provisions
Item 2 sets out a table of amendments to listed provisions of the *Therapeutic Goods (Charges) Regulations 1990* (the Charges Regulations).

The effect of these amendments is to increase all annual charges for therapeutic goods and manufacturing licences by 1.65 per cent, subject to the TGA's rounding policy, from 1 July 2017, and subject to a reduction in annual charges for some medical devices.

When the ACE scheme commenced on 1 July 2015, annual charges for several types of entries in the Australian Register of Therapeutic Goods (the Register) were reduced to minimise the impact of the new scheme:

- non-biological prescription medicines (other than generic medicines) - 5 per cent;
- non-biological prescription medicines (generic medicines) – 23 per cent; and
- medical devices classified as class IIA and above – 5 per cent.

On introduction of the ACE scheme, the TGA committed to monitor the impact of the new scheme on the therapeutic goods industry and adjust annual charges, if needed, to ensure appropriate cost recovery from each industry sector.

After a full year of operation, an impact assessment of the new scheme was undertaken which suggested that annual charges revenue from medical devices was higher than forecast, due to lower than anticipated cancellations of entries from the Register. It was therefore proposed to further reduce annual charges for medical devices (other than class 1 medical devices covered by paragraph 3(1B)(a) of the Charges Regulations, which currently incur an annual charge of $80 and are not to change as part of these amendments) by 6.5 percent, subject to the general indexation increase of 1.65 per cent to all TGA fees and charges- resulting in an overall reduction in annual charges for most medical devices of 4.96 per cent.

Item 26 of the table makes an amendment to the note to subregulation 3(3) of the Charges Regulations.

This note refers to the fact that under regulation 43AAJ of the *Therapeutic Goods Regulations 1990* (the TG Regulations), the annual charge for a manufacturing licence under Part 3-3 of the *Therapeutic Goods Act 1989* (other than a licence to manufacture human blood and blood components) that is payable by a person whose wholesale turnover of goods in a financial year is not more than $94,500, is half the amount mentioned in subregulation 3(2) of the Charges Regulations. Subregulation 3(2) of the Charges Regulations lists annual charges for manufacturing licences.

Item 26 of the table replaces the current reference in this note to the amount of $94,500 with a reference to the proposed updated amount of $96,100, for 2017-18. This ensures consistency with changes to the TG Regulations that also commence on 1 July 2017, which include an amendment to regulation 43AAJ of the TG Regulations to increase the wholesale turnover threshold mentioned above, from $94,500 to $96,100.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Charges) Amendment (2017 Measures No.1) Regulations 2017

The *Therapeutic Goods (Charges) Amendment (2017 Measures No.1) Regulations 2017* (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 Charges Act). The purpose of the Regulations is, principally, to amend the *Therapeutic Goods (Charges) Regulations 1990* (the Charges Regulations) to increase TGA annual charges by 1.65 per cent for the financial year 2017-18, with some exceptions, and also to introduce an annual charge for certain IVD medical devices from 1 July 2017.

The increase applies to annual charges relating to the registration, listing or inclusion of therapeutic goods in the Register. This encompasses registered goods, listed goods, biologicals and Class 1 medical devices. The Amendment Regulations, however, reduce annual charges for medical devices other than some Class I medical devices, in recognition that annual charges revenue from medical devices has been higher than expected following the introduction of the Annual Charges Exemption (ACE) scheme on 1 July 2015. Annual charges for manufacturing licences are also covered by the increase of 1.65 per cent.

The 1.65 per cent figure is based on a formula used to calculate adjustments to TGA fees and charges in most previous years, and is based on the Australian Bureau of Statistics' Wage Price Index (50 per cent) (in this case, for the year to September 2016) and Consumer Price Index (50 per cent)) (also for the year to September 2016). This increase is designed to ensure that the TGA is able to continue to recover its costs of administering the *Therapeutic Goods Act 1989*.

Human rights implications

As the Regulations do not introduce any changes to the Charges Regulations other than to implement the changes outlined above, it does not engage any of the applicable rights or freedoms.

Conclusion

This legislative instrument is compatible with human rights as it does not raise any human rights issues.

Greg Hunt, Minister for Health