

## **REPLACEMENT EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

### *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2020*

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 (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.

Amongst other matters, 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 2020* (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 the fees set out in those respective regulations by 1.95 per cent, for the financial year 2020-21.

The increase applies, for example, to: application fees for the registration, listing or inclusion of therapeutic goods (including medicines, biologicals and medical devices) 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; 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.

Fees relating to conformity assessments and abridged conformity assessments of medical devices (these are assessments of the quality of a medical device manufacturer's manufacturing process and of the product design of a medical device), and application fees for conformity assessment certificates for medical devices, are also covered by the increase.

These fees are designed to reflect the full recovery of the costs of administering the Act, consistent with the Australian Government Cost Recovery Guidelines.

The 1.95 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 2019) and Consumer Price Index (50 per cent) (also for the same period).

In applying this increase, the following rounding policy has been applied:

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

In addition, the Regulations also:

- introduce a new fee structure for requests to the Secretary for consent to import, supply or export therapeutic goods that do not comply with an applicable standard or, for medical devices, that do not comply with the essential principles (these are minimum benchmarks of safety and performance for devices), particularly to clarify the fees that apply where such requests involve more than one entry in the Register;
- introduce an exemption from entry in the Register for medicinal cannabis products that are manufactured in Australia under a licence granted under Part 3-3 of the Act and held under the direct control of the sponsor until a relevant pathway for the use of unapproved therapeutic goods applies or, where an application for the registration or listing of the products has been submitted, a decision has been made on that application. This is intended to more closely align the regulation of such products with existing arrangements for imported therapeutic goods, to ensure a more level playing field between imported medicinal cannabis products and such products manufactured in accordance with good manufacturing practice; and
- remove a small number of fees relating to therapeutic devices, to reflect that therapeutic devices have been a superseded product category for quite some time.

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 2020.

## **Consultation**

In relation to consultation, the TGA held bilateral meetings with 13 key industry representative bodies in December 2019 to consult on the proposed revision of TGA fees and charges for 2020-21. The industry bodies included Medicines Australia (MA), the Generic and Biosimilar Medicines Association (GBMA), AusBiotech, the Medical Technology Association of Australia (MTAA), Consumer Healthcare Products Australia (CHPA), Complementary Medicines Australia (CMA) and Accord Australasia. A majority of the bodies indicated their support for the proposed 1.95 per cent increase. The TGA also undertook public consultation to obtain broader stakeholder feedback, with a consultation paper released on the TGA website ([www.tga.gov.au](http://www.tga.gov.au)) and submissions sought from 20 January 2020 to 28 February 2020. 8 submissions on the proposed increase were received (6 from industry representative bodies and 2 from sponsors), of which 4 indicated support for the proposed increase. CMA, and 2 industry representative bodies in the medical devices sector (Assistive Technology Suppliers Australia and Pathology Technology Australia), did not support the increase, in light (respectively) of the likely impact of COVID-19 on business and the economy, and increasing costs of doing business in the device sector. The Australasian Leukaemia and Lymphoma Group, a not for profit organisation that sponsors clinical trials, did not support the increase and requested that fee increases not apply to not for profit organisations.

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

**Details of the Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2020**

**Section 1 – Name**

This section provides for the Regulations to be referred to as the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2020*.

**Section 2 – Commencement**

This section provides for the commencement of the Regulations on 1 July 2020.

**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 this instrument 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**

**Part 1 – Fees**

***Therapeutic Goods (Medical Devices) Regulations 2002***

**Item 1 – Amendments of listed provisions**

This item sets out a table of amendments to listed provisions of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations).

The effect of these amendments is to increase the fees for all relevant items by 1.95 per cent, subject to the TGA's rounding policy.

***Therapeutic Goods Regulations 1990***

**Item 2 – Amendments of listed provisions**

This item sets out a table of amendments to listed provisions of the *Therapeutic Goods Regulations 1990* (the TG Regulations).

The effect of these amendments is to increase the fees for all relevant items by 1.95 per cent, subject to the TGA's rounding policy.

**Part 2 – Other Measures**

***Therapeutic Goods (Medical Devices) Regulations 2002***

### **Item 3 – Part 1 of Schedule 5 (table item 1.15)**

Sections 41MA and 41MAA of the Act set out criminal offences and a civil penalty provision for the importation into, supply in or exportation from, Australia of a medical device that does not comply with the essential principles (these are minimum benchmarks of safety and performance for medical devices).

However, the Secretary may consent, under sections 41MA and 41MAA of the Act, to the import, supply or export of medical devices that do not comply with the essential principles, and section 41MC of the Act makes it clear that the Secretary's consent in this regard may be given unconditionally or subject to conditions, or in respect of particular medical devices or kinds of medical devices.

Item 1.15 of Part 1 of Schedule 5 to the MD Regulations sets out a fee of \$460 for applications for the consent of the Secretary to the importation into Australia, supply for use in Australia or exportation from Australia of a medical device (including an in vitro diagnostic medical device).

Concerns have arisen over the potential uncertainty of the current terms of item 1.15, particularly when applications for consent involve more than one medical device or more than one kind of medical device.

To address such concerns, this item repeals this fee item and substitutes a new item 1.15 that sets out a new, tiered structure for fees for applications for the Secretary's consent to the importation, supply or exportation of medical devices that do not comply with the essential principles.

Under this new approach:

- the 2020-21 fee of \$490 will apply for an application that involves a single entry in the Register (under new paragraph 1.15(a));
- that fee, plus a fee of \$100 per additional entry, will apply for applications involving more than one entry in the Register – provided that the way in which the devices in those entries do not comply with the essential principles is the same (under new paragraph 1.15(b)).

For example:

- if an application involves medical devices covered by a single entry in the Register, the fee will be \$490 (irrespective of how many individual devices within that entry are involved); and
- if an application involves medical devices from 3 entries in the Register and non-compliance with essential principle 13 for all the devices to which the application relates (essential principle 13 is in clause 13 of Schedule 1 to the MD Regulations, and sets out requirements for information that must be provided with medical devices), the fee payable will be  $\$490 + \$100 \times 2 = \$690$ ;
- if an application involves medical devices from 2 entries in the Register and the devices differ in the way in which they do not comply with the essential principles (e.g. if the devices from one entry do not comply with essential principle 1 (general principles) and the devices from the other entry do not comply with essential principle 13 (information to be provided with medical devices), the fee payable will be  $\$490 + \$490 = \$980$ .

The fee of \$490 (and the overall structure of the revised item 1.15 including the additional fee of \$100 per additional entry for common non-compliance applications) has been determined on the basis of the work involved for the Department’s Medical Devices Surveillance Branch to process such requests.

### ***Therapeutic Goods Regulations 1990***

#### **Item 4 – Regulation 2**

This item amends the TG Regulations to introduce, for the purposes of the amendment made by item 5 below, a definition of medicinal cannabis products.

The definition identifies that such products are therapeutic goods that contain, or are manufactured from, any part of a plant of the genus *Cannabis*, including for example, the flowers, fruiting tops, seeds, stems and leaves of the plant.

This definition is based on, and combines, the definitions of medicinal cannabis products and cannabis plant in *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017*, the principal quality standard for such products in Australia, made by the Minister under section 10 of the Act.

#### **Items 5-8 – Subregulation 45AA(1) and subparagraphs 45AA(4)(c)(ii)-(iii)**

Item 5 makes a minor, consequential amendment to subregulation 45AA(1) to remove the reference to fee items 6 or 7 of Part 2 of Schedule 9 to the TG Regulations, to reflect the amendment made by item 16 below.

Items 6-8 make related consequential amendments to subparagraphs 45AA(4)(c)(ii) and (iii), to remove references to therapeutic devices and subsection 25(3) of the Act, to reflect the amendment made by item 22 below and the removal of references to this redundant product category.

#### **Item 9 – Schedule 5A (table item 1A, columns 3, subparagraph (a)(ii))**

This item makes a minor amendment to subparagraph (a)(ii) of item 1A of Schedule 5A to the TG Regulations, to replace “supply” with “give” in that subparagraph, for improved clarity and greater consistency with the terminology of items 1 and 13 of Schedule 5A, and with the amendments introduced by item 10 below.

#### **Item 10 – Schedule 5A (after table item 1A)**

Item 1 of Schedule 5A to the TG Regulations has the effect of exempting therapeutic goods that are imported into Australia from the requirement to be registered, listed or included in the Register if:

- the goods are held under the direct control of the sponsor until one of the pathways for the supply of unapproved therapeutic goods identified in paragraphs (a)-(d) of column 2 of item 1 applies (e.g. supply to a patient by a medical practitioner authorised by the Secretary under subsection 19(5) of the Act), or the goods are exported from Australia; and
- the conditions in column 3 of item 1 are complied with - in particular, in relation to ensuring that the goods are kept in a warehouse or properly secured area, and that records of the source and supply of the goods are maintained.

In practice, this has meant that imported medicinal cannabis products are able to be brought into Australia and held in warehouses or sponsors' premises, ready to be released for supply when one of the unapproved pathways applies, but medicinal cannabis products that are manufactured in Australia are not able to be the subject of such preparatory arrangements.

This item is designed to address this imbalance, by introducing a similar exemption to item 1 to Schedule 5A, for medicinal cannabis products that are manufactured in Australia under a licence granted under Part 3-3 of the Act and held under the sponsor's direct control until supply under an unapproved pathway.

The new item will not cover such products that are held for supply under the Special Access Scheme Category A where product supply to a seriously ill patient is notified to the TGA. This is to ensure consistency with the effect of section 11K of the *Narcotic Drugs Act 1967* (the ND Act), which precludes the Secretary from granting a manufacture licence under the ND Act for supply for treatment of a Category A patient (such licences are distinct from licences issued under Part 3-3 of the Act).

The new item also does not cover such products that are held under a sponsor's control until they are exported, as this could undermine the proper controls and checks associated with such products being the subject of an application for entry in the Register if they are intended for export.

The same conditions that apply in item 1 of Schedule 5 (relevantly) apply to the new item, in relation principally to ensuring that the products are kept in a warehouse or properly secured area under the sponsor's control, and that records relating to their source and supply are maintained and given to the Secretary if requested.

Separately, for consistency this item also introduces a new item 2A to Schedule 5A to the TG Regulations, to provide a similar mechanism for medicinal cannabis products that are manufactured in Australia under a licence granted under Part 3-3 of the Act and held under the sponsor's direct control until a decision is made to register or list them in the Register under section 25 or 26 of the Act.

This ensures symmetry of the arrangements for such products with the existing exemption for imported therapeutic goods provided in item 1A of Schedule 5A. However, the condition that applies at subparagraph (b)(i) of item 1A that products that are imported in reliance on item 1A must be destroyed if the goods are not entered in the Register is not included in the new item 2A, as this would preclude such products from being available through one of the unapproved pathways under new item 2 (outlined above).

#### **Item 11 – Schedule 5A (table item 3, column 3, paragraph (b))**

This item makes a minor, consequential amendment to paragraph (b) of column 3 of table item 3 in Schedule 5A to the TG Regulations to remove the reference to fee item 14A of Part 2 of Schedule 9 to the TG Regulations, to reflect the amendment made by item 26 below.

#### **Item 12 – Clause 3 of Schedule 9 (table item 1A)**

This item amends Schedule 9 to the TG Regulations to repeal and substitute current fee item 1A of Schedule 9 to introduce an equivalent new fee item for registered or listed therapeutic goods (principally, these are medicines) as that outlined for medical devices in item 3 above, in relation to fees for applications to the Secretary for consent to import, supply or export

registered or listed therapeutic goods that do not comply with an applicable standard (under sections 14 and 14A of the Act).

The fee of \$490 (and the overall structure of the revised item 1.15 including the additional fee of \$100 per additional entry for common non-compliance applications) has been determined on the basis of the work involved for the Department's Complementary and Over the Counter Medicines Branch, Prescription Medicines Authorisation Branch, Scientific Evaluation Branch or Laboratories Branch to process such requests.

**Items 13 – 19 – Clause 3 of Schedule 9 (table item 1, columns 2 and 3, paragraphs (c) and (d) and table item 2, columns 2 and 3, paragraph (g))**

These items amend Schedule 9 to the TG Regulations to repeal paragraphs (c) and (d) of table item 1 of the table in Part 2 of Schedule 9, the reference to “therapeutic devices” in subparagraph (d)(i) of item 1 and paragraph (g) of item 2 of that table - with the effect of omitting or repealing references in that table to therapeutic devices.

‘Therapeutic device’ has been a superseded product category for quite some time, as it reflects that the products that are now known as medical devices were regulated as therapeutic devices, before Chapter 4 was added to the Act in 2002 by the *Therapeutic Goods Amendment (Medical Devices) Act 2002* (the 2002 Amendment Act) to introduce a specific regulatory regime for such products. The transitional arrangements associated with the 2002 Amendment Act ended in 2007.

**Items 20 – 22 – Clause 3 of Schedule 9 (table items 2A, 4 (paragraphs aa and bb), 6, 6AD, 7, 9B, 9C and 14A)**

These items amend a number of table items in the table in Part 2 of Schedule 9 to the TG Regulations, with the effect of omitting or repealing references in that table to therapeutic devices, as this is a superseded product category that has not been in use for some time.

Table item 2A is amended to remove references to registered or listed therapeutic devices, paragraphs (aa) and (bb) of item 4 are amended to remove references to therapeutic devices and items 6, 6A, 7, 9B and 9C are repealed.

**Item 23 – Clause 3 of Schedule 9 (table item 9D)**

This item makes a minor, consequential amendment to repeal and substitute item 9D of the table in Part 2 of Schedule 9 to the TG Regulations, to remove the references in that item to items 6, 7 or 9B of that table, to reflect the amendments made by item 22 above.

This item also has the effect of removing the reference in item 9D to item 5A of that table, as there is no item 5A in the table in Part 2 of Schedule 9.

**Items 24 and 25 – Clause 3 of Schedule 9 (table items 12 and 13, column 3)**

These items make minor, consequential amendments to remove the references to items 6 or 7 of the table in Part 2 of Schedule 9 from each of items 12 and 13 of that table, to reflect the amendments made by item 22 above.

**Item 26 – Clause 3 of Schedule 9 (table item 14A)**

This item amends the table in Part 2 of Schedule 9 to the TG Regulations to repeal item 14A from that table, as that fee item relates to the notification of a clinical trial involving

therapeutic devices. Consistent with the amendments outlined above, this item removes item 14A to reflect that therapeutic devices are a superseded product category.

**Item 27 – Part 2 of Schedule 9A (after table item 11)**

This item amends Schedule 9A to the TG Regulations (which sets out fees relating to biologicals) to repeal and substitute current fee item 11A of Schedule 9A and introduce an equivalent new fee item for biologicals as that outlined for medical devices in item 3 and for registered or listed goods in item 12 above, in relation to fees for applications to the Secretary for consent to import, supply or export biologicals that do not comply with an applicable standard (under sections 14 and 14A of the Act).

The fee of \$490 (and the overall structure of the revised item 1.15 including the additional fee of \$100 per additional entry for common non-compliance applications) has been determined on the basis of the work involved for the Department's Scientific Evaluation Branch to process such requests.

## 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 2020***

The *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2020* (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 Act). The purpose of 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 the fees set out in those respective regulations by 1.95 per cent, for the financial year 2020-21.

The increase applies, for example, to: application fees for the registration, listing or inclusion of therapeutic goods (including medicines, biologicals and medical devices) 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; 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. Fees relating to conformity assessments and abridged conformity assessments of medical devices (these are assessments of the quality of a medical device manufacturer's manufacturing process and of the product design of a medical device), and application fees for conformity assessment certificates for medical devices, are also covered by the increase.

These fees are designed to reflect the full recovery of the costs of administering the Act, consistent with the Australian Government Cost Recovery Guidelines.

The 1.95 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 2019) and Consumer Price Index (50 per cent) (also for the same period).

In applying this increase, the following rounding policy has been applied:

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

In addition, the Regulations also:

- introduce a new fee structure for requests to the Secretary for consent to import, supply or export therapeutic goods that do not comply with an applicable standard or, for medical devices, that do not comply with the essential principles (these are minimum benchmarks of safety and performance for devices), particularly to clarify the fees that apply where such requests involve more than one entry in the Register;
- introduce an exemption from entry in the Register for medicinal cannabis products that are manufactured in Australia under a licence granted under Part 3-3 of the Act and held

under the direct control of the sponsor until a relevant pathway for the use of unapproved therapeutic goods applies or, where an application for the registration or listing of the products has been submitted, a decision has been made on that application. This is intended to more closely align the regulation of such products with existing arrangements for imported therapeutic goods, to ensure a more level playing field between imported medicinal cannabis products and such products manufactured in accordance with good manufacturing practice; and

- remove a small number of fees relating to therapeutic devices, to reflect that therapeutic devices have been a superseded product category for quite some time.

### **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.

**Greg Hunt, Minister for Health**