

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Amendment (2018 Measures No. 1) Regulations 2018

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.

Under section 16 of the Act, medicines are taken to be separate and distinct from one another if they are different in a number of specified ways, for instance if they have a different name, different dosage form or model or have different indications or directions for use.

The purpose of the *Therapeutic Goods Amendment (2018 Measures No.1) Regulations 2018* (the Regulations) is to amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) to allow the Secretary of the Department of Health to reduce the application and evaluation fees that would otherwise be payable for an application for marketing approval for a prescription medicine, in certain circumstances.

These circumstances are, principally, where:

- the applicant already has a medicine with marketing approval that is registered in the Australian Register of Therapeutic Goods (the Register), and the new medicine would be the same as the existing product except for the dosage model or directions for use;
- the Secretary is satisfied that those differences are necessary to ensure the safe use of the goods (e.g. by a particular patient group), and that the application does not require the evaluation of non-clinical or quality data; and
- the Secretary has information that would enable the application to be processed and evaluated in an abridged manner.

The Regulations also make a small number of other, more minor amendments to the TG Regulations, to:

- make a consequential amendment to remove the reference to antiperspirants from Schedule 5 to the TG Regulations, to reflect that these products were recently excluded from the scope of the regulatory regime by the Minister under section 7AA of the Act;
- introduce two fees relating to licences to manufacture therapeutic goods that were inadvertently left out of the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2018*, earlier this year (being, a fee for an application to vary the steps of manufacture that a holder of a manufacturing licence is authorised to undertake at a particular site, and a fee for an application to vary a manufacturing licence to remove a manufacturing site); and
- remove a number of redundant references to applications relating to therapeutic devices, to reflect that such products are now (and have been for some time) regulated as medical

devices under Chapter 4 of the Act and the *Therapeutic Goods (Medical Devices) Regulations 2002*.

If a sponsor of a medicine that is registered in the Register wishes to make a change to the dosage model or directions for use for safety reasons they must make a fresh application for marketing approval for that product, rather than simply treating the change as a variation to their existing medicine in the Register.

In such circumstances, significant fees apply for applications involving prescription medicines – an application fee of \$18,600 and an evaluation fee of \$74,200 (together - \$92,800). Sponsors have cited the level of these fees as a disincentive to seeking marketing approval for versions of their existing prescription medicines with such changes.

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 the day after they are registered on the Federal Register of Legislation.

Consultation

The TGA contacted peak therapeutic goods industry bodies Medicines Australia, and the Generic and Biosimilar Medicines Association directly in September 2018 in relation to the proposed introduction of the mechanism to reduce medicines fees. Both bodies indicated support for this measure.

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

Details of the *Therapeutic Goods Amendment (2018 Measures No. 1) Regulations 2018*

Section 1 – Name

This section provides for the Regulations to be referred to as the *Therapeutic Goods Amendment (2018 Measures No. 1) Regulations 2018*.

Section 2 – Commencement

This section provides for the commencement of the Regulations on the day after registration.

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

Therapeutic Goods Regulations 1990

Item 1– Subregulation 43A(1)

Subregulation 43A(1) of the *Therapeutic Goods Regulations 1990* (the TG Regulations) provides that a fee is not payable in accordance with Schedule 9 to the TG Regulations for an application for the registration or listing of a therapeutic device, if the circumstances specified in paragraphs 43A(1)(a) and (b) apply.

This reference to therapeutic devices is outdated and is no longer necessary, as these products are now regulated as medical devices under Chapter 4 of the Act and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations).

As such, this item repeals subregulation 43A(1).

Items 2 and 3 – Before subregulations 43A(2) and (4)

These items makes minor amendments to regulation 43A of the TG Regulations, to introduce a sub-heading before each of subregulations 43A(2) and (4) to improve clarity and readability.

Item 4 – Paragraph 43A(4)(d)

This item makes a minor amendment to paragraph 43A(4)(d) of the TG Regulations, to replace the current reference in that paragraph to the day that Schedule 2 to the *Therapeutic Goods Amendment (2017 Measures No.1) Act 2018* commences with a reference to 6 March 2018, as that is the day on which that Schedule of that Act commenced.

Items 5, 6, 9, 10 and 11 – Before subregulations 45(1), (2), (3A), (4) and (4AA)

These items make minor amendments to regulation 45 of the TG Regulations, to introduce a sub-heading before each of subregulations 45(1), (2), (3A), (4) and (4AA) to improve clarity and readability.

For clarification, it is noted that regulation 45 of the TG Regulations is authorised by paragraph 63(3)(b) of the Act, as this is not referred to in regulation 45 itself.

Item 7 – Paragraph 45(2)(a)

Subregulation 45(2) of the TG Regulations provides that the Secretary of the Department of Health (the Secretary) may waive or reduce an evaluation fee in Schedule 9 or 9A to the TG Regulations in relation to an application (e.g. an application for marketing approval) (other than an application relating to therapeutic goods mentioned in Part 1 of Schedule 10 to the TG Regulations – these are mainly prescription medicines) if the applicant has more than one such application and if the circumstances set out in paragraphs 45(2)(a) and (b) apply. One of these circumstances is, at subparagraph 45(2)(a)(ii), where the goods to which the applications relate are therapeutic devices.

This reference to therapeutic devices is outdated and is no longer necessary, as these products are now regulated as medical devices under Chapter 4 of the Act and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations). Accordingly, this item substitutes a new paragraph 45(2)(a) that omits the current reference in that paragraph to therapeutic devices.

Item 8 – Subregulation 45(3)

This item repeals subregulation 45(3) of the TG Regulations, as it is now spent and redundant.

Item 12 – Subregulations 45(4A), (8), (9), (10) and (11)

This item repeals subregulations 45(4A), (8), (9), (10) and (11) from the TG Regulations, as each of these subregulations relate to the reduction of fees for therapeutic devices and, as noted above, these references are now no longer required.

This item, however, also introduces an important new power for the Secretary to reduce application and evaluation fees relating to applications for the registration in the Australian Register of Therapeutic Goods (the Register) of prescription medicines, in certain circumstances.

Principally, these are where:

- the medicine is the same as another medicine that is already registered in the Register, but for differences in the dosage model or directions for use; and
- the Secretary is satisfied that the differences in the dosage model or directions for use are necessary to ensure the safe use of the medicine (e.g. by a particular patient group);
- the Secretary is satisfied that there is no need to evaluate non-clinical or quality data in connection with the application; and
- the Secretary has information relating to the medicine that would allow the preliminary assessment and evaluation of the application to be abridged.

Where these circumstances apply, the Secretary will have the power to reduce the fees payable by an applicant for the registration of such a medicine to \$1,100 (application fee) and \$4,360 (evaluation fee).

These amounts are considerably lower than the fees that would otherwise apply in respect of such applications, which would involve an application fee of \$18,600 and an evaluation fee of \$74,200 (totalling \$92,800) (items 2(bi) and 4(g) of Part 2 of Schedule 9 to the TG Regulations refer).

The introduction of the new power for the Secretary to reduce application and evaluation fees to these levels is designed to remove disincentives for sponsors of prescription medicines to apply for marketing approval of versions of their products that may be of particular benefit for patient groups who are not able to use an existing medicine safely at its current settings.

Sponsors have cited the current level of these fees as a disincentive to such action, meaning the current fees are a barrier to the availability of updated versions of these products for use by patient groups that would benefit from access to them – for example, a version of a medicine with a reduced maximum daily dose, from two tablets per day to one, so that it would be suitable for patients with renal impairment.

There may be, however, significant benefits for some patient groups in having access to existing prescription medicines with different dosage models or directions for use – for example, to reduce the maximum daily dose of a medicine from two tablets per day to one for patients with renal impairment, or those patients that are taking other medicines at the same time. As such, there is an important public health benefit in having the capacity to reduce these fees to address the concern that they may be a barrier to the availability of updated versions of these medicines.

The new fee amounts reflect the effort involved in processing and evaluating such applications for staff of the Department's Prescription Medicine Authorisation Branch and Pharmacovigilance and Special Access Branch. It is considered that this effort will be commensurate with the staff effort involved in processing certain existing requests under subsection 9D(3) of the Act to vary an entry in the Register for (principally) prescription medicines (items 2AC and 2C of Part 2 of Schedule 9 refer). In particular, the new fees reflect that in the circumstances outlined above, less processing and evaluation of such applications would be needed, as the TGA would already be familiar with the existing medicine.

A decision of the Secretary to reduce fees under new subregulation 45(6) will be subject to review and appeal rights, as it would be covered by existing paragraph 48(1)(g) of the TG Regulations.

Item 13 – Schedule 5 (table item 8, column 2, paragraph (b))

This item amends Schedule 5 to the TG Regulations, which lists therapeutic goods which are exempt from the requirement to be registered or listed in the Register, to remove the reference in that Schedule to antiperspirant preparations that derive their antiperspirant properties from inorganic salts of aluminium, zinc or zirconium only.

This reflects that these products were recently excluded from the scope of the regulatory scheme for therapeutic goods, by the *Therapeutic Goods (Excluded Goods) Determination*

2018, made a delegate of the Minister under section 7AA of the Act, which commenced on 1 October 2018 (item 2 of the table in Schedule 1 to that instrument refers).

Item 14 – Clause 3 of Schedule 9 (table item 8A)

This item amends the table in Part 2 of Schedule 9 to the TG Regulations to substitute a new item 8A of that table incorporating a minor clarification (to make it clear that the fee in that item is an application fee), and to introduce the following new manufacturing fees:

- an application fee for the purposes of paragraph 40B(7)(d) of the Act, for an application under subsection 40B(6) of the Act to vary a manufacturing site authorisation (such authorisations set out what steps of manufacture the Secretary authorises a manufacturer to undertake at their manufacturing site), in the amount of \$770; and
- an application fee for the purposes of paragraph 40B(9B)(c) of the Act, for an application under subsection 40B(9A) of the Act to vary a manufacturing licence to remove one or more manufacturing sites covered by the licence, in the amount of \$770.

In each instance, the new fee reflects the staff effort involved for staff of the Department's Manufacturing Quality Branch in processing these applications. These fees were inadvertently left out of amendments that updated TGA fees and charges for the 2018-19 financial year.

STATEMENT OF COMPATIBILITY FOR A DISALLOWABLE LEGISLATIVE INSTRUMENT THAT RAISES HUMAN RIGHTS ISSUES

Statement of Compatibility with Human Rights

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

Therapeutic Goods Amendment (2018 Measures No.1) Regulations 2018

The *Therapeutic Goods Amendment (2018 Measures No.1) Regulations 2018* (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), and amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) to allow the Secretary of the Department of Health to reduce the application and evaluation fees that would otherwise be payable for an application for marketing approval for a prescription medicine, in certain circumstances.

These circumstances are, principally, where:

- the applicant already has a medicine with marketing approval that is registered in the Australian Register of Therapeutic Goods, and the new medicine would be the same as the existing product except for the dosage model and/or directions for use;
- the Secretary is satisfied that those differences are necessary to ensure the safe use of the goods (e.g. by a particular patient group), and that the application does not require the evaluation of non-clinical or quality data; and
- the Secretary has information that would enable the application to be processed and evaluated in an abridged manner.

Under section 16 of the Act, medicines are taken to be separate and distinct from one another if they are different in a number of specified ways, for instance if they have a different name, different dosage form or model or have different indications or directions for use.

If a sponsor of a medicine that is registered in the Australian Register of Therapeutic Goods (the Register) wishes to make a change to the dosage model or directions for use for safety reasons they must make a fresh application for marketing approval for that product, rather than simply treating the change as a variation to their existing medicine in the Register.

In such circumstances, significant fees apply for applications involving prescription medicines – an application fee of \$18,600 and an evaluation fee of \$74,200 (together - \$92,800).

Sponsors have cited the level of these fees as a disincentive to seeking marketing approval for versions of their existing prescription medicines with such changes.

There may be, however, significant benefits for some patient groups in having access to existing prescription medicines with different dosage models and directions for use – for example, to reduce the maximum daily dose of a medicine from two tablets per day to one for patients with renal impairment, or those patients that are taking other medicines at the same time.

As such, there is an important public health benefit in having the capacity to reduce these fees to address the concern that they may be a barrier to the availability of updated versions of these medicines, in the circumstances outlined above.

The Regulations also make a small number of other, more minor amendments to the TG Regulations, to:

- make a consequential amendment to remove the reference to antiperspirants from Schedule 5 to the TG Regulations, to reflect that these products were recently excluded from the scope of the regulatory regime by the Minister under section 7AA of the Act;
- introduce two fees relating to licences to manufacture therapeutic goods that were inadvertently left out of the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2018*, earlier this year (being, a fee for an application to vary the steps of manufacture that a holder of a manufacturing licence is authorised to undertake at a particular site, and a fee for an application to vary a manufacturing licence to remove a manufacturing site); and
- remove a number of redundant references to applications relating to therapeutic devices, to reflect that such products are now (and have been for some time) regulated as medical devices under Chapter 4 of the Act and the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Human rights implications

The Regulations engage the right to health in article 12 of the International Covenant on Economic, Social and Cultural Rights (the ICESCR). This right is understood as the right of everyone to enjoy the highest attainable standard of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

By removing the current disincentive for medicines sponsors to apply for marketing approval for versions of their medicines with different dosage models and/or directions for use (and therefore making it more likely that medicine sponsors will apply for approval for such products, and make them available for consumers), the Regulations address the elements of the right to health that relates to the availability and accessibility of health goods, especially for patient groups who are unable to safely use existing medicines at current dosages.

Conclusion

The Regulations are compatible with human rights because they promotes the right to health in article 12 of the ICESCR as outlined above, and otherwise do not raise any human rights issues.

Greg Hunt, Minister for Health