EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Amendment (Fees for Relisted Medicine) Regulations 2019

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, and may provide for the refund, reduction or waiving of such fees.

The *Therapeutic Goods Amendment (2017 Measures No.1) Act 2018* ("the Amendment Act") amended the Act to implement a number of elements of the Government's response to the Expert Panel Review of Medicines and Medical Devices Regulation. One such measure was the introduction of a power for the Minister to make a legislative instrument specifying indications (statements of therapeutic use) considered to be safe and appropriate for listed medicines, and requirements relating to the use of such indications.

Sponsors of listed medicines (other than assessed listed medicines or export only medicines) may only use indications from this instrument for their medicines, and must certify that they will do so when applying for marketing approval by listing their medicines in the Australian Register of Therapeutic Goods ("the Register"). Such medicines may also be cancelled from the Register if they have indications that are not permitted under the instrument.

The Amendment Act included transitional provisions for medicines that were listed in the Register immediately before the commencement of Schedule 2 to the Amendment Act on 6 March 2018. Under these, sponsors of such medicines may apply to relist their medicines in the Register for a period of up to three years (i.e. until 6 March 2021).

To assist sponsors of transitioning medicines, the *Therapeutic Goods Legislation Amendment (2018 Measures No.1) Regulations 2018* amended the *Therapeutic Goods Regulations 1990* ("the Principal Regulations") to ensure that sponsors relisting their medicines would not incur the application fee in Schedule 9 to the Principal Regulations that would otherwise be payable for such applications, if they apply before 6 September 2019.

The main purpose of the *Therapeutic Goods Amendment (Fees for Relisted Medicines) Regulations 2019* ("the Regulations") is to amend the Principal Regulations to extend this fee-free period, to allow sponsors to apply before 6 March 2021 without incurring the fee.

This is designed to provide affected sponsors with more time to manage the process of relisting their medicines with indications that comply with the permitted indications instrument, and in so doing will support that process and the continued availability of such medicines for consumers.

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 will commence the day after they are registered in the Federal Register of Legislation.

Consultation

Since March 2018 the TGA has been involved in ongoing communication with listed medicine sponsors and key industry associations Complementary Medicines Australia ("CMA"), Consumer Health Products Australia ("CHP Australia") and Accord, about the management of the complementary medicines reforms introduced by the Amendment Act. This has included face to face meetings, teleconferences and written correspondence.

In particular, during discussions in April 2019, CHP Australia and CMA asked that consideration be given to extending the fee-free period beyond 6 September 2019, and in July 2019 CMA wrote to formally request that measure, based on the needs of sponsors with quite large numbers of affected medicines and the needs of smaller sponsors who do not have dedicated regulatory affairs officers to assist with relisting matters.

The Regulations address those concerns and ensure the additional time for affected sponsors.

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

ATTACHMENT A

Details of the *Therapeutic Goods Amendment (Fees for Relisted Medicine) Regulations 2019*

Section 1 – Name
This section provides for the Regulations to be referred to as the *Therapeutic Goods Amendment (Fees for Relisted Medicine) Regulations 2019* ("the Regulations").

Section 2 – Commencement
This section provides for the commencement of Regulations on the day after they are registered in the Federal Register of Legislation.

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– Paragraph 43A(4)(d)
This item amends paragraph 43A(4)(d) of the *Therapeutic Goods Regulations 1990* ("the Principal Regulations") to replace the reference in that paragraph to the fee-free period provided for in subregulation 43A(4) applying within the period of 18 months beginning on 6 March 2018 (i.e. until 6 September 2019), with a reference that would have the effect of extending that period until the end of 5 March 2021.

Item 2 – At the end of Part 9
This item introduces a new Division 11 to the Principal Regulations. The new Division sets out application and transitional provisions relating to the amendment of regulation 43A by item 1 above, in new regulation 68.

New subregulation 68(1) makes it clear that the amendment of regulation 43A by the Regulations applies in relation to applications to relist medicines that are made on or after 6 September 2019.

New subregulation 68(2) introduces a refund mechanism for sponsors who apply for relisting between 6 September 2019 and the commencement of the Regulations, to require the Secretary to refund an amount equal to the application fee paid by affected sponsors for relisting during that period.

Taken together, these two mechanisms are designed to ensure that sponsors who apply to relist their medicines in the Register between 6 September 2019 and the commencement of the Regulations, and who in so doing pay the application fee for such an application ($840, under paragraph 3(b) of Part 2 of Schedule 9 to the Principal Regulations), will not be disadvantaged in comparison to sponsors who applied before then, or who apply after the Regulations commence, for relisting.

ATTACHMENT B

Statement of Compatibility with Human Rights

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

Therapeutic Goods Amendment (Fees for Relisted Medicine) Regulations 2019

The *Therapeutic Goods Amendment (Fees for Relisted Medicine) Regulations 2019* (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* (TG Regulations), principally to extend the fee-free period introduced by the *Therapeutic Goods Legislation Amendment (2018 Measures No.1) Regulations 2018* (the "2018 Amendment Regulations") for sponsors of certain low risk medicines to apply to re-list their medicines in the Australian Register of Therapeutic Goods (the Register) without charge.

The *Therapeutic Goods Amendment (2017 Measures No.1) Act 2018* ("the Amendment Act") amended the Act to implement a number of elements of the Government's response to the Expert Panel Review of Medicines and Medical Devices Regulation. One such measure was the introduction of a power for the Minister to make a legislative instrument specifying indications (these are statements of therapeutic use) considered to be safe and appropriate for listed medicines, and requirements relating to the use of such indications.

Sponsors of listed medicines (other than assessed listed medicines or export only medicines) may only use indications from this instrument for their medicines, and must certify that they will do so when applying for marketing approval by listing their medicines in the Australian Register of Therapeutic Goods ("the Register"). Such medicines may also be cancelled from the Register if they have indications that are not permitted under the instrument.

The Amendment Act included transitional provisions for medicines that were listed in the Register immediately before the commencement of Schedule 2 to the Amendment Act on 6 March 2018. Under these, sponsors of such medicines may apply to relist their medicines in the Register for a period of up to three years (i.e. until 6 March 2021).

To assist sponsors of transitioning medicines, the 2018 Amendment Regulations amended the *Therapeutic Goods Regulations 1990* ("the Principal Regulations") to ensure that sponsors relisting their medicines would not incur the application fee in Schedule 9 to the Principal Regulations that would otherwise be payable for such applications, if they apply before 6 September 2019.

However, there is now a need to extend this period, to allow sponsors of such products more time to relist their medicines.

The main purpose of the *Therapeutic Goods Amendment (Fees for Relisted Medicines) Regulations 2019* ("the Regulations") is therefore to amend the Principal Regulations to

extend this fee-free period, to allow sponsors to apply before 6 March 2021 without incurring the fee.

This is designed to provide affected sponsors with more time to manage the process of relisting their medicines with indications that comply with the permitted indications instrument, and in so doing will support that process and the continued availability of such medicines for consumers.

Human rights implications
As the Regulations do not introduce any changes to the TG Regulations other than to implement the measures outlined above, they do 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