

REPLACEMENT EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Legislation Amendment (2021 Measures No. 1) Regulations 2021

The instrument supports the streamlining of applications for new ingredients for use in listed and assessed listed medicines, and enhance the data protection scheme for such medicines.

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, 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.

The purpose of the *Therapeutic Goods Legislation Amendment (2021 Measures No. 1) Regulations 2021* (the Regulations) is, principally, to amend the TG Regulations to support two measures introduced to the Act by the recent *Therapeutic Goods Amendment (2020 Measures No. 2) Act 2021* (the Amendment Act).

These amendments have the effect of:

- streamlining applications for the approval of a new ingredient for use in listed or assessed listed medicines, by prescribing the period after which such an application will lapse if the evaluation fee for the application remains unpaid; and
- enhancing the data protection scheme for assessed listed medicines, by prescribing clinical trial registries that sponsors and researchers may utilise in connection with the scheme to enable the publication of a subset of the clinical trial information about their products while they are being evaluated for marketing approval, without losing access to data protection.

The Regulations also make a very minor amendment to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) in relation to the transitional arrangements for the personalised medical devices reforms introduced by the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019*, to remove unnecessary and duplicative requirements for sponsors to notify the Secretary of certain information about their products in order to qualify for those arrangements.

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*, and, in most part, commence on the day after they are registered. Items 1 and 2 of Schedule 1 to the Regulations commence at the same time as Schedules 5 and 6 to the Amendment Act commence.

Consultation

A proposed one-month timeframe after which applications for the approval of new ingredients for use in listed and assessed listed medicines would lapse if the evaluation fee remains unpaid was consulted on with the Complementary and Over-the-Counter Medicines Regulatory and Technical Consultative Forum (ComTech) in June 2020. ComTech members include industry representative bodies Accord Australasia, Complementary Medicines Australia, Consumer Health Products Australia and the Generic Biosimilar Association, as well as the Association of Therapeutic Goods Consultants. ComTech members raised concerns at that meeting that a one-month timeframe would be too short.

Reflecting these concerns, a two-month timeframe was proposed at a subsequent ComTech meeting in December 2020, and there were no objections from the members. The Regulations introduce this two-month timeframe.

The TGA established an industry feedback group with industry representatives in 2020 to discuss a number of aspects of the data protection scheme for assessed listed medicines. The clinical trial registries that would be introduced by the Regulations were agreed on with members of the group at three meetings across July and August 2020. Feedback on the proposed registries was also sought from ComTech members at the December 2020 ComTech meeting, with no objections.

While the removal of duplicative notification requirements for personalised medical devices was not specifically consulted on given its minor nature, there have been some concerns from the sector in relation to duplicative requirements and, as such, it is anticipated that this measure will be welcomed as a step towards addressing such concerns.

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

Details of the *Therapeutic Goods Legislation Amendment (2021 Measures No. 1) Regulations 2021*

Section 1 – Name

This section provides for the Regulations to be referred to as the *Therapeutic Goods Legislation Amendment (2021 Measures No. 1) 2021*.

Section 2 – Commencement

This section provides for the commencement of the Regulations, in most part, on the day after they are registered. Items 1 and 2 of Schedule 1 to the Regulations commence at the same time as Schedules 5 and 6 to the Amendment Act commence.

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 instrument has effect according to its terms.

Schedule 1 – Amendments

Therapeutic Goods Regulations 1990

Item 1 – After regulation 15

This item amends the *Therapeutic Goods Regulations 1990* (the TG Regulations) to introduce new regulation 15AA, to prescribe clinical trial registries for the purposes of the data protection scheme for assessed listed medicines in section 26AF of the Act (subparagraph 26AF(2)(b)(ii) of the Act refers).

The scheme protects information about an assessed listed medicine that is listed in the Australian Register of Therapeutic Goods (the Register) under section 26AE of the Act, if the information is derived from a clinical trial relating to an indication (these are statements of therapeutic use) of the medicine and provided that a number of other specified criteria apply.

Before the enhancements made to the scheme by the *Therapeutic Goods Amendment (2020 Measures No. 2) Act 2021* (the Amendment Act), any information covered by the scheme was required to not be available to the public. Concerns were raised by industry and researchers that this was impractical and would preclude the publication of any information about clinical trials involving such medicines for the five years in which the scheme provides protection (paragraph 26AF(2)(f) of the Act refers).

Following stakeholder engagement with industry on this aspect, the Amendment Act amended the scheme to allow for a subset of such information to be published in a clinical trial registry prescribed for the purposes of subparagraph 26AF(2)(b)(ii) of the Act while such a medicine is being evaluated for marketing approval, without a person losing access to data protection (the Amendment Act also allows such information to be published more broadly after that evaluation has been completed and the medicine is listed in the Register, also without losing access to data protection).

This item gives effect to the reforms introduced by the Amendment Act in this regard, by prescribing a set of scientifically well-known clinical trial registries for the purpose of the scheme – being, a primary registry that is at any time in the World Health Organization’s International Clinical Trial Registry Platform, as such a registry exists from time to time, and the database known as ClinicalTrials.gov, as the database exists from time to time.

The World Health Organization’s International Clinical Trial Registry Platform may be accessed from the WHO website: www.who.int/clinical-trials-registry-platform. The public can access this website free of charge. The database known as ClinicalTrials.gov may also be accessed free of charge.

Paragraph 63(4)(a) of the Act provides the authority for providing for such matters on that basis.

Item 2 – After regulation 16GI

Section 26BDA of the Act sets out circumstances in which an application to vary the legislative instrument made by the Minister under section 26BB of the Act (principally, to approve the use of new ingredients for use in listed and assessed listed medicines, or to vary the terms of existing such approvals) may lapse.

One such circumstance, introduced by the Amendment Act, is where the evaluation fee for the application has not been paid before the end of the period worked out in accordance with the regulations.

This is designed to address situations where applicants do not pay the evaluation fee or delay payment of the evaluation fee, significantly delaying the evaluation of the application.

This can be particularly problematic where a number of applicants apply for the approval of the same ingredient, each seeking exclusive use of the ingredient for a period. Such applications are evaluated in the order in which they are received, provided that each application passes preliminary assessment, and if the evaluation fee remains unpaid for the “first” such application this can also delay the evaluation of subsequent applications relating to the same ingredient.

To address these concerns, and streamline the application process for new ingredients for use in listed and assessed listed medicines, this item amends the TG Regulations to prescribe, for the purposes of paragraph 26BDA(c) of the Act, a period of two months beginning on the day that the applicant is notified of the amount of their evaluation fee and of the requirement for that fee to be paid.

Item 3 – Regulation 43AAGG

Regulation 43AAGG of the TG Regulations provides that, for section 44A of the Act, Subdivision 2B of Part 7 of the TG Regulations makes provision for and in relation to waiving an annual registration charge, annual listing charge or annual charge for inclusion in the Register of therapeutic goods for a financial year.

This item makes a minor amendment to correct an error in regulation 43AAGG as to the source of power for Subdivision 2B of Part 7, to reflect that this is paragraph 63(3)(b) of the Act, rather than section 44A of the Act.

This reflects that paragraph 63(3)(b) of the Act allows the making of regulations to provide for (among other matters) the waiving of fees in cases identified in the regulations, while section 44A allows the making of regulations to provide for and in relation to exempting a person from liability to pay specified annual charges.

Schedule 2 – Amendments

Therapeutic Goods (Medical Devices) Regulations 2002

Item 1 – Subregulation 11.51(3)

This item replaces the current subregulation 11.51(3) of the MD Regulations and replaces it with a new subregulation 11.51(3), principally with the effect of removing an unnecessary and duplicative requirement for sponsors or manufacturers of patient-matched medical devices to give the Secretary certain information about their products as part of the transitional arrangements for the reforms for personalised medical devices that were introduced by the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019*.

Subregulation 11.51(3) relates to the application of new item 2.14 of Part 2 of Schedule 4 to the MD Regulations, and together subregulation 11.51(3) and item 2.14 exempt certain patient-matched medical devices from the requirement to be included in the Register, until 1 November 2024.

The effect of this item is to remove the requirement in paragraph 11.51(3)(b) of the MD Regulations for a sponsor or manufacturer of such a device to provide information to the Secretary in order for the exemption to apply.

This information is not required as, principally, it overlaps with existing requirements to provide information to the Secretary in item 2.14 itself.

This removal of paragraph 11.51(3)(b) also reflects that it relates to the provision of information to the Secretary under regulation 10.3 of the MD Regulations, which relates to the provision of information about custom-made medical devices, and that, since the commencement of the personalised medical device reforms on 25 February 2021, patient-matched medical devices and custom-made medical devices are regulated as distinct device categories.

Item 2 – Part 2 of Schedule 4 (table item 2.14)

This item makes a minor consequential amendment to item 2.14 of Part 2 of Schedule 4 to the MD Regulations to reflect the effect of item 1 above, and to make it clearer that the condition in column 3 of item 2.14 is intended to relate to the provision of the information in paragraphs (a)-(e) about patient-matched medical devices (and not to custom-made medical devices).

Statement of Compatibility with Human Rights

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

Therapeutic Goods Legislation Amendment (2021 Measures No. 1) Regulations 2021

The *Therapeutic Goods Legislation Amendment (2021 Measures No. 1) Regulations 2021* (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 *Therapeutic Goods Legislation Amendment (2021 Measures No. 1) Regulations 2021* (the Regulations) is, principally, to amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) to support two measures introduced to the Act by the recent *Therapeutic Goods Amendment (2020 Measures No. 2) Act 2021* (the Amendment Act).

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Human rights implications

The Regulations engage the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health. In General Comment No.14: The Right to the Highest Attainable Standard of Health (Art.12) (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a ‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The Regulations take positive steps to support the right to health by:

- streamlining application processes relating to (principally) the approval of new ingredients for use in listed and assessed listed medicines, and by doing so reducing the likelihood of delay for consumers in accessing new products containing such ingredients;
- supporting the development of new assessed listed medicines through enhancing the data protection scheme for such medicines and further encouraging innovation and investment in new therapeutic goods; and
- supporting the availability of patient-matched medical devices in Australia by removing unnecessary, duplicative burden for sponsors and manufacturers of such products.

Conclusion

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

Greg Hunt, Minister for Health and Aged Care