EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Legislation Amendment (2023 Measures No. 2) Regulations 2023

The Regulations extend the transitional timeframes for medical device reforms to align with recent delays in the European Union (the EU). This helps ensure the continued availability of a range of important medical devices in Australia, such as heart implants.

The *Therapeutic Goods Act 1989* (the Act) establishes and maintains a national system of controls for the quality, safety, efficacy, performance and timely availability of therapeutic goods used in, or exported from, Australia. Subsection 63(1) of the Act enables the Governor-General to make regulations, not inconsistent with the Act, prescribing matters required or permitted by the Act or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019* introduced reforms (the 2019 reforms) to reclassify certain medical devices to ensure that the level of pre-market scrutiny applied to applications for marketing approval for such products is commensurate with the risk they may pose to users, and to align with the EU.

Recent delays for equivalent EU reforms require extension of the 2019 reforms to ensure access to these products for Australian patients. The *Therapeutic Goods Legislation Amendment (2023 Measures No. 2) Regulations 2023* (the Regulations) amends the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to extend the transitional arrangements for the 2019 reforms to better align with the EU.

The Regulations also amend the MD Regulations and the *Therapeutic Goods Regulations 1990* (the TG Regulations), to implement a small number of other, more minor, measures including to:

- support the safe use of medical devices in clinical trials in Australia, by ensuring that authorised persons may enter the site of a clinical trial operating under the Therapeutic Goods Administration's (TGA) Clinical Trial Notification (CTN) scheme to verify that the supply of devices under the trial complies with good clinical practice and is safe for the trial participants;
- reduce regulatory burden for medical practitioners, and improve access to unapproved medicinal cannabis products for Australian patients, by expanding the list of such medicinal cannabis products that a medical practitioner may supply to their patient under the Authorised Prescriber (AP) scheme, without ethics committee approval;
- reduce regulatory burden for sponsors of influenza, RSV and COVID-19 vaccines, by introducing new, reduced, application and evaluation fees for an application to register a vaccine that targets a new strain of one of these diseases and that is closely related to a vaccine that is already included in the Australian Register of Therapeutic Goods (the Register) in relation to the applicant;
- support the safe use of sunscreen preparations by removing outdated exemption provisions for sunscreens with a SPF of less than 4, as such products do not provide adequate protection from the sun's ultraviolet radiation; and
- make a small number of other minor amendments, e.g. to correct unintended errors.

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 the day after registration on the Federal Register of Legislation, except Part 5 of Schedule 1 which commences on 1 January 2024.

Consultation

Extending transitional arrangements for reclassification reforms
On 2 March 2023, the TGA consulted with the Regulatory and Technical Consultative Forum for medical devices (RegTech) on the proposal to extend the transition deadlines for medical device reclassification reforms. RegTech is a forum of industry bodies and associations that facilitates consultation between the TGA and the medical device industry. RegTech was supportive of the proposal.

Clinical trials
Between August 2022 and September 2022, the TGA consulted publicly on the proposal to expand the powers of authorised persons in relation to medical device clinical trials. Sixty six responses were received from various stakeholders including, sponsors, manufacturers, research organisations, Human Research Ethics Committees (HRECs), consumers and state and territory governments. Subsequent, targeted, consultations were also undertaken between November 2022 and May 2023 with HRECs, state and territory governments and other respondents to the public consultation, in relation to requiring sponsors to provide information about the safety or performance of the device used in the trial. No concerns were raised with the proposals.

Authorised Prescriber scheme
On 21 June 2023, the TGA informed the Australian Advisory Council on the Medicinal Use of Cannabis (the Council) of the proposal to expand the list of medicinal cannabis products a medical practitioner may supply under the AP scheme, without ethics committee approval. No concerns were raised. The Council comprises 15 members from various professional backgrounds, including cancer, epilepsy and palliative care.

Removal of exemptions for sunscreens with SPF less than 4
Between 24 April 2023 and 31 May 2023, the TGA consulted publicly on the proposal to remove exemption provisions for sunscreens with a SPF of less than 4. Nineteen responses were received from various stakeholders including, sponsors, manufacturers, regulatory agents, industry groups, government organisations, consumers, consumer representatives and a not-for-profit organisation. All responses were supportive of the proposal.

Other measures
For all other measures consultation was not undertaken as the proposed amendments are minor machinery or de-regulatory in nature.

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

ATTACHMENT

Details of the *Therapeutic Goods Legislation Amendment (2023 Measures No. 2) Regulations 2023*

Section 1 – Name

This section provides that the title of the Regulations is the *Therapeutic Goods Legislation Amendment (2023 Measures No. 2) Regulations 2023*.

Section 2 – Commencement

This section provides for the commencement of the Regulations on the day after registration on the Federal Register of Legislation, except Part 5 of Schedule 1 which commences on 1 January 2024.

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 this instrument has effect according to its terms.

Schedule 1 – Amendments

Part 1—Extension of transitional arrangements for reclassified medical devices and personalised medical devices

Section 41DB of the Act provides that the regulations may specify classifications, to be known as medical device classifications, applying to medical devices or kinds of medical devices, and related matters. Medical device classifications are designed to reflect the level of risk a device may pose to a user or other person, based on the manufacturer's intended use for a device. Devices with a higher classification are subjected to a higher level of regulatory scrutiny in light of such risks.

Regulation 3.1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) specifies the medical device classifications for section 41DB of the Act. These classifications comprise:

- Classes I, IIa, IIb and III, for medical devices other than IVD medical devices; and
- Classes 1, 2, 3 and 4, for IVD medical devices and in-house IVD medical devices.

Under regulation 3.2 of the MD Regulations, Schedules 2 and 2A set out the classification rules for determining which of these classes apply to a medical device other than an IVD medical device (Schedule 2) or an IVD medical device (Schedule 2A).

Regulation 3.3 of the MD Regulations sets out general principles to be followed in applying the classification rules in Schedules 2 and 2A to a medical device. For example, that a medical device other than an IVD medical device is classified having regard to its intended purpose – in practice, this means the manufacture's intended purpose for the device (paragraph 3.3(2)(a) of the MD Regulations refers).

In practice, most medical devices included in the Australian Register of Therapeutic Goods (the Register) are supported by conformity assessment evidence from a notified body based in the European Union (the EU). The EU is currently undergoing a major transition in relation to certification requirements, involving transitioning from the Medical Device Directive (93/42/EEC) (EU MDD) to the newer Medical Device Regulations (2017/745/EU) (EU MDR). The EU MDR commenced on 26 May 2021, with transitional arrangements that were proposed to be in place until 26 May 2024.

Due to delays in the re-certification of certain devices in the EU under the EU MDR, on 16 February 2023 the European Commission extended EU MDR transition dates from 26 May 2024 to:

- 26 May 2026, for Class III implantable custom-made medical devices;
- 31 December 2027, for Class III medical devices other than Class III implantable custom-made medical devices, and for Class IIb implantable medical devices;
- 31 December 2028, for Class IIb medical devices other than Class IIb implantable medical devices, and for Class IIa and Class I medical devices that are supplied in a sterile state and Class I medical devices with a measuring function; and
- 31 December 2028, for medical devices that, under EU requirements, did not previously need EU certification.

The changes in EU timeframes impact equivalent medical device reforms underway in Australia, particularly those relating to the reclassification of certain kinds of medical

devices. These reforms were introduced by the *Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019* (the 2019 Amendments) and reclassified a range of kinds of medical devices at higher classification levels, e.g. spinal implantable medical devices and medical devices that administer medicines or biologicals by inhalation, to better reflect the risks that such products may pose to users, consistent with the approach taken in the EU. Transitional arrangements for the reclassification reforms are set out in Division 11.10 of the MD Regulations, which currently specify that those arrangements end on 1 November 2024.

As a result of the changes to EU timeframes a need has arisen to similarly extend the transitional arrangements for the reclassification reforms in Australia, as it is unlikely that manufacturers of affected devices will be able to obtain recertification in Europe for all of their products before the current 1 November 2024 deadline. Without such amendments there may potentially be widespread supply disruption of medical devices in Australia.

Therapeutic Goods (Medical Devices) Regulations 2002

Items 1 and 2 – Subregulation 11.40(2) and subparagraph 11.40(3)(a)(iii)
These items amend subregulation 11.40(2) and subparagraph 11.40(3)(a)(iii) of the MD Regulations with the effect of extending the transitional arrangements applying to the reclassification of the following kinds of medical devices, from 1 November 2024 to 1 July 2029:

- implantable medical devices intended to be motion-preserving devices for the spine (i.e. spinal disc replacements);
- medical devices that administer medicines or biologicals by inhalation;
- medical devices comprised of substances intended to be introduced into the human body through a body orifice, or applied to and absorbed by the skin;
- active medical devices for therapy that include a diagnostic function the purpose of which is to significantly determine patient management by the device;
- medical devices, other than reusable surgical instruments, that are used in direct contact with the heart, central circulatory system or central nervous system.

The extension of the transitional dates to 1 July 2029 is designed to provide sponsors of such medical devices supplying to the Australian market with an additional six months compared to the later of the EU MDR transition dates. The effect of these amendments is to ensure that sponsors with medical devices supported by EU MDD certification have sufficient time to re-apply to the Therapeutic Goods Administration (TGA) to include their device in the Register at the higher classification level with the appropriate EU MDR certification evidence.

The amendments do not extend the transitional arrangements applying to active implantable medical devices (AIMD), as the AIMD reforms involved the replacement of the AIMD class with the Class III certification. The conformity assessment certification required to be provided by sponsors to re-apply to include their device in the Register as a Class III medical device remains unchanged, and therefore additional time for such products is not required.

Items 3 and 4 – Subregulations 11.51(3) and 11.52(2) and subparagraph 11.52(3)(a)(iii)
These items amend subregulations 11.51(3) and 11.52(2) and subparagraph 11.52(3)(a)(iii) of the MD Regulations with the effect of extending the transitional arrangements applying to the reclassification of personalised medical devices, from 1 November 2024 to 1 July 2029.

The extension of the transitional dates to 1 July 2029 for personalised medical devices is designed to provide sponsors of such devices supplying to the Australian market with an additional six months compared to the later of the EU MDR transition dates, to ensure sufficient time for sponsors of such devices to comply with the Australian regulatory framework for such products.

Items 5 and 6 – Part 2 of Schedule 4 (table item 2.14, column headed "Conditions")
These items make minor amendments to item 2.14 in the table in Part 2 of Schedule 4 to the MD Regulations with the effect of extending the notification period for patient-matched medical devices.

Item 5 extends the period in which the sponsor of a patient-matched medical device must notify the Secretary (in writing) of each kind of patient-matched device they intend to supply in Australia, from 25 August 2022 to 1 November 2024. Item 6 makes it clear that such notifications relate to patient-matched medical devices that the sponsor intends to supply in Australia on or after 1 July 2029 (item 2.14 currently refers to 1 November 2024 in this regard).

These amendments enable eligible sponsors of patient-matched medical devices who were not aware that their products were impacted by the reforms introduced by the 2019 Amendments and who did not provide the current required notification by 25 August 2022, to now qualify for transitional arrangements and therefore minimising supply disruptions.

Part 2—Clinical trials

Therapeutic Goods (Medical Devices) Regulations 2002

Item 7 – Subregulation 7.4(1)
Paragraph 41HB(1)(e) of the Act allows the Secretary to approve the importation, exportation or supply of unapproved medical devices for use solely for experimental purposes in humans. This exemption is referred to in practice as the Clinical Trials Approval (CTA) scheme. Subsection 41HB(3) of the Act provides that the regulations may prescribe the conditions that apply to such an approval.

Relevantly, section 41HA of the Act has the effect that the regulations may exempt specified kinds of medical devices from the requirement to be included in the Register, and that such exemptions may be subject to conditions prescribed in the regulations. Item 2.3 of Part 2 of Schedule 4 to the MD Regulations exempts medical devices to be used solely for experimental purposes in humans, subject to compliance with the conditions listed in column 3 of item 2.3. This exemption is referred to in practice as the Clinical Trial Notification (CTN) scheme.

Regulation 7.4 of the MD Regulations identifies, for the purposes of subregulation 7.3(2) of the MD Regulations, what a sponsor of a clinical trial approved under paragraph 41HB(1)(e) of the Act must allow an authorised person to do in relation to the clinical trial. This includes, for example, entering and inspecting the site of a CTA scheme trial to ensure that is being operated lawfully and safely.

However, concerns have arisen that there are no corresponding powers for authorised persons that would support the Good Clinical Practice (GCP) inspection program (in regulation 7.3 of the MD Regulations) in relation to medical devices that are exempt under the CTN Scheme (item 2.3 in the table in Part 2 of Schedule 4 to the MD Regulations).

This item therefore amends subregulation 7.4(1) of the MD Regulations to make it clear that authorised persons also have the powers set out in paragraphs 7.4(1)(a) to (f) of the MD Regulations in relation to a clinical trial mentioned in item 2.3 of Part 2 of Schedule 4 to the MD Regulations.

This amendment is designed to ensure the safe use of medical devices that are used in all clinical trials, noting in particular that the great majority of clinical trials in Australia are undertaken under the CTN scheme rather than the CTA scheme.

Item 8 – Paragraphs 7.4(1)(b), (c), and (d)
This item makes minor editorial amendments to paragraphs 7.4(1)(b), (c) and (d) of the MD Regulations to update the reference of "anything" to "any thing" for consistency with equivalent provisions in the *Therapeutic Goods Regulations 1990* (the TG Regulations).

Items 9 and 10 – Paragraph 7.4(1)(e) and at the end of subregulation 7.4(1)
These items amend subregulation 7.4(1) of the MD Regulations to make it clearer that an authorised person may search, inspect, examine, take measurements of, or conduct tests on, or take photographs, make video recordings or make sketches of, any book, record or document that is on the trial site and that relates to the trial. Item 10 does this through the introduction of a clarificatory note at the end of subregulation 7.4(1), and item 9 reduces

duplication by repealing paragraph 7.4(1)(e), which is not needed as its effect is already covered by paragraph 7.4(1)(c).

Item 11 – In the appropriate position in Part 11
This item introduces new Division 11.18 to the MD Regulations to provide the application provision relating to the amendments to the MD Regulations made by Part 2 of Schedule 1 to the Regulations.

New subregulation 11.72(1) of the MD Regulations provides that the amendments to subregulation 7.4(1) of the MD Regulations made by Part 2 of Schedule 1 to the Regulations applies in relation to things done on or after the commencement of Part 2 of Schedule 1 to the Regulations in relation to a clinical trial that began before, on or after that commencement.

New subregulation 11.72(2) of the MD Regulations provides that the amendments to Schedule 4 of the MD Regulations would apply in relation to:

- requests made on or after the commencement of Part 2 of Schedule 1 to the Regulations to give information acquired before, on or after that commencement, in relation to a clinical trial that began before, on or after that commencement; and
- things mentioned in regulation 7.4 of the MD Regulations done on or after the commencement of Part 2 of Schedule 1 to the Regulations, in relation to a clinical trial that began before, on or after that commencement.

Item 12 – Part 2 of Schedule 4 (at the end of the cell at table item 2.3, column headed "Conditions")
Section 41HA of the Act provides for the regulations to exempt medical devices from the operation of Division 3 of Part 4-11 of the Act, and its effect enables the regulations to exempt certain medical devices from the requirement to be included in the Register.

Subregulation 7.1(2) exempts medical devices mentioned in column 2 of an item in Part 2 of Schedule 4 to the MD Regulations from the operation of Division 3 of Part 4-11 of the Act, subject to compliance with the conditions mentioned in column 3. Relevantly, item 2.3 in the table in Part 2 of Schedule 4 to the MD Regulations exempts medical devices used solely in clinical trials, subject to a number of conditions that are specified in column 3.

This item amends column 3 of item 2.3 in the table in Part 2 of Schedule 4 to the MD Regulations to introduce 4 new conditions, in new paragraphs (i) to (l), to ensure the safe use of medical devices in clinical trials that rely on item 2.3, by making it clear that:

- the sponsor must comply with requests by an authorised person, whether made before or after the start of the trial, to provide information about the conduct of the trial (whether the sponsor is themselves conducting the trial or another body or organisation is doing so for the sponsor) (new paragraph (i));
- if a body or organisation is conducting the trial for the sponsor, the body or organisation must comply with requests by an authorised person, whether before or after the start of the trial, to provide information about the trial (new paragraph (j));
- the sponsor (if the sponsor is conducting the trial themselves) or the body or organisation conducting the trial for the sponsor must allow an authorised person to do the things mentioned in subregulation 7.4(1) (including for example, entering the site of a clinical trial and inspecting, examining, taking measurements of, or conducting tests on, any thing on the site that related to the trial (new paragraph (k)); and

- the sponsor must, on written request from the Secretary, provide specified information or documents relating to the safety or performance of the medical device covered by the trial, within 14 days of such a request (or any such longer period as agreed by the Secretary) (new paragraph (l)).

Therapeutic Goods Regulations 1990

Items 13 and 14 – Paragraph 12AC(1)(e) and at the end of subregulation 12AC(1)
These items amend subregulation 12AC(1) of the TG Regulations to make it clearer that an authorised officer may search, inspect, examine, take measurements of, or conduct test on, or take photographs, make video recordings or sketches of any book, record or document that is on the trial site and that relates to the trial. Item 14 does this through the introduction of a clarificatory note at the end of subregulation 12AC(1), and item 13 reduces duplication by repealing paragraph 12AC(1)(e), which is not needed as its effect is already covered by paragraph 12AC(1)(c).

Item 15 – In the appropriate position in Part 9
This item introduces new Division 22 to the TG Regulations to provide the application provision relating to the amendments to the TG Regulations made by Part 2 of Schedule 1 to the Regulations.

New regulation 91 of the TG Regulations provides that the amendments relating to clinical trials made by items 13 and 14 apply in relation to things done on or after the commencement of Part 2 of Schedule 1 to the Regulations in relation to a clinical trial that began before, on or after that commencement.

Item 16 – Schedule 5A (table item 3, column 3, paragraph (h))
Item 3 in the table in Schedule 5A to the TG Regulations exempts medicines and biologicals used solely in clinical trials from the operation of Part 3-2 of the Act (except sections 30EA, 31A and 31C to 31F) and Division 4 of Part 3-2A of the Act, subject to the conditions specified in column 3.

In 2011, this item was amended to introduce new paragraph (h) in column 3, in relation to Class 4 biologicals (item 66 of the *Therapeutic Goods Amendment Regulations 2011 (No. 1)* (the 2011 Amendments) refers).

Currently, the wording of the condition in paragraph (h) has the effect that for a CTN exemption to apply to a Class 4 biological, the biological would need to have both received clinical trial approval from an overseas national regulatory agency (subparagraph (h)(i)) and have a history of previous usage supported by clinical evidence received by the TGA (subparagraph (h)(ii)).

However, this is inconsistent with current practice and the intended operation of this condition. Relevantly, the explanatory statement to the 2011 Amendments sets out that the intended effect of the amendment was that the CTN scheme may include Class 4 biologicals where only one of the circumstances in subparagraphs (h)(i) or (ii) applies.

This item amends paragraph (h) in column 3 of item 3 in the table in Schedule 5A to the TG Regulations to correct this unintended error.

Part 3—Authorised Prescriber scheme

The Authorised Prescriber (AP) scheme enables medical practitioners to supply unapproved therapeutic goods for use in the treatment of their patients. Subsection 19(5) of the Act, and related provisions in section 19, provide the arrangements for this scheme in relation (principally) to medicines.

Subsection 19(6) of the Act provides that an authority under subsection 19(5) may only be given in specified circumstances, including, to a medical practitioner who has the approval of an ethics committee to supply the therapeutic goods (paragraph 19(6)(aa) refers). However, subsection 19(6) also provides that paragraph 19(6)(aa) does not apply in the circumstances prescribed by the regulations.

Subregulation 12B(1C) of the TG Regulations enables the Secretary to authorise a medical practitioner to supply certain unapproved medicinal cannabis products (specified in column 2 of an item in the table in subregulation 12B(1C)) under the AP scheme, where the medical practitioner does not have ethics committee approval. This is known in practice as the 'established history of use' pathway, and is principally designed to better facilitate access to unapproved therapeutic goods that have a history of use within Australia or internationally for a particular indication during the preceding 3-year period, where there are no significant safety concerns associated with the product in Australia or internationally, during that 3-year period.

The amendments in Part 3 make a small number of amendments to subregulation 12B(1C) to expand the circumstances in which certain medicinal cannabis products may be supplied by medical practitioners to their patients under this pathway, without an ethics committee approval, to reflect that such products are considered to be safe for medical practitioners to prescribe without an ethics committee.

Therapeutic Goods Regulations 1990

Item 17 – Subregulation 12B(1C) (at the end of the cell at table item 1, column 5)
This item makes a minor amendment to column 5 of item 1 in the table in subregulation 12B(1C) of the TG Regulations to introduce 3 new indications in relation to medicinal cannabis products containing 98% or more cannabidiol and 2% or less other naturally derived cannabinoids and no other active ingredients, that are supplied in liquid form for oral administration. The 3 new indications are treatment of refractory sleep disorders in adult patients, treatment of autism spectrum disorder in adult patients and treatment and management of refractory cancer pain in adult patients. This amendment reflects that such medicinal cannabis products have an established history of use in relation to these 3 new indications.

Item 18 – Subregulation 12B(1C) (after table item 1)
This item introduces new item 1A in the table in subregulation 12B(1C) with the effect of permitting medicinal cannabis products containing 98% or more cannabidiol and 2% or less other naturally derived cannabinoids and no other active ingredients, that are supplied in spray form for oral administration for the treatment of refractory chronic pain in adults to be supplied to a patient by a medical practitioner under the AP scheme without ethics committee approval. This amendment reflects that such medicinal cannabis products have an established history of use in relation to the treatment of refractory chronic pain in adults.

Item 19 – Subregulation 12B(1C) (at the end of the cell at table item 3, column 5)
This item makes a minor amendment to column 5 of item 3 in the table in subregulation 12B(1C) of the TG Regulations to introduce 2 new indications for medicinal cannabis products containing 60 to 98% naturally derived cannabidiol, with the remaining cannabinoid content naturally derived (e.g. naturally derived tetrahydrocannabinol) and no other active ingredients, that are supplied in liquid form for oral administration. The 2 new indications are the treatment of refractory sleep disorders in adult patients and the treatment and management of refractory cancer pain in adult patients. This amendment reflects that such medicinal cannabis products have an established history of use in relation to these 2 new indications.

Item 20 – Subregulation 12B(1C) (cell at table item 5, column 5)
This item makes a minor amendment to replace the cell in column 5 of item 5 in the table in subregulation 12B(1C) of the TG Regulations, with new wording to introduce 2 new indications for medicinal cannabis products containing 40 to 60% naturally derived cannabidiol, with the remaining cannabinoid content naturally derived (e.g. naturally derived tetrahydrocannabinol), and no other active ingredients, that are supplied in liquid form for oral administration. The 2 new indications are the treatment of sleep disorders in adult patients and the treatment and management of refractory cancer pain in adult patients. This amendment reflects that such medicinal cannabis products have an established history of use in relation to these 2 new indications.

Part 4—Fee for certain vaccine strain updates

Section 23 of the Act provides that a person may make an application to the Secretary for the registration or listing of therapeutic goods. Section 23B of the Act sets out the preliminary assessment requirements that an application for registration, or an application for listing under the assessed listed pathway, must meet in order to progress to evaluation. These requirements include, at paragraph 23B(2)(b) of the Act, that the prescribed application fee for the relevant class of therapeutic goods must be paid.

Separately, subsection 24(1A) of the Act provides that for an application for registration that has passed preliminary assessment, a fee specified in, or determined in accordance with, the regulations is payable in respect of the evaluation of the goods for registration.

Regulation 43 of the TG Regulations provides that the fee mentioned in column 3 of an item in Part 2 of Schedule 9 is prescribed for the matter set out in column 2.

Vaccines for COVID-19, respiratory syncytial virus (RSV) and influenza, may regularly evolve or be updated to address new strains of the disease to which they relate, compared to the version of the vaccine that is already included in the Register (i.e. the parent vaccine).

Currently, when an application is made to register a new vaccine that addresses a new strain of COVID-19, RSV or influenza, it is considered a 'new chemical entity' (as defined in subclause 1(1) of Part 1 of Schedule 9 to the TG Regulations), and the fee payable for such an application would be the fee prescribed in item 2(ba) and item 4(a) of Part 2 of Schedule 9 to the TG Regulations. Currently, the fees for these items are $54,292 and $217,598, respectively.

However, it has been identified that the amount of clinical data required to be considered for the Secretary to process an application and complete the evaluation for such an application is considerably less where the application is to register a therapeutic good with a new vaccine strain that involves a different, but closely related strain of a vaccine that is already included in the Register in relation to the same sponsor. As such, the fees currently prescribed for processing and evaluating an application for a new chemical entity that involves a new vaccine strain in these circumstances, do not accurately reflect the work in assessing such applications. A need has therefore arisen for new, reduced fees that better reflect the work involved in processing and evaluating such applications. This is what the amendments in this Part are designed to achieve.

Therapeutic Goods Regulations 1990

Item 21 – Clause 3 of Schedule 9 (after paragraph (bca) of table item 2)
This item introduces new paragraph (bcb) in item 2 in the table in clause 3 of Schedule 9 to the TG Regulations, to introduce a new application fee of $1,241 for the processing of an application under section 23 of the Act to register a medicine to which the evaluation fee under new paragraph (ac) of item 4 is payable.

This fee amount has been determined based on the work involved for officers of the TGA's Prescription Medicine Authorisation Branch and Scientific Evaluation Branch in processing an application for the registration of a vaccine designed to address a new strain of COVID-19, RSV or influenza in the circumstances described in new paragraph 4(ac) (item 23

below refers). The new fee applies in relation to applications made on or after the commencement of the Regulations.

Item 22 – Clause 3 of Schedule 9 (table item 4, column 2, paragraph (a))
This item makes a minor editorial amendment to accommodate the introduction of the new evaluation fee in item 23 below.

Item 23 – Clause 3 of Schedule 9 (after paragraph (ab) of table item 4)
This item introduces new paragraph (ac) in item 4 in the table in clause 3 of Schedule 9 to the TG Regulations, to introduce a new evaluation fee of $4,954 for the evaluation of a COVID-19, RSV or influenza vaccine that is a new chemical entity. Importantly, the new fee only applies to such vaccines where the vaccine is a new chemical entity because the vaccine addresses a new strain of COVID-19, RSV or influenza, and that vaccine is a closely related form of an existing vaccine, for another strain of that disease, that is included in the Register in relation to the same person as the applicant for the new vaccine.

This fee amount has been determined based on the work involved for officers of the TGA's Prescription Medicine Authorisation Branch and Scientific Evaluation Branch in evaluating an application for the registration of a vaccine designed to address a new strain of COVID-19, RSV or influenza, noting in particular that in the circumstances outlined in paragraph 4(ac) the TGA would hold a range of information about the existing vaccine that would enable the abridgement of such a new application. The new fee applies in relation to applications made on or after the commencement of the Regulations.

Part 5—Removal of exemptions for sunscreens preparations

Section 18 of the Act provides for the regulations to exempt therapeutic goods, or classes of therapeutic goods, from the operation of Part 3-2 of the Act (except sections 31A and 31C to 31F), enabling the regulations to exempt certain therapeutic goods from the requirement to be listed or registered in the Register.

Subregulation 12(1) of the TG Regulations exempts therapeutic goods mentioned in an item in Schedule 5 to the TG Regulations from the operation of Part 3-2 of the Act (except sections 30EA, 31A, 31C to 31F) and Division 4 of Part 3-2A of the Act.

Paragraph (g) of item 8 in the table in Schedule 5 to the TG Regulations exempts sunscreen preparations from the requirement to be registered or listed in the Register, where the claimed sun protection factor (SPF) has been established by testing according to the method described in *AS/NZS 2604:2012 Sunscreen products – Evaluation and classification* (the 2012 Sunscreen Standard), the performance statements and markings on the label comply with the 2012 Sunscreen Standard and the sunscreen preparation has a SPF of less than 4, and provided that the goods:

- do not contain ingredients of human origin or of animal origin from specified parts of cattle, sheep, goats or mule deer; and
- are not for the treatment, cure, prevention, diagnosis or monitoring of, or testing susceptibility of persons to, a disease, condition, ailment or defect.

Subsection 34(1) of the Act provides for the regulations to exempt therapeutic goods, or classes of therapeutic goods from the operation of Part 3-3 of the Act, enabling the regulations to exempt certain therapeutic goods from the requirement to be covered by a manufacturing licence issued under Part 3-3 of the Act.

Regulation 17 of the TG Regulations exempts therapeutic goods specified in an item in Schedule 7 to the TG Regulations from the operation of Part 3-3 of the Act. Item 14 in the table in Schedule 7 to the TG Regulations exempts sunscreens from the manufacturing licence requirements, where the label of the sunscreen preparation states that the sunscreen has a SPF of less than 4, and when tested as described in the 2012 Sunscreen Standard are established to have a SPF of less than 4.

Under the *AS/NZS 2604:1998 Sunscreen products – Evaluation and classification* (the 1998 Sunscreen Standard) sunscreen preparations were permitted to make SPF claims of less than 4. Following the introduction of the 2012 Sunscreen Standard (which does not permit sunscreens to make SPF claims of less than 4), it was intended that, subject to transitional arrangements, such claims would no longer be permitted, and that such goods would no longer be exempt from the requirement to be included in the Register or the requirement that their manufacture be subject to the manufacturing requirements in Part 3-3 of the Act.

However, due to concerns in 2012 regarding potential sunscreen shortages as a result of the adoption of the 2012 Sunscreen Standard, transitional provisions were provided, allowing existing exempt products to continue to comply with the 1998 Sunscreen Standard (regulation 49 of the TG Regulations refers) for an indefinite period. However, the risk of sunscreen shortages due to increased testing standards is no longer considered to be a concern. Further, products with such a low SPF are not considered to provide adequate protection from the sun's ultraviolet radiation for users, particularly in Australia.

As such, the amendments in this Part amend Schedules 5 and 7 to the TG Regulations to repeal the exemptions from inclusion in the Register and licensing requirements in paragraph 8(g) of Schedule 5 and item 14 of Schedule 7, subject to appropriate transitional arrangements for existing products.

Therapeutic Goods Regulations 1990

Item 24 – Paragraph 49(a)
This item repeals paragraph 49(a) of the TG Regulations as the transitional arrangements provided by this paragraph are no longer required. With the implementation of the permitted indications for listed medicines, sponsors of listed medicines (including sunscreens) were required to relist their medicines between 2018 and 2021. As such, there are no longer any sunscreen preparations in the Register that were included prior to 9 November 2012.

Items 25 to 28 – Paragraphs 49(b) and (c)
These items amend paragraphs 49(b) and (c) of the TG Regulations with the effect that paragraph 8(g) of Schedule 5, and item 14 of Schedule 7, as in force on 9 November 2012, continue to apply until the end of 31 December 2026 in relation to sunscreen preparations that were in existence and relied on those provisions as at 9 November 2012. The effect of this is to provide sponsors and Australian manufacturers of such products until the end of 2026 to transition away from relying on the 1998 Sunscreen Standard.

Item 29 – At the end of Division 22 of Part 9
This item introduces new regulation 92 to the TG Regulations to provide the transitional provisions relating to the removal of exemptions for certain sunscreen preparations by Part 5 of Schedule 1 to the Regulations.

New paragraph 92(a) provides that despite the amendments made by Part 5 of Schedule 1 to the Regulations, paragraph (g) of item 8 of Schedule 5 to the TG Regulations as in force immediately before the commencement of those amendments, continues to apply until 31 December 2026, in relation to therapeutic goods exempt from the operation of Parts 3-2 and 3-2A of the Act immediately before that commencement.

The effect of which, is that sunscreen preparations that were exempt from the requirement to be included in the Register before 1 January 2024 (including in particular on the basis that such preparations comply with the 2012 Sunscreen Standard), will continue to be exempt for a further 3-year period, ending on 31 December 2026.

New paragraph 92(b) provides that despite the amendments made by Part 5 of Schedule 1 to the Regulations, item 14 of Schedule 7 to the TG Regulations as in force immediately before the commencement of those amendments, continues to apply until 31 December 2026, in relation to therapeutic goods exempt from the operation of Part 3-3 of the Act immediately before that commencement.

The effect of which, is that sunscreen preparations that were exempt from the requirement that their manufacture be subject to the manufacturing requirements in Part 3-3 of the Act before 1 January 2024 will continue to be exempt for a further 3-year period, ending on 31 December 2026.

Item 30 – Schedule 5 (table item 8, paragraph (f))
This item makes a minor editorial amendment consequent to the amendment made by item 31 below.

Item 31 – Schedule 5 (table item 8, paragraph (g))
This item repeals paragraph (g) of item 8 in the table in Schedule 5 to the TG Regulations, with the effect that sunscreen preparations with a SPF of less than 4 will no longer be exempt from the requirements to be registered or listed in the Register under Part 3-2 of the Act.

This amendment reflects that the exemption of such products from the requirement to be included in the Register is no longer considered appropriate, as sunscreen preparations with a SPF of less than 4 do not provide adequate protection from the sun's ultraviolet radiation.

Item 32 – Schedule 7 (table item 14)
This item repeals item 14 in the table in Schedule 7 to the TG Regulations, with the effect that sunscreen preparations with a SPF of less than 4 will no longer be exempt from the requirement that their manufacture be subject to the manufacturing requirements in Part 3-3 of the Act.

Part 6—Minor amendments

Therapeutic Goods (Medical Devices) Regulations 2002

Item 33 – Subregulation 10.7(1) (paragraph (b) of the definition of *initial decision*)
This item repeals paragraph 10.7(1)(b) of the MD Regulations (definition of 'initial decision') to remove an outdated reference to paragraph 9.4(2)(a). Regulation 9.4 of the MD Regulations was repealed by the *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2018*.

Therapeutic Goods Regulations 1990

Item 34 – Schedule 4 (table item 8)
Section 26AE of the Act provides the pathway for listing 'assessed listed medicines' in the Register. This pathway allows medicines to be included in the Register following a sponsor self-assessment and certification of specified matters relating to the safety and quality of the product, coupled with a pre-market assessment by the Secretary of efficacy evidence supporting the medicine's proposed claims and indications.

Paragraph 9A(4)(a) of the Act provides that the regulations may prescribe the therapeutic goods, or classes of therapeutic goods, that are required to be included in each part of the Register. Regulation 10 of the TG Regulations provides that therapeutic goods, or classes of therapeutic goods mentioned in the table in Schedule 4 to the TG Regulations that are included in the Register, are to be included in the part of the Register for goods known as listed goods.

Item 8 in the table in Schedule 4 to the TG Regulations enables sponsors of assessed listed medicines to use 'intermediate level' indications that are not included in an instrument made by the Minister under section 26BF of the Act (i.e. the permissible indications determination), reflecting that a sponsor of an assessed listed medicine has undertaken the work and investment to obtain evidence to support that higher level indication.

Item 8 of Schedule 4 was introduced to provide a basis for the eligibility for listing of assessed listed, or assessed listable, medicines in the Register; however, item 8 does not specifically stipulate that it is only applicable to assessed listed medicines. Concerns have therefore arisen that Schedule 4 in its current form may allow sponsors of listed medicines other than assessed listed medicines to seek to rely on item 8 to use intermediate level indications that were not designed for such products and claim to still be eligible for listing on the basis of item 8, which could lead to potential compliance and enforcement difficulties.

To address such concerns, this item amends item 8 in the table in Schedule 4 to the TG Regulations to make it clear that item 8 is only applicable to assessed listed medicines (i.e. medicines to be listed under section 26AE of the Act). The effect of which is that if other listed medicines (i.e. those listed under section 26A of the Act) were to use intermediate level indications, they are no longer be eligible for listing and may be subject to cancellation from the Register on that basis.

Statement of Compatibility with Human Rights

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

Therapeutic Goods Legislation Amendment (2023 Measures No. 2) Regulations 2023

The *Therapeutic Goods Legislation Amendment (2023 Measures No. 2) Regulations 2023* (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 *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019* introduced reforms (the 2019 reforms) to reclassify certain medical devices to ensure that the level of pre-market scrutiny applied to applications for marketing approval for such products is commensurate with the risk they may pose to users, and to align with the European Union (the EU).

Recent delays for equivalent EU reforms require extension of the 2019 reforms to ensure access to these products for Australian patients. The *Therapeutic Goods Legislation Amendment (2023 Measures No. 2) Regulations 2023* (the Regulations) amends the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to extend the transitional arrangements for the 2019 reforms to better align with the EU.

The Regulations also amend the MD Regulations and the *Therapeutic Goods Regulations 1990* (the TG Regulations), to implement a small number of other, more minor, measures including in particular to:

- support the safe use of medical devices in clinical trials in Australia, by ensuring that authorised persons may enter the site of a clinical trial operating under the Therapeutic Goods Administration's (TGA) Clinical Trial Notification (CTN) scheme to verify that the supply of devices under the trial complies with good clinical practice and is safe for the trial participants;
- reduce regulatory burden for medical practitioners, and improve access to unapproved medicinal cannabis products for Australian patients by expanding the list of such medicinal cannabis products that a medical practitioner may supply to their patient under the Authorised Prescriber (AP) scheme, without ethics committee approval;
- reduce regulatory burden for sponsors of influenza, RSV and COVID-19 vaccines, by introducing new, reduced, application and evaluation fees for an application to register a vaccine that targets a new strain of one of these diseases and that is closely related to a vaccine that is already included in the Australian Register of Therapeutic Goods (the Register) in relation to the applicant;
- support the safe use of sunscreen preparations by removing outdated exemption provisions for sunscreens with a SPF of less than 4, as such products do not provide adequate protection from the sun's ultraviolet radiation; and
- make a small number of other minor amendments, e.g. to correct unintended errors.

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). 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:

- extending timeframes for the reclassification of certain kinds medical devices (e.g. heart implants) in Australia to align with the European Union, to help ensure the continued availability of such devices for Australian patients;
- supporting the safe use of medical devices for clinical trial participants in Australia, by enabling authorised persons to enter and inspect clinical trial sites to verify that the use and supply of devices in that trial complies with good clinical practice and is safe for clinical trial participants;
- enabling a number of new unapproved medicinal cannabis products to be supplied to patients in Australia by an authorised medical practitioner more flexibly, without the need for ethics committee approval;
- reducing regulatory burden for sponsors of certain vaccines by ensuring that the fees applying to applications to register those vaccines with updated strains is commensurate with the work required to consider such applications, removing potential impediments to their supply; and
- ensuring the safe use of sunscreen products by removing outdated exemptions applying to sunscreens with a SPF of less than 4, reflecting the need for sunscreen preparations available in the Australian market to provide adequate protection from the sun's ultraviolet radiation.

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.

Mark Butler, Minister for Health and Aged Care