EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Amendment (2024 Measures No. 2) Regulations 2024

The Regulations improve patient access to important treatments by supporting the implementation of the TGA's Medicines Repurposing Program, support patient safety by enhancing regulatory oversight of the extemporaneous compounding of semaglutide-like medicines, and implement other measures.

The *Therapeutic Goods Act 1989* (the Act) establishes and provides for the maintenance of a national system of controls for the quality, safety, efficacy or performance, and timely availability of therapeutic goods used in, or exported from, Australia. The Act is administered by the Therapeutic Goods Administration (the TGA) within the Australian Government Department of Health and Aged Care, and provides for the Secretary to maintain the Australian Register of Therapeutic Goods (the Register).

Subsection 63(1) of the Act enables the Governor-General to make regulations, not inconsistent with the Act, prescribing matters that are 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 (2024 Measures No. 2) Regulations 2024* (the Regulations) amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) to support the implementation of the TGA's Medicines Repurposing Program (the MRP). The Medicines Regulation Program improves patient access to important treatments by encouraging sponsors of certain medicines in the Register to seek approval to supply those medicines for new uses (so those medicines are no longer supplied "off-label" in Australia).

The Regulations also amend the TG Regulations and the *Therapeutic Goods (Medical Devices) Regulations 2002* to:

- enhance regulatory oversight of the compounding of medicines containing glucagon-like peptide-1 receptor agonist (GLP-1 RA) analogues — which are principally indicated for the treatment of type 2 diabetes, but are also commonly prescribed "off-label" for weight management in adults — to address safety concerns with compounding of these medicines;
- update testing and (certain) labelling requirements that apply to sunscreen products included in the Register as listed goods, to align the requirements with a more recent Sunscreen Standard;
- enable the TGA to adopt a more flexible and risk-based approach to the auditing of applications to include medical devices in the Register;
- reclassify certain kinds of medical devices that contain only materials of microbial or recombinant origin, or certain non-viable tissues or cells of animal origin or their derivatives, to align with the classification of such devices in the European Union;
- exempt prescription spectacle lenses that are intended to be used only to provide refractive corrections from the requirement to be included in the Register;
- revise the transitional arrangements relating to the reclassification of software-based medical devices, so that those arrangements apply to devices that are the subject of an application for a conformity assessment certificate submitted before 1 November 2024; and
- make a small number of more minor amendments to the TG Regulations.

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 for Schedule 2 (sunscreen, audit framework and reclassification amendments) and Schedule 3 (GLP-1 RA compounding amendments) which commence on 1 July 2024 and 1 October 2024 respectively.

Consultation

In the context of the MRP, the TGA engaged in public and targeted consultation between 2021 and 2022. In further targeted consultation between December 2023 and February 2024, the TGA received 27 submissions including from industry, health professionals and their representative bodies, and patient organisations. Most respondents supported the MRP in principle. However, some sponsors noted that they would require additional incentives to repurpose their medicines. The TGA will continue to engage with these stakeholders in relation to the effectiveness of the MRP.

In the context of proposed changes to the regulation of compounded medicines containing GLP-1 RA analogues, the TGA engaged in targeted consultation between February and March 2024. This included representative bodies for health professionals, industry, consumers, and state and territory health departments. A minority of respondents (namely, the Pharmacy Guild of Australia, the Australian Society of Compounding Pharmacists, and the Australian Patients Association) did not support this measure, principally because of the need to ensure continuity of care for patients affected by the global shortages of semaglutide medicines. This concern was addressed by delaying the commencement of this measure, allowing patients time to consult their health practitioner about alternative treatment plans.

The TGA's consultation on other proposed amendments between 2022 and 2024 showed broad support for the measures, including:

- with the Optical Distributors and Manufacturers Association on the proposal to exempt prescriptions spectacle lenses from requiring inclusion in the Register;
- with the Complementary and OTC Medicines Regulatory and Technical Consultative Forum and the public, in relation to adopting the updated sunscreen standard;
- public consultation on the application audit framework and reclassification of medical devices that contain certain materials of animal, microbial or recombinant origin;
- the Medical Software Industry Association in relation to the transitional arrangements for the reclassification of software-based medical devices.

Consultation was not undertaken on other measures as they are minor or machinery in nature.

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

ATTACHMENT

Details of the *Therapeutic Goods Amendment (2024 Measures No. 2) Regulations 2024*

Section 1 – Name

This section provides that the title of the Regulations is the *Therapeutic Goods Legislation Amendment (2024 Measures No. 2) Regulations 2024.*

Section 2 – Commencement

This section provides for the commencement of the Regulations on the day after registration on the Federal Register of Legislation, except Schedule 2 and Schedule 3, which commence on 1 July 2024 and 1 October 2024 respectively.

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 the 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 commencing day after registration

Part 1—Medicines Repurposing Program

Therapeutic Goods Regulations 1990

Part 1 of this Schedule amends the *Therapeutic Goods Regulations 1990* (the TG Regulations) to support the implementation of the Medicines Repurposing Program (the MRP).

Medicines repurposing is the process of identifying new indications (i.e., therapeutic uses) for existing medicines. In a regulatory context, it may involve a person in relation to whom marketing approval has been provided for a medicine applying for an 'extension of indications' of that medicine. That is, an application for marketing approval to also supply the medicine for the proposed new indication(s).

To extend the indications of a medicine that is registered in the Australian Register of Therapeutic Goods (the Register), the person in relation to whom the medicine is registered (the sponsor) must apply to the Secretary under section 23 of the Act for the medicine to be registered for the proposed new indication(s).

There are numerous public health benefits associated with the registration of approved medicines for new indications. Broadly, these include expanded treatment options for prescribers and more equitable patient access to such treatments. However, for various reasons, there is often very little commercial incentive for sponsors to apply for an extension of indications for their medicines.

The MRP was announced as part of a broader Pharmaceutical Benefits Scheme reform package in the 2023-2024 Federal Budget and its principal purpose is to:

- identify, through a nomination and review process, registered prescription medicines with 'off-label' indications that deliver substantial public health benefits; and
- encourage the sponsors of those medicines, through the offer of appropriate incentives, to apply for the registration of their medicines for such indications.

To encourage sponsors to apply for registration of their medicines for a proposed new indication, this Part introduces a fee waiver for applications for an 'extension of indication' for medicines that are a part of the MRP, and makes other related amendments.

Item [1] – After paragraph 35A(1)(e)

This item introduces new paragraph 35A(1)(ea) to the TG Regulations, which provides that it is a function of the Advisory Committee on Medicines (the ACM) to advise and make recommendations to the Secretary about the repurposing of medicines under the program known as the MRP.

Paragraph 63(2)(a) of the Act provides that the regulations may make provision in relation to the establishment of committees to advise the Minister or Secretary on issues relating to therapeutic goods, and the functions and powers of those committees.

The ACM is established under regulation 35 of the TG Regulations and its functions are set out in subregulation 35A(1). Broadly, its role is to provide independent medical and scientific advice to the Minister or Secretary on issues relating to the safety, quality, and efficacy of medicines that are supplied in Australia.

The ACM's new function is to provide advice and make recommendations about the suitability of a nominated medicine for repurposing under the MRP. Specifically, the ACM will advise the Secretary on the safety, quality, and efficacy of the medicine for the proposed new indication(s), and the potential public health benefits that an extension of indications would deliver.

It is intended that this advice will assist the Secretary to objectively assess whether a medicine is suitable for repurposing under the MRP, and whether a fee waiver should be granted under new subregulation 45(4AB).

Item [2] – After subregulation 45(4AA)

This item amends regulation 45 of the TG Regulations to introduce new subregulations (4AB) and (4AC). These amendments enable the Secretary, on their own initiative or following an application, to waive certain fees in relation to an application for an extension of indications under the MRP.

Specifically, new subregulation 45(4AB) provides that the Secretary may waive an application or evaluation fee that is prescribed in Schedule 9 to the TG Regulations in relation to an application under section 23 of the Act if:

- the application is for an extension of indications of a registered medicine; and
- the Secretary is satisfied that the medicine is suitable for repurposing under the program known as the MRP.

The relevant application and evaluation fees are prescribed in Part 2 of Schedule 9 to the TG Regulations. These fees are currently $32,381 and $129,091, respectively (table items 2(bd) and 4(b) refer), which reflect the regulatory effort that is required of the TGA to process an application for an extension of indications.

It is therefore intended that a waiver of the application and evaluation fee (in full) will serve as a meaningful incentive for sponsors of medicines that have been selected for repurposing under the MRP to apply for the registration of their medicines for new and important therapeutic uses.

From a cost recovery perspective, the regulatory effort required of the TGA to process an extension of indications application under the MRP will be offset by the funding allocated to the program by the 2023-2024 Federal Budget.

New subregulation 45(4AC) provides that the Secretary may waive a fee under subregulation (4AB) on the Secretary's own initiative or on application.

Items [3] and [4] – Subregulation 48(1) (definitions of *eligible person* and *initial decision*)

These items amend subregulation 48(1) of the TG Regulations to revise the definitions of '*eligible person*' and '*initial decision*'. The purpose of these amendments is to limit the persons who may seek merits review of a decision made under new subregulation 45(4AB), and the circumstances in which they may do so.

Subregulation 48(1) sets out a list of decisions that are made by the Secretary under the TG Regulations ('*initial decisions*') that are reviewable by the Minister and, subsequently, the Administrative Appeals Tribunal. It also sets out a list of persons ('*eligible persons*') who may seek review of an initial decision.

Relevantly, in accordance with subregulation 48(1), a decision made by the Secretary under regulation 45 of the TG Regulations is an '*initial decision*' (paragraph (g) of that definition refers). Further, '*eligible persons*' in relation a decision under regulation 45 include any persons whose interests are affected by such a decision (table item 1 of that definition refers).

However, these review arrangements are not appropriate given the nature and purpose of a decision made by the Secretary under new subregulation 45(4AB). Broad review rights would undermine the important public health objective of the MRP, which is to improve patient access to important treatments, and address currently unmet therapeutic needs. In this context, there is consequently a need to provide certainty and finality to decisions made under subregulation 45(4AB).

Item [3] introduces new table item 5A to the definition of '*eligible person*' in subregulation 48(1), which provides that a decision of the Secretary under subregulation 45(4AB) is only reviewable if:

- the decision is to refuse to waive a fee under that subregulation, following an application referred to in new subregulation 45(4AC); and
- the person seeking review is the person who made the application for the fee waiver under new subregulation 45(4AC).

This ensures that a person who is most immediately affected by a refusal to waive the application and evaluation fees (i.e., the sponsor of the relevant medicine) is able to seek review of such a decision, and third parties are unable able to seek review in the circumstances.

Item [4] amends paragraph (g) of the definition of '*initial decision*' to exclude a decision to waive a fee under subregulation 45(4AB). This amendment complements item [3] by making it clear that a decision of the Secretary to waive a fee under new subregulation 45(4AB) is not an initial decision.

Part 2—Exemption for certain prescription spectacle lenses

Therapeutic Goods (Medical Devices) Regulations 2002

Part 2 of this Schedule amends the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to provide that certain medical devices that are prescription spectacle lenses are exempt from the requirement to be included in the Register. Specifically, the exemption applies in relation to prescription spectacle lenses (whether or not supplied with a mounting) if the lenses (disregarding any lens treatments) are intended, by the person under whose name the device is or is to be supplied, to be used only to provide refractive corrections.

Paragraph 41HA(1)(b) of the Act provides that the regulations may exempt specified kinds of medical devices ('*exempt devices*') from the operation of Division 3 of Part 4-11 of the Act. The effect of this provision is to enable the regulations to exempt certain kinds of medical devices from the requirement to be included in the Register — and therefore the requirement to undergo pre-market assessment by the TGA — before they can be imported into, manufactured or supplied in, or exported from, Australia.

Subregulation 7.1(1) of the MD Regulations provides that, for the purposes of paragraph 41HA(1)(b) of the Act, a kind of medical device mentioned in Part 1 of Schedule 4 to the MD Regulations is an exempt device.

Importantly, an exempt device is distinct from a kind of medical device that the Minister has determined by legislative instrument under section 7AA of the Act to be an '*excluded good*'. The former is only exempt from the operation of Division 3 of Part 4-11 of the Act. The latter is not a therapeutic good and is therefore not regulated under the Act.

Item [5] – Part 1 of Schedule 4 (after table item 1.4)

This item introduces new table item 1.4A in Part 1 of Schedule 4 to the MD Regulations. This table item provides that a medical device that is prescription spectacle lenses (whether or

not supplied with a mounting) is an exempt device if the lenses (disregarding any coatings) are intended, by the person under whose name the device is or is to be supplied, to be used only to provide refractive corrections (corrective lenses).

A prescription spectacle lens is a kind of personalised medical device. Specifically, it is a glass or plastic device that is intended to be worn by a patient, typically in a spectacle frame, in accordance with a prescription. In this context, a 'prescription' is a request that is made by a health practitioner (often an optometrist, following an eye examination or visual acuity test) specifying the design characteristics of the spectacle lens.

Some prescription spectacle lenses supplied in Australia are included in the Register, but others are not. This stems from a misunderstanding of the regulatory requirements that apply in relation to prescription spectacle lenses. This amendment provides clarity to industry around the regulatory requirements applying to medical devices that are prescription spectacle lenses.

This exemption reflects that corrective lenses are low risk kinds of medical devices that are prescribed and fitted by persons with appropriate qualifications. Its intended effect is to:

- firstly, provide sponsors with greater clarity in relation to the regulatory requirements that apply to such devices; and
- secondly, reduce regulatory burden on sponsors by eliminating the need for such devices to undergo pre-market assessment by the TGA.

However, corrective lenses still need to comply with other legislative requirements that apply to medical devices under the Act. In particular, sponsors still need to ensure that their devices comply with the essential principles and are the subject of appropriate conformity assessment procedures. Such devices are also still subject to post-market review and action (including recalls) by the TGA if necessary.

The exemption applies regardless of whether the device is supplied as single item (e.g., spare lenses), or as a single product (e.g., a pair of glasses). It also applies regardless of any lens treatments (including coatings) that are applied to the corrective lens (including, for example, UV protection, antiglare, polarised, and blue light coatings). If the only purpose of the prescription spectacle lenses, other than the purpose of the lens treatments, is corrective refraction, the prescription spectacle lenses are exempt from inclusion in the Register.

Importantly, the exemption does not apply to prescription spectacle lenses that are intended to do more than just provide refractive corrections (disregarding the effects of lens treatments). For example, the exemption does not apply to prescription spectacle lenses intended for use in treating or slowing the progression of myopia in children. These lenses may have refractive corrections, but are specially designed and have additional technology in the lenses that also have a treatment effect. Devices of these kinds still need to be included in the Register before they can be lawfully imported into, manufactured or supplied in, or exported from Australia.

Part 3—Classification rules for programmed or programmable medical device or software that is a medical device

Therapeutic Goods (Medical Devices) Regulations 2002

Part 3 of this Schedule amends the MD Regulations to supplement the existing transitional arrangements for the reclassification of programmed or programmable medical devices or software that is a medical device (the transitional arrangements). The purpose of the amendments is to minimise supply disruptions caused by the reclassification of these kinds of devices by providing sponsors with an alternative means of accessing the transitional arrangements.

Clauses 4.5 to 4.8 in Schedule 2 to the MD Regulations set out the classification rules that apply to programmed or programmable medical devices or software that is a medical device. These rules were introduced in 2019 to reclassify (and in most cases up-classify) such devices.

The transitional arrangements are set out in Subdivision C in Division 11.10 of Part 11 of the MD Regulations. They apply to programmed or programmable medical devices, or software that is a medical device, that are '*transitional kinds of medical devices*' — that is, a kind of medical device included in the Register because of an application for inclusion that was made by a sponsor before 25 February 2021.

Subregulation 11.45(2) of the MD Regulations provides that, subject to subregulations (3) and (5), classification rules 4.5 to 4.8 apply in relation to a transitional kind of medical device on and after 1 November 2024. Subregulation 11.45(3) of the MD Regulations enables the sponsor of a transitional kind of medical device to effectively extend the transitional period for their device beyond 1 November 2024 if certain requirements are met. Conversely, subregulation 11.45(5) has the effect that these transitional arrangements are not available if the sponsor of a transitional kind of medical device fails to comply with the notice requirements in regulation 11.46.

The TGA is concerned that if sponsors do not meet the 1 November 2024 deadline to apply for the inclusion of their kind of device (at the new classification) in the Register, this may result in significant supply disruptions with respect to these kinds of devices (as they may be liable to be cancelled from the Register under paragraph 41GN(1)(f) of the Act on the basis that they are incorrectly classified).

The amendments in this Part have the effect that the transitional arrangements will still be available to sponsors who apply for a conformity assessment certificate before 1 November 2024. Following issue of the conformity assessment certificate, sponsors will then have 6 months to submit their application to include the transitional kind of device at the new classification in the Register.

Item [6] – Subregulation 11.45(2)

This item amends subregulation 11.45(2) of the MD Regulations to insert a reference to new subregulation (4A). This amendment is consequential to the amendments that are made by item [7] below.

Item [7] – After subregulation 11.45(4)

This item introduces new subregulations 11.45(4A), (4B) and (4C) in the MD Regulations.

The effect of these new subregulations, together with existing subregulations (3) and (5), is that sponsors of transitional kinds of medical devices, who have given the Secretary a notice in compliance with regulation 11.46, have until 1 November 2024 to lodge and pay the prescribed application fee for either:

- an application under section 41C of the Act for the inclusion of their reclassified (i.e., '*new kind*' of) device in the Register; or
- an application under section 41EB of the Act for a conformity assessment certificate in respect of their new kind of device.

New subregulation 11.45(4A) provides that classification rules 4.5 to 4.8 in Schedule 2 to the MD Regulations do not apply to a transitional kind of medical device before the day applicable under subregulation (4B), if:

- on or after 25 February 2021, and before 1 November 2024, the person makes an application under section 41EB of the Act for a conformity assessment certificate in respect of a kind (the ***new kind***) of medical device; and
- the person has not, before 1 November 2024, made an application under the Act to have the new kind of medical device included in the Register; and
- the person has not withdrawn the conformity assessment certificate application, and that application has not lapsed under section 41EG of the Act, before 1 November 2024; and
- the person gives the Secretary a notice under regulation 11.46 in relation to the transitional kind of medical device; and
- the unique product identifier of the new kind of medical device contained in the conformity assessment certificate application is the unique product identifier, or one of the unique product identifiers, stated in the notice.

New subregulation 11.45(4B) provides that for the purposes of new subregulation (4A), the applicable day is the later of 1 November 2024 and the day after the earliest of the following days:

- the day the person withdraws the conformity assessment certificate application;
- the day that application lapses under section 41EG of the Act;
- in the case of a decision to not issue the conformity assessment certificate and where there is no longer any possibility of a change in the outcome of that decision — the first day on which there is no longer that possibility;
- in the case of a decision to issue the conformity assessment certificate:
    - if, at the end of the period of 6 months beginning on the day of the issue of the certificate, the person has not made an application under the Act to have the new kind of medical device included in the Register — the last day of that 6-month period; or
    - if, before the end of the period of 6 months beginning on the day of the issue of the certificate, the person has made an application under the Act to have the new kind of medical device included in the Register — the day applicable under new subregulation (4C).

New subregulation 11.45(4C) provides that for the purposes of subparagraph (4B)(d)(ii), the applicable day is the day after the day on whichever of the following events occurs first:

- the person withdraws the application mentioned in that subparagraph;
- that application lapses under section 41FK of the Act;
- that application is finally determined.

Part 4—Minor and technical amendments

Therapeutic Goods Regulations 1990

Part 4 of this Schedule makes a small number of minor technical and editorial amendments to the TG Regulations.

Item [8] – Subregulation 12AC(2) (note)

This item amends the note at the end of subregulation 12AC(2) of the TG Regulations to replace the reference to "section 52 of the Act" with a reference to "regulation 46AA" instead.

This amendment ensures that the note correctly identifies new regulation 46AA of the TG Regulations as being relevant to identity cards for persons who are '*authorised officers*' under the TG Regulations. That is, instead of section 52 of the Act, which relates to identity cards for persons who are '*authorised persons*' under the Act.

Items [9] to [11] – Subregulations 23(1) and (2)

These items amend regulation 23 of the TG Regulations, principally to repeal the definition of '*appropriately fastened and sealed*'. The effect of these amendments is that those words, when used in Part 5 of the TG Regulations, are given their ordinary meaning.

Part 5 of the TG Regulations sets out procedures relating to a subset of the TGA's sampling and laboratory testing activities. Relevantly, Part 5 requires that:

- when taking samples of therapeutic goods pursuant to regulation 24 of the TG Regulations, an authorised officer must ensure the samples are appropriately fastened and sealed, before forwarding them to a laboratory for analysis (regulation 26 refers); and
- when receiving samples that have been taken by an authorised officer or delivered by sponsors in compliance with paragraph 28(5)(h) or subsection 41FN(2) of the Act, analysts and other officers of the TGA must determine whether the sample is appropriately fastened and sealed (regulations 26A and 27 refer).

Subregulation 23(2) provides the definition of '*appropriately fastened and sealed*' for the purposes of Part 5 of the TG Regulations. This definition is intended to ensure the integrity of test results relating to samples of therapeutic goods that are tested under Part 5.

However, the definition is highly prescriptive and impractical to apply. Many samples that are suitable for testing may not meet the definition of appropriately fastened and sealed. This definition therefore causes administrative burden for the TGA and regulatory burden for sponsors.

In particular, paragraph 23(2)(b) provides that a sample will not satisfy the definition unless it is fastened and sealed so as to prevent the opening of the container or package, and the removal of the information referred to in paragraph (2)(a), without breaking the seal. This means, for example, that if a sponsor delivers a sample to the TGA that is packaged in a way that makes it possible to remove the sponsor's name and address from the package or container, without perforating that package or container, the sample is not appropriately fastened and sealed. This is so notwithstanding that the integrity of the sample within the package or container itself has not been compromised. In such cases, the TGA must either return the sample to the sponsor or test it outside of Part 5 of the TG Regulations.

Item [10] amends subregulation 23(1) of the TG Regulations to remove '*appropriately fastened and sealed*' as a defined term, and item [11] repeals subregulation 23(2) in its entirety. As a result, these words are given their ordinary meaning, and it is intended that this will reduce both regulatory and administrative burden, and improve the efficiency of the TGA's laboratory testing activities under Part 5 of the TG Regulations.

Item [9] makes a consequential editorial amendment to regulation 23 to remove the subregulation number.

Item [12] – Regulation 33

This item replaces regulation 33 of the TG Regulations.

New subregulation 33(1) provides that an authorised officer is not entitled to exercise any powers under Part 5 of the TG Regulations in relation to premises if:

- the occupier of the premises has required the authorised officer to produce their identity card (issued under new regulation 46AA) for inspection; and
- the authorised officer fails to comply with the request.

New subregulation 33(1) largely replicates current subregulation 33(2) of the TG Regulations. However, unlike current subregulation 33(2), new subregulation 33(1) specifies the consequence of an authorised officer's failure to produce their identity card for inspection if required to do so by the occupier of the premises.

New subregulation 33(2) provides that, for the purposes of subregulation (1), 'occupier', in relation to premises, includes a person present at the premises who is in apparent control of the premises.

Item [13] – Before regulation 46A

This item introduces new regulation 46AA in the TG Regulations to effectively relocate current subregulations 33(1), (3) and (4), which are repealed by item [12] above, into the new regulation 46AA.

New subregulation 46AA(1) provides that the Secretary is to ensure that each person who is an authorised officer under the TG Regulations is issued with an identity card that incorporates a recent photograph of that person.

New subregulation 46AA(2) provides that when a person ceases to be an authorised officer, the person must, as soon as practicable after so ceasing, return the person's identity card to the Secretary. A person's failure to comply with this requirement constitutes an offence punishable by one penalty unit.

New subregulation 46AA(3) provides that an offence under subregulation (2) is an offence of strict liability.

When strict liability applies to an offence, the prosecution is only required to prove the physical elements of the offence, not the fault elements, beyond reasonable doubt for the defendant to be found guilty. However, the defence of honest and reasonable mistake of fact is available to the defendant (section 9.2 of the *Criminal Code* refers).

Strict liability is used in circumstances where there is a public interest in ensuring that regulatory schemes are observed, and it can be reasonably expected that the person was aware of their duties and obligations. Strict liability offences can be considered a limitation of the presumption of innocence because the defendant can be found guilty without the prosecution needing to prove the fault elements of the offence.

However, the inclusion of a strict liability offence for a contravention of new subregulation 46AA(2) is necessary to prevent the incidence of persons attempting to impersonate an authorised officer.

Items [14] to [16] – Schedule 5 (table items 1 and 11) and Schedule 5A (table item 4)

These items amend a small number of table items in Schedule 5 and Schedule 5A to the TG Regulations to update the references in those items to the *Customs (Prohibited Imports) Regulations 1956* (the PI Regulations).

Table items 1 and 11 of Schedule 5, and table item 4 of Schedule 5A, currently refer to the PI Regulations as the 'Customs (Prohibited Imports) Regulations'. This is not a defined term in the TG Regulations. Conversely, in other table items in those Schedules, the title of the PI Regulations is cited in full and in italics.

Item [14] amends table item 1 (column 2, paragraph (c)) of Schedule 5 to replace the reference to "Customs (Prohibited Imports) Regulations" with "*Customs (Prohibited Imports) Regulations 1956*".

Items [15] and [16] make the same amendments, respectively, to:

- table item 11 (column 2, paragraph (a)) of Schedule 5; and
- table item 4 (column 3, paragraph (c)) of Schedule 5A.

Part 5—Transitional provisions

Therapeutic Goods (Medical Devices) Regulations 2002

Item [17] – In the appropriate position in Part 11

This item introduces new Division 11.20 to Part 11 of the MD Regulations, which comprises transitional provisions relating to the Regulations.

Definitions

New regulation 11.74 provides that, in new Division 11.20, the term ***amending regulations*** means the Regulations.

Exemption for certain prescription spectacle lenses

New regulation 11.75 provides that new table item 1.4A of Part 1 of Schedule 4 to the MD Regulations, as inserted by Part 2 of Schedule 1 to the Regulations, applies in relation to medical devices imported into, exported from, or manufactured or supplied in Australia, on or after the commencement of that item.

Therapeutic Goods Regulations 1990

Item [18] – In the appropriate position in Part 9

This item introduces new Division 25 to Part 9 of the TG Regulations. In effect, new Division 25 provides transitional arrangements for the amendments that are made by Schedule 1 to the Regulations.

Definitions

New regulation 99 provides that, in new Division 25, the term ***amending regulations*** means the Regulations.

Fee waivers in relation to the Medicines Repurposing Program

New regulation 100 provides that new subregulation 45(4AB) of the TG Regulations, as inserted by Part 1 of Schedule 1 to the Regulations, applies in relation to applications (i.e., for an extension of indications under the MRP) that are made on or after the date that Schedule 1 to the Regulations commences.

Examination, testing and analysis of goods

New regulation 101 provides that the amendments of regulation 23 of the TG Regulations, as made by Part 4 of Schedule 1 to the Regulations, apply in relation to samples that are taken or delivered on or after the commencement of that Schedule.

Identity cards

New regulation 102 provides that if an identity card has previously been issued to an authorised officer under regulation 33 of the TG Regulations, and was in the possession of the authorised officer immediately before the commencement of Schedule 1 to the Regulations, the identity card is taken (after that commencement) to have been issued to the authorised officer under new regulation 46AA of the TG Regulations.

Schedule 2—Amendments commencing 1 July 2024

Part 1—Standard for sunscreen preparations

Therapeutic Goods Regulations 1990

Part 1 of this Schedule amends the TG Regulations to update the efficacy testing requirements, and some of the labelling requirements, for sunscreen products that are marketed as therapeutic goods in Australia. This is necessary to ensure that such products are tested to International Organization for Standardization (ISO) standards and adequately protect users from the harmful effects of ultraviolet (UV) radiation, and that users are instructed on the correct way to apply certain sunscreens (i.e., sunscreen aerosols and spray pump packs).

In Australia, the TGA regulates sunscreen preparations that are therapeutic goods (therapeutic sunscreens) to ensure their quality, safety, and efficacy. Such preparations include:

- all 'primary' sunscreen products—i.e., products that are represented as being primarily to protect a user's skin from UV radiation; and
- some 'secondary' sunscreen products, depending on their presentation and claimed sun protection factor (SPF)—i.e., products that are represented as having a primary function other than skin protection, but which still provide some protection from UV radiation (e.g., some moisturiser products).

Unless they are exempt, or the subject of an approval or authority under the Act, therapeutic sunscreens must be included in the Register as either listed or registered goods before they can be lawfully imported into, supplied within, or exported from Australia.

Table item 7 of Schedule 4 to the TG Regulations sets out the eligibility criteria that a therapeutic sunscreen must satisfy to be included in the Register as a listed good. Listed goods are considered low risk and are not individually evaluated by the TGA before they are made available on the market. Instead, sponsors must certify that their listed good meets minimum requirements in relation to safety, quality, and efficacy. It is an offence for a sponsor to make a false certification.

Relevantly, paragraphs (a) and (b) of table item 7 require listed therapeutic sunscreens to comply with the efficacy testing and labelling requirements that are set out in Australian/New Zealand Standard AS/NZS 2604:2012, *Sunscreen products – Evaluation and classification* ("the 2012 Standard"). If a therapeutic sunscreen does not satisfy these criteria, it must undergo a full pre-market evaluation by the TGA for safety, quality, and efficacy, and be included in the part of the Register for registered goods, before it can be lawfully imported into, supplied within, or exported from Australia.

Item [1] – Regulation 2 (definition of *Standard AS/NZS*)

This item repeals the definition of '*Standard AS/NZS*' in regulation 2 of the TG Regulations, as this term is no longer used in the TG Regulations.

Item [2] – Schedule 4 (table item 7, column headed "Therapeutic goods", paragraph (a))

This item amends table item 7 of Schedule 4 to the TG Regulations to update the efficacy testing requirements, and some labelling requirements, for therapeutic sunscreens that are listed in the Register.

Specifically, this item replaces the reference to the 2012 Standard in paragraph (a) of table item 7 with a reference to the 'Australian/New Zealand Standard AS/NZS 2604:2021, *Sunscreen products – Evaluation and classification*, published jointly by, or on behalf of, Standards Australia and Standards New Zealand' (the new Standard).

The new Standard was published on 25 June 2021, and updated in 2022. It replaced the 2012 Standard, principally to:

- align Australian and New Zealand test methods for determining the SPF, broad spectrum, and water resistance of sunscreen preparations with internationally adopted ISO standards; and
- introduce labelling requirements that require sunscreen preparations that are supplied as sunscreen aerosols or in spray pump packs to contain instructions in relation to dosage, optimum conditions for application, and the avoidance of inhalation.

The effect of this amendment is that all therapeutic sunscreens that are listed in the Register on or after 1 July 2024 must comply with the testing and labelling requirements specified in the new Standard. However, for therapeutic sunscreens that are already listed in the Register, transitional arrangements are implemented to provide industry with sufficient time to bring those goods into compliance with the updated testing and labelling requirements. These transitional arrangements are detailed in item [11] of this Schedule.

Subsection 63(4) of the Act relevantly provides that the regulations may make provision for a matter by applying, adopting, or incorporating, with or without modification, any matter contained in an instrument, as that instrument is in force from time to time. The Regulations are intended to have the effect of incorporating the new Standard by reference, with the intended manner of incorporation being as it exists from time to time. Subsection 63(4) is intended to provide the intention to incorporate by reference as in force from time to time, in accordance with subsection 14(2) of the *Legislation Act 2003* which would otherwise preclude such incorporation by reference.

The new Standard may be purchased from www.saiglobal.com. It is not freely available, as it is subject to copyright. However, it is anticipated that the persons who are most affected by the adoption of the new Standard in the TG Regulations are likely to possess the publication. As important benchmarks for the quality, safety, and efficacy of sunscreen preparations, it would be infeasible from a regulatory perspective to not adopt such benchmarks on the basis that the publication is not freely available. Alternatively, by prior written arrangement where possible, and without charge, the new Standard can be viewed by members of the public at the TGA office in Fairbairn, ACT.

Part 2—Auditing applications for inclusion of medical devices in the Register

Therapeutic Goods (Medical Devices) Regulations 2002

Part 2 of this Schedule amends the MD Regulations to revise the application audit framework for medical devices.

Part 4-5 of the Act sets out administrative procedures that apply to applications for a kind of medical device to be included in the Register (applications for inclusion). These procedures are principally aimed at ensuring that a kind of medical device that is the subject of an application for inclusion complies with all relevant legislative requirements before the Secretary makes a decision to include the device in the Register.

Relevantly, paragraph 41FH(1)(a) of the Act provides that the Secretary must select for auditing any application for inclusion that is of a kind prescribed by the regulations (mandatory application audit). The purpose of such an audit is to verify that an application for inclusion has been made in accordance with the requirements set out in Division 1 of Part 4-5 of the Act, and that the matters which the applicant has certified under section 41FD of the Act are correct.

Subregulation 5.3(1) of the MD Regulations prescribes, for the purposes of paragraph 41FH(1)(a) of the Act, the kinds of applications for inclusion that the Secretary must select for a mandatory application audit. The prescribed applications relate to a range of medical devices which, due to their nature, may pose a higher degree of risk to users. All other applications (i.e., those that are not of a kind prescribed by subregulation 5.3(1)) may be selected for audit at the Secretary's discretion.

However, subregulations 5.3(2), (2AA) and (2A) set out circumstances in which subregulation 5.3(1) does not apply. In such cases, although the Secretary may exercise their discretion to select a prescribed application for audit, they are not required to do so.

Item [3] – Subregulation 5.3(1)

This item replaces subregulation 5.3(1) of the MD Regulations to prescribe a narrower range of applications for inclusion for the purposes of paragraph 41FH(1)(a) of the Act. The effect of this amendment is to limit mandatory application audits to only applications for inclusion of those kinds of medical devices that pose the greatest risk of harm to users, and provide greater flexibility for the Secretary to select (at the Secretary's discretion) any other applications for audit.

For the purposes of paragraph 41FH(1)(a) of the Act, new subregulation 5.3(1) prescribes applications for inclusion that relate to:

- a Class III medical device;
- a Class 3 IVD medical device;
- a Class 4 IVD medical device;
- a Class 4 in-house IVD medical device;
- an IVD medical device that is intended for self-testing; and
- an IVD medical device that is intended for point of care testing.

The purpose of new subregulation 5.3(1) is to provide the TGA with greater flexibility in terms of the allocation of its pre-market assessment resources. It is intended that, by prescribing fewer kinds of application for inclusion that must be selected for a mandatory application audit, the TGA will be able to adopt a more proactive and risk-based approach to the selection of applications for audit. This would be based on post-market signals, emerging issues and situational risks, regulatory reforms, and regulatory intelligence.

It is also intended that the amendment will reduce regulatory burden on sponsors, including by improving pre-market assessment timeframes for medical devices generally. Notably, the amendment will also result in significant cost savings for sponsors of certain kinds of medical devices—namely, those that would continue to be prescribed by subregulation 5.3(1) were it not for the amendment. This is because application audit fees are only payable by sponsors whose applications for inclusion are selected for mandatory audit.

Item [4] – After subregulation 5.3(2AA)

This item introduces new subregulation 5.3(2AB) to the MD Regulations to set out additional circumstances in which an application for inclusion of a medical device that is of a kind prescribed by subregulation 5.3(1) does not need to be selected for a mandatory application audit. The new exemption applies to kinds of medical devices that have, in effect, been given pre-market approval by certain overseas regulators.

Specifically, new subregulation 5.3(2AB) provides that subregulation (1) does not apply to an application for a kind of medical device to be included in the Register if the kind of medical device:

- is the subject of a medical device licence issued by Health Canada under the *Medical Devices Regulations* (Canada);
- is the subject of an order approving an application for premarket approval from the US Food and Drug Administration under the *Federal Food, Drug, and Cosmetic Act* (United States of America);
- is the subject of a pre-market certification or approval issued by the Japanese Ministry of Health, Labour and Welfare, or the Japanese Pharmaceuticals and Medical Devices Agency, under *The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices* (Japan);
- is the subject of an entry in the Register of Health Products kept and maintained by the Health Sciences Authority of Singapore under the *Health Products Act 2007* (Singapore); or
- has been certified in accordance with the Australia-UK Mutual Recognition Agreement, the EC Mutual Recognition Agreement, or the EFTA Mutual Recognition Agreement.

However, new subregulation 5.3(2AB) does not apply if the relevant licence, order, approval, certification, or entry has been restricted, suspended or revoked, or has otherwise ceased to be in effect.

The new exemption is intended to reflect confidence that, by approving a kind of medical device, relevant overseas regulators have signified that the kind of device, and the process by which it has been manufactured, meet certain minimum benchmarks for safety and performance.

Like the amendment that is made by item [3] above, the purpose of new subregulation 5.3(2AB) is to enable the TGA to target its pre-market assessment resources where they are most needed, and to reduce regulatory burden on sponsors of devices that have already been the subject of robust pre-market evaluation by overseas regulators.

Importantly, new subregulation 5.3(2AB) does not incorporate or prescribe any matters by reference to the comparable overseas legislation referred to in that subregulation. Instead, references to the relevant legislation are simply to the fact of whether certain actions have been taken, or decisions have been made, by the relevant overseas regulator in accordance with that legislation.

Item [5] – Subregulation 5.12(1)

This item replaces subregulation 5.12(1) of the MD Regulations because of the amendment that is made by item [4] above.

Regulation 5.12 applies (relevantly) in relation to a kind of medical device that is specified in paragraph 5.3(1)(j) of the MD Regulations. These are in-vitro diagnostic ("IVD") medical devices that are used for a range of specific purposes, such as for example self-testing, point of care testing, or detecting the presence of or exposure to a sexually transmitted agent.

As item [4] above replaces subregulation 5.3(1), paragraph 5.3(1)(j) no longer exists. Consequently, this item replaces subregulation 5.12(1) to specify the kinds of IVD medical devices to which the condition of inclusion applies.

New subregulation 5.12(1) applies in relation to the following kinds of medical devices:

- a Class 3 IVD medical device;
- a Class 4 IVD medical device;
- a Class 4 in-house IVD medical device;
- an IVD medical device that is intended for self-testing;
- an IVD medical device that is intended for point of care testing; and
- a spinal fusion implantable device.

Item [6] – Regulation 11.22

This item repeals regulation 11.22 of the MD Regulations, which sets out transitional arrangements relating to the reclassification of joint replacement medical devices between 2012 and 2015, as that provision is no longer needed.

Part 3—Classification rules for medical devices containing substances of animal or microbial origin

Therapeutic Goods (Medical Devices) Regulations 2002

Part 3 of this Schedule amends the MD Regulations, principally to reclassify (and in most cases down-classify) kinds of medical devices that only contain:

- tissues, cells, or substances of microbial or recombinant origin; and

- certain tissues or cells of animal origin that have been rendered non-viable, or their derivatives.

Since the commencement of the MD Regulations in 2002, the TGA has regulated medical devices that contain tissues, cells, or substances of animal, microbial, or recombinant origin as Class III (high risk) medical devices. This was considered necessary to protect users from the transmission of rare degenerative brain disorders through exposure to contaminated materials — including, for example, the human equivalent of 'mad cow disease' — the risk of which was previously considered high.

However, due to a range of control measures that have been introduced in many countries, the risk of transmission of such diseases has diminished. Further, many comparable overseas regulators do not assess devices containing tissues, cells, or substances of microbial or recombinant origin as high risk. This is a key point of distinction between the Australian regulatory framework for medical devices, and those of comparable overseas regulators such as in the European Union.

The amendments made by this Part to reclassify such products are intended to align Australia's risk classification rules for medical devices that contain the materials identified above, with those implemented by comparable overseas jurisdictions. This, in turn, removes the regulatory burden faced by sponsors wishing to import such devices into Australia, who are currently required to undertake further conformity assessment procedures relevant to Class III medical devices before the device can be included in the Register.

Item [7] – Subclause 13.4(3) of Schedule 1 (table item 25A)

This item amends subclause 13.4(3) of Schedule 1 to the MD Regulations to replace table item 25A. This amendment complements item [8] below.

Clause 13.4 of Schedule 1 requires that instructions for use be provided with a medical device. Relevantly, subclause 13.4(3) sets out in a table the information that must be included in the instructions for use, as applicable.

New table item 25A of subclause (3) provides that, for a medical device to which clause 5.5 of Schedule 2 to the MD Regulations applies (other than an IVD medical device), the instructions for use of the device must include information to the effect that the device contains or incorporates any of the following:

- non-viable tissues, or cells, of animal origin;
- derivatives of such tissues or cells.

Item [8] – Clause 5.5 of Schedule 2

This item replaces clause 5.5 of Schedule 2 to the MD Regulations to remove its application to medical devices that only contain tissues, cells, or substances of microbial or recombinant origin, or certain non-viable tissues or cells of animal origin, or their derivatives. New clause 5.5 reflects the low-risk nature of these kinds of devices, which will most likely be down-classified as a result of this amendment.

Section 41DB of the Act provides that the regulations may specify classifications, to be known as '*medical device classifications*', that apply to medical devices or kinds of medical

devices, as well as matters in relation to the classification of medical devices or kinds of medical devices. Regulation 3.1 of the MD Regulations specifies the medical device classifications for section 41DB of the Act, with Class III being the highest.

Regulation 3.2 of the MD Regulations provides for the making of medical device classification rules. The purpose of these rules is to enable a manufacturer to classify their medical device according to the potential risks associated with the use of the device. The higher a device's risk profile, the higher its classification. Schedule 2 to the MD Regulations sets out the classification rules for medical devices other than IVD medical devices.

The practical relevance of a medical device's risk classification is that the pre- and post-market scrutiny applied to the device is commensurate with that risk. By classifying their medical device, a manufacturer can readily identify the conformity assessment procedures that must be applied to the device before it can be included in the Register. The post-market record-keeping requirements that a sponsor must adhere to also differ between medical devices of different classifications.

The effect of new subclauses 5.5(1) and (3) is that, subject to subclause (2), a medical device is Class III (high risk) if it contains any of the following:

- non-viable tissues, or cells, of animal origin (other than tissues or cells from hair or wool);
- derivatives of such tissues or cells (other than sintered hydroxyapatite or tallow derivatives).

This means that if the only tissues or cells in a medical device are tissues or cells from hair or wool, or sintered hydroxyapatite or tallow derivatives, or a combination of those, the device is no longer classified as Class III under clause 5.5. In addition, if a medical device only contains tissues, cells, or substances of microbial or recombinant origin, the device is also no longer classified as Class III under clause 5.5. Instead, these medical devices are classified under other applicable classification rules.

New subclause 5.5(2) excludes from the operation of the clause any device that is intended by the manufacturer to come into contact with intact skin only. Such a device is instead classified as Class I (low risk), in accordance with clause 2.1 of Schedule 2 to the MD Regulations, unless the device is classified at a higher level under another clause of that Schedule.

Part 4—Transitional provisions

Therapeutic Goods (Medical Devices) Regulations 2002

Part 4 of this Schedule provides for transitional arrangements in relation to the amendments that are made to the MD Regulations by Part 2 and Part 3 of this Schedule.

Item [9] – Regulation 11.74

This item inserts the following definitions into new regulation 11.74 of the MD Regulations:

- ***finally determined***, in relation to an application, means the first time that both of the following conditions are met:
    - a decision has been made whether or not to grant the application; and

    - there is no longer any possibility of a change in the outcome of the decision;
- ***inclusion day*** for an entry of a kind of medical device in the Register means the day on which the inclusion of that kinds of device in the Register commences; and
- ***transitional medical device*** means a medical device of a kind that:
    - was, immediately before 1 July 2024, included in the Register, and a kind of device to which clause 5.5 of Schedule 2 to the Regulations applied; and
    - is, on 1 July 2024, a kind of medical device to which clause 5.5 of Schedule 2 to the MD Regulations no longer applies.

Item [10] – In the appropriate position in Division 11.20

This item introduces new regulations 11.76 and 11.77 in the MD Regulations.

Auditing of applications

New subregulation 11.76(1) provides that the amendments of regulation 5.3 of the MD Regulations, made by Part 2 of Schedule 2 to the Regulations, apply in relation to applications made on or after 1 July 2024.

New subregulation 11.76(2) provides that the amendment of regulation 5.12 of the MD Regulations, made by Part 2 of Schedule 2 to the Regulations, applies in relation to a kind of medical device that is included in the Register on or after 1 July 2024. This is so regardless of whether the inclusion day for the entry of that kind of medical device occurred before, on, or after 1 July 2024. Therefore, all devices that are in the Register on or after 1 July 2024 must comply with the condition in regulation 5.12, as applicable.

Reclassification of medical devices

New regulation 11.77 provides for the application of the amendment of clause 5.5 of Schedule 2 to the MD Regulations that is made by Part 3 of Schedule 2 to the Regulations (the reclassification amendment).

Subregulation 11.77(1) provides that the reclassification amendment applies in relation to the following:

- an application for a kind of medical device to be included in the Register that is made on or after 1 July 2024;
- a kind of medical device that is included in the Register as a result of such an application.

Subregulation 11.77(2) provides that, subject to subregulations (3) and (4), the reclassification amendment applies in relation to a transitional medical device on and after 1 July 2026. This provides sponsors of transitional medical devices two years to apply for the inclusion of their (reclassified) devices in the Register.

Subregulation 11.77(3) provides that the reclassification amendment does not apply in relation to a transitional medical device before the day applicable under subregulation (4), if:

- a person applies under the Act to have a kind (the new kind) of medical device included in the Register:
    - on or after the inclusion day for the entry of the transitional medical device; and
    - on or after 1 July 2024; and

    - before 1 July 2026; and
- the new kind of device would, but for the reclassification amendment, be the same kind of medical device as the transitional medical device.

Subregulation 11.77(3) effectively enables sponsors of transitional medical devices to extend the transitional period for their kind of device beyond 1 July 2026, provided they apply for the inclusion of the new kind of device before that date.

Subregulation 11.77(4) provides that, for the purposes of subregulation (3), the day is the day following the day on which the application mentioned in paragraph (3)(a):

- is withdrawn; or
- lapses under section 41FK of the Act; or
- is finally determined.

Subregulation 11.77(5) provides that subregulation 5.3(1) of the MD Regulations does not apply to an application for inclusion of the new kind of device in the Register.

Therapeutic Goods Regulations 1990

Item [11] – In the appropriate position in Division 25 of Part 9

This item inserts new regulation 103 into Division 25 of Part 9 to the TG Regulations.

Subregulation 103(1) provides that, subject to subregulations (2) and (3), the amendments of the TG Regulations made by Part 1 of Schedule 2 to the Regulations apply to sunscreen preparations from 1 July 2024. Therefore, any sunscreen preparations to be listed in the Register on or after 1 July 2024 must comply with the new sunscreen requirements in the new Standard.

Subregulation 103(2) applies to sunscreen preparations that were included in the Register as listed goods immediately before 1 July 2024. Its effect is to enable such preparations to continue to comply with the efficacy testing requirements that are set out in the 2012 Standard until 30 June 2029. From 1 July 2029, these sunscreen preparations must comply with the new Standard.

Subregulation 103(3) applies to sunscreen preparations that are supplied as an aerosol or in a spray pump and are included in the Register as listed goods immediately before 1 July 2024. Its effect is to enable such preparations to continue to comply with the labelling requirements that are set out in the 2012 Standard until 30 June 2025. From 1 July 2025, these sunscreen preparations must comply with the new Standard.

Schedule 3—Amendments commencing 1 October 2024

Therapeutic Goods Regulations 1990

The Regulations amend the TG Regulations to increase regulatory oversight of the extemporaneous compounding and supply of ‘unapproved’ medicines that contain glucagon-like peptide-1 receptor agonist (GLP-1 RA) analogues.

Extemporaneous compounding is the manufacture of a medicine, typically within a community pharmacy or hospital setting, where the medicine ("the compounded medicine") is necessary to treat a specific patient because a commercially manufactured medicine (i.e., one that is included in the Register) is unavailable or otherwise unsuitable for that patient.

Compounded medicines are exempt from the requirement to be included in the Register because they are manufactured in small quantities for a particular patient on a 'one-off' basis. For the same reason, pharmacists that compound medicines do not require a manufacturing licence under the Act. This reflects that persons who engage in the compounding of medicines (generally pharmacists) have appropriate training and qualifications, and are bound by ethical and professional practice obligations, standards and guidelines issued by their regulatory bodies (e.g., the Pharmacy Board of Australia).

However, compounded medicines are unapproved therapeutic goods, meaning they have not been evaluated by the TGA for quality, safety, or efficacy. Consequently, the extemporaneous compounding of medicines, and supply of the same, should be reserved for exceptional clinical circumstances—namely, where all suitable alternative treatments using approved therapeutic goods are unavailable, have failed or are deemed unsuitable for the patient.

Medicines containing GLP-1 RA analogues (including semaglutide-like medicines) are principally indicated for the treatment of type 2 diabetes, but they are also commonly prescribed 'off-label' for weight management in adults. There are currently two medicines in the Register that contain semaglutide. Due to increased demand for these products—caused mainly by a rapid increase in prescribing for off-label purposes—there has been an increase in the compounding of medicines containing GLP-1 RA analogues.

Of particular concern, the TGA is aware of an emerging trend for online weight loss clinics with integrated pharmacy services to offer compounded medicines containing GLP-1 RA analogues on a commercial-like scale. These online-only clinics are responsible for the supply of compounded medicines containing GLP-1 RA analogues to at least 20,000 patients across Australia. The TGA is also concerned that some clinics may be compounding these medicines for export purposes.

This poses significant public health and safety risks because medicines containing GLP-1 RA analogues are sterile medicines (i.e., must be free from contamination as the route of administration is by injection) and contain high-risk active substances. Manufacturing (including compounding) that occurs on a commercial-like scale should be the subject of a manufacturing licence, and products that are not manufactured for a particular patient and instead for bulk supply should be included in the Register (or the subject of some other approval or authority) to provide appropriate regulatory oversight for such activities.

The TGA does not evaluate compounded medicines containing GLP-1 RA analogues, nor the processes by which they are manufactured, as compounded medicines are currently exempt from inclusion in the Register. The TGA also has no oversight of the nature and safety of the raw ingredients that are imported into Australia and used in the manufacture of these medicines. Further, the TGA may not receive reports of adverse events experienced by patients. As such, the quality and safety of such medicines is uncertain.

Item [1] – Schedule 5 (table item 6)

This item replaces table item 6 of Schedule 5 to the TG Regulations to, in effect, exclude medicines that contain GLP-1 RA analogues from the exemption for extemporaneously compounded medicines. It is intended that this amendment will address the risks posed by the compounding of medicines containing GLP-1 RA analogues (including where this occurs on a commercial-like scale).

The amendment commences on 1 October 2024 and applies in relation to medicines containing GLP-1 RA analogues that are dispensed, or extemporaneously compounded, on or after that date. While there is a need to address the significant risks associated with the extemporaneous compounding of such medicines, commencement on 1 October 2024 ensures that patients affected by the amendment have adequate time to discuss alternative treatment and general healthcare plans with their health practitioner. The amendment strikes a balance between the public health reason for ensuring patients have access to safe and quality medicines containing GLP-1 RA analogues and allowing patients and practitioners sufficient time to appropriately manage treatment options.

Statement of Compatibility with Human Rights

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

Therapeutic Goods Legislation Amendment (2024 Measures No. 2) Regulations 2024

The *Therapeutic Goods Legislation Amendment (2024 Measures No. 2) Regulations 2024* (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 (2024 Measures No. 2) Regulations 2024* (the Regulations) amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) to support the implementation of the TGA's Medicines Repurposing Program (the MRP). The MRP improves patient access to important treatments by encouraging sponsors of certain medicines in the Australian Register of Therapeutic Goods (the Register) to seek approval to supply those medicines for new uses (so those medicines are no longer supplied "off-label" in Australia).

The proposed Regulations also amend the TG Regulations and the *Therapeutic Goods (Medical Devices) Regulations 2002* to:

- enhance regulatory oversight of the compounding of medicines containing glucagon-like peptide-1 receptor agonist (GLP-1 RA) analogues — which are principally indicated for the treatment of type 2 diabetes, but are also commonly prescribed "off-label" for weight management in adults — to address safety concerns with compounding of these medicines;
- update testing and (certain) labelling requirements that apply to sunscreen products included in the Register as listed goods, to align the requirements with a more recent Sunscreen Standard;
- enable the TGA to adopt a more flexible and risk-based approach to the auditing of applications to include medical devices in the Register;
- reclassify certain kinds of medical devices that contain only materials of microbial or recombinant origin, or certain non-viable tissues or cells of animal origin or their derivatives, to align with the classification of such devices in the European Union;
- exempt prescription spectacle lenses that are intended to be used only to provide refractive corrections from the requirement to be included in the Register;
- revise the transitional arrangements relating to the reclassification of software-based medical devices, so that those arrangements apply to devices that are the subject of an application for a conformity assessment certificate submitted before 1 November 2024; and
- make a small number of more minor amendments to the TG Regulations.

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:

- improving patient access to prescription medicines with 'off-label' therapeutic uses that are safe, efficacious, and deliver substantial public health benefits, by expanding treatment options for prescribers and providing for more equitable patient access to such treatments;
- supporting the timely availability of medical devices that:
    - contain tissues, cells or substances of microbial or recombinant origin, and certain tissues or cells (or their derivatives) of animal origin; or
    - are of a kind in respect of which an overseas regulator has evaluated and granted marketing approval;
- supporting the timely availability of medical devices that are prescription spectacle lenses, by clarifying that although such devices are subject to the therapeutic goods regulatory scheme, they do not require inclusion in the Register if they are solely intended to be used for the provision of refractive corrections (disregarding the effect of any lens treatments; and
- updating the testing and (certain) labelling requirements that apply to sunscreen preparations that are therapeutic goods, to reduce the incidence and adverse outcomes of skin cancer.

The Regulations also support patient safety by enhancing regulatory oversight of the extemporaneous compounding and supply of medicines containing glucagon-like-peptide-1 receptor agonist (GLP-1 RA) analogues (including semaglutide-like medicines). This is an important measure as these products are being compounded for off-label use, for weight management, and the TGA is aware of an emerging trend for online weight loss clinics with integrated pharmacy services to offer compounded medicines containing GLP-1 RA analogues on a commercial-like scale.

This poses significant public health and safety risks because medicines containing GLP-1 RA analogues are sterile medicines (i.e., must be free from contamination as the route of administration is by injection) and contain high-risk active substances. Manufacturing (including compounding) that occurs on a commercial-like scale should be the subject of a manufacturing licence, and products that are manufactured for bulk supply (i.e. not for a particular patient) should be included in the Register (or the subject of some other approval or authority) to provide appropriate regulatory oversight for such activities.

The TGA does not currently have oversight of the manufacturing of medicines containing GLP-1 RA analogues, nor the nature and safety of the raw ingredients that are imported into

Australia and used in the manufacture of these medicines. Further, the TGA may not receive reports of adverse events experienced by patients. As such, the quality and safety of such medicines is uncertain.

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 human rights issues.

Mark Butler, Minister for Health and Aged Care