EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines) Amendment Order 2024

The *Therapeutic Goods Act 1989* ("the Act") provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy or performance, and timely availability of therapeutic goods that are 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 ("the Department").

Subsection 10(1) of the Act provides that the Minister may, by way of legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods. Under subsection 10(2), an order establishing a standard for therapeutic goods may require, among other things, that therapeutic goods (or a class of therapeutic goods identified in the order) be labelled or packaged in a manner specified in the order. Subsection 10(3A) of the Act provides that the Minister may, by legislative instrument, vary or revoke an order made under subsection 10(1).

Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines ("TGO 91") sets out a range of requirements relating to the kinds of information to be included on the labels and packaging of prescription medicines, primarily, and the presentation of the information. These requirements support the safe use and quality of medicines which enables health practitioners and consumers to select health management options appropriately, provides key information about medicines such as their contents, potency and storage requirements, and supports the use of medicines safely and effectively.

The *Therapeutic Goods (Therapeutic Goods Order No. 91 –Standard for labels of prescription and related medicines) Amendment Order 2024* ("the Amendment Order") amends TGO 91 to introduce new labelling requirements for certain injectable medicines intended for electrolyte replacement.

Background

Standards made under section 10 of the Act may relate to any matter relevant to the quality, safety or efficacy of a therapeutic good. Generally, a therapeutic good must not be imported, exported or supplied if it does not conform to an applicable standard. Paragraph 10(2)(c) of the Act states that an order establishing a standard for therapeutic goods may require that therapeutic goods, or a class of therapeutic goods identified in the order, be labelled or packaged in a manner, or kept in containers that comply with requirements, specified in the order.

TGO 91 mandates information that must be on labels of prescription and related medicines, as well as the format and placement in which it must be presented on the label. Examples of information required by TGO 91 include the name of the medicine, the name of the active ingredient and its strength or quantity, storage requirements, expiry date and the declaration of certain inert or inactive substances in the medicine. TGO 91 applies to medicines that are supplied, or for supply, in Australia that are of a kind specified in Part 1 of Schedule 10 to the *Therapeutic Goods Regulations 1990*, save for those that are expressly excluded by subparagraphs 3(1)(a)(i) to (iv) of TGO 91 or are exempt under section 5 of TGO 91.

Purpose

The Amendment Order introduces new labelling requirements for certain injectable medicines intended for electrolyte replacement. Potassium and other concentrated electrolytes for injection are

considered high risk medicines, including by the Australian Commission on Safety and Quality in Health Care.

In clinical practice in Australia, concentrations and doses of these medicines is often based in millimoles (mmol). However, paragraph 11(2)(f) of TGO 91 requires that the quantity or proportion of the active ingredients for these medicines for injection must be expressed as the 'stated weight' in the total volume of the injection. Medicines greater than 100 millilitres (mL) that are intended for electrolyte replacement are required to express quantity in mmol in the stated volume, but medicines that are 100 mL or less do not have this requirement.

The TGA has been alerted to the potential safety risk of these labelling requirements not providing for the clinically relevant unit of quantity to be displayed prominently for some active ingredients. As health care clinicians are most familiar with concentration and doses of these medicines specified in millimoles, rather than in grams or milligrams, expression of quantity only in weight may cause confusion and has the potential to lead to medication errors and harm to consumers.

The Amendment Order amends TGO 91 to require that quantities of active ingredients contained in injectable medicines intended for electrolyte replacement are clearly expressed in millimoles. The purpose of this amendment is to support clinical practice, give clarity to health professionals, and support the safe use of such medicines.

Consultation

Between 30 May and 18 July 2024, the TGA conducted a public consultation including on a proposal to amend labelling requirements for how the quantity of active ingredients in injectable medicines intended for electrolyte replacement with a volume of 100 mL or less must be expressed. To raise awareness, the TGA notified over 300 stakeholders of the consultation period, including sponsors of injectable electrolyte medicines, medicine industry associations, and health professional organisations and representative groups.

Sixty respondents provided feedback to the consultation. Of the 35 submissions that responded to questions regarding the expression of potassium chloride quantities, 25 supported the proposed changes. Of the 33 submissions that responded to the questions regarding the expression of other electrolyte quantities, 19 supported the proposed changes. Only one respondent opposed the proposed changes as they considered it should be applied more broadly, however, this was determined to be outside the scope of the current proposal.

With respect to the proposed transition timeframe, 3 of 29 respondents opposed the proposed two-year period, with one respondent preferring label changes sooner if it didn't impact medicine availability, one respondent stating legislative changes should be postponed until TGO 91 is due to sunset, and one respondent did not provide reasoning.

The Office of Impact Analysis has been consulted and advised that the preparation of an impact analysis is not required in relation to the creation of the Amendment Order as it is unlikely to have more than a minor impact (OIA24-06534).

Other details

Details of the Amendment Order are set out in **Attachment A**.

The Amendment Order is compatible with human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

The Amendment Order is a disallowable legislative instrument for the purposes of the *Legislation Act 2003*, and commences on the day after registration on the Federal Register of Legislation.

Attachment A

Details of the *Therapeutic Goods (Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines) Amendment Order 2024*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines) Amendment Order 2024* ("the Amendment Order").

Section 2 – Commencement

This section provides that the Amendment Order commences on the day after it is registered on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the legislative authority for making the Amendment Order is section 10 of the *Therapeutic Goods Act 1989.*

Section 4 – Schedules

This section gives legal effect to the amendments in Schedule 1 to the Amendment Order.

Schedule 1 – Amendments

This Schedule amends the *Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines* ("TGO 91").

Item 1 – At the end of subsection 10(2)

This item introduces new requirements for medicines for injection in a container with a capacity greater than 100 millilitres (mL), that are intended for electrolyte replacement, that have a stated volume of 100 millilitres or less, and that are manufactured on or after 1 December 2026.

Under new paragraph 10(2)(g), such medicines are required to include a statement on the label on the container and on the primary pack, located immediately below the text mentioned in subsection 9(3), of:

- for potassium chloride—the equivalent quantity of potassium chloride in weight, in relation to the stated volume of fill of the injection; and
- for all other active ingredients—the equivalent quantity of each active ingredient in millimoles in relation to the stated volume of fill of the injection.

The equivalent quantity of an ingredient, in relation to the stated volume of fill of the injection, could be expressed as the total amount in the injection or the concentration of the active ingredient in the injection. For example, the equivalent quantity of potassium chloride in an injection could be expressed as 'Each 10 mL contains: potassium chloride 750 mg' or 'contains potassium chloride 750 mg'**.**

This requirement applies in addition to the requirements under sections 8 and 9 applying to the label on the container and on the primary pack, and only applies to medicines manufactured or imported on or after 1 December 2026.

Item 2 – At the end of subsection 10(3)

This item introduces new requirements for medicines for injection in a container with a capacity less than or equal to 100 millilitres, and greater than 25 millilitres, that are intended for electrolyte replacement and are manufactured on or after 1 December 2026.

Under new paragraph 10(3)(e), such medicines are required to include a statement on the label on the container and on the primary pack, located immediately below the text mentioned in subsection 9(3), of:

- for potassium chloride—the equivalent quantity of potassium chloride in weight, in relation to the stated volume of fill of the injection; and
- for all other active ingredients—the equivalent quantity of each active ingredient in millimoles in relation to the stated volume of fill of the injection.

The equivalent quantity of an ingredient could be expressed as the total amount in the injection or the concentration of the active ingredient in the injection**.** For example, the equivalent quantity of potassium chloride in an injection could be expressed as 'Each 10 mL contains: potassium chloride 750 mg' or 'contains potassium chloride 750 mg'**.**

This requirement applies in addition to the requirements under sections 8 and 9 applying to the label on the container and on the primary pack, and only applies to medicines manufactured or imported on or after 1 December 2026.

Item 3 – At the end of subsection 10(4)

This item introduces new requirements for medicines for injection in a container with a capacity less than or equal to 25 millilitres, and greater than 3 millilitres, that are intended for electrolyte replacement and are manufactured on or after 1 December 2026.

Under new paragraph 10(4)(m), such medicines are required to include a statement on the label on the container and on the primary pack, located immediately below the text mentioned in subsection 9(3), of:

- for potassium chloride—the equivalent quantity of potassium chloride in weight in relation to the stated volume of fill of the injection; and
- for all other active ingredients—the equivalent quantity of each active ingredient in millimoles in relation to the stated volume of fill of the injection.

However, medicines to which subparagraph 10(4)(m)(i) applies do not have to comply with the requirement for the equivalent quantity of potassium chloride if, to include such a statement, it would not be possible to comply with text size requirements. That is, in instances where the container size precludes a label that has this statement in the text size required, sponsors and manufacturers are not required to have this statement on the label.

The equivalent quantity of an ingredient could be expressed as the total amount in the injection or the concentration of the active ingredient in the injection**.** For example, the equivalent quantity of potassium chloride in an injection could be expressed as 'Each 10 mL contains: potassium chloride 750 mg' or 'contains potassium chloride 750 mg'**.**

This requirement applies in addition to the requirements under sections 8 and 9 applying to the label on the container and on the primary pack, and only applies to medicines manufactured or imported on or after 1 December 2026.

Item 4, 5 and 6 – Subparagraph 11(2)(f)(i), subparagraph 11(2)(f)(v) and at the end of subparagraph 11(2)(f)

These items introduce updated requirements for medicines for injection which are intended for electrolyte replacement and have a stated volume of 100 millilitres or less.

Subsection 11(2) of TGO 91 prescribes how the quantity or proportion of an active ingredient to be included on a label must be expressed. New subparagraph 11(2)(f)(vi) provides that where the stated volume of a medicine for injection is 100 millilitres or less, and the medicine is intended for electrolyte replacement, the active ingredient/s must be expressed as:

- for potassium chloride—the number of millimoles of potassium chloride in the stated volume of fill in the injection in the container; and
- for all other active ingredients—the stated weight of each active ingredient in the stated volume of fill in the injection in the container.

Item 7 – At the end of section 11

This item provides that section 11 of TGO 91, as immediately in force before the amendments made by the Amendment Order, continues to apply to medicines manufactured or imported before 1 December 2026.

The effect of this item is that, until 1 December 2026, medicines to which new subparagraph 11(2)(f)(vi) applies may comply with either the requirements set out in section 11 of TGO 91 immediately prior to the Amendment Order coming into effect, or with the new requirements set out in the Amendment Order. However, on and from 1 December 2026, all medicines to which the amendments apply must comply with the new requirements introduced by the Amendment Order.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines) Amendment Order 2024

This disallowable legislative instrument is 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 legislative instrument

Subsection 10(1) of the *Therapeutic Goods Act 1989* ("the Act") provides that the Minister may, by way of legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods. Under subsection 10(2), an order establishing a standard for therapeutic goods may require, among other things, that therapeutic goods (or a class of therapeutic goods identified in the order) be labelled or packaged in a manner specified in the order. Subsection 10(3A) of the Act provides that the Minister may, by legislative instrument, vary or revoke an order made under subsection 10(1).

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